
Article

Regulating Cumulative Risk

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INTRODUCTION

No problem has ever been solved by ignoring it. So why is it that regulators have largely turned their backs to issues of cumulative exposure from chemicals and pesticides? Why is it that more than 85,000 chemicals are approved for distribution in the United States¹ and yet there are no routine assessments of public health risks from the combined exposure to multiple chemicals over multiple pathways? It is certainly not because policymakers or scientists fail to understand the importance of cumulative risk to issues of public health. The risk science literature routinely and openly acknowledges that cumulative risk assessments are the tool for tackling real-world problems of exposure.² Individuals, after all, do not live in a bubble. And chemical exposure is not neatly and independently divided between fire retardants in couches, BPA in plastics, and endocrine disruptors in soaps. No. Life is messy and full of compounding consequences.³

1. *About the TSCA Chemical Substance Inventory*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/tscainventory/about-tscachemical-substance-inventory> (last visited Apr. 24, 2017) (“The Inventory was initially published in 1979, and a second version, containing about 62,000 chemical substances, was published in 1982. The TSCA Inventory has continued to grow since then, and now lists about 85,000 chemicals.”).

2. See, e.g., Sarah S. Gallagher et al., *Cumulative Risk Assessment Lessons Learned: A Review of Case Studies and Issue Papers*, 120 CHEMOSPHERE 697, 698 (2015); see also *infra* Part I.A (discussing the risk science literature).

3. Major environmental laws like the National Environmental Policy Act, the Clean Air Act, and the Clean Water Act have some regulatory provisions aimed at understanding cumulative impacts of their targeted regulatory programs. For example, the Clean Air Act sets national ambient air quality standards (NAAQS) for six criteria pollutants and requires states to adopt implementation plans that ensure the aggregate air emissions in that state will not exceed the ambient standards. 42 U.S.C. §§ 7408–7410 (2012). Similarly, the Clean Water Act requires states to develop Total Maximum Daily Loads (TMDLs) for all water bodies that fail to meet ambient water quality standards. 33 U.S.C. § 1313(d) (2012). These TMDLs provide a means of addressing water quality problems that arise from multiple point sources, unregulated nonpoint sources, and background levels of pollution that collectively impair a water body despite the issuance of individual discharge permits. For an in-depth discussion of TMDLs, see OLIVER A. HOUCK, *THE CLEAN WATER ACT TMDL PROGRAM: LAW, POLICY, AND IMPLEMENTATION* (2d. ed. 2002). Finally, the National Environmental Policy Act requires all federal agencies to consider cumulative impacts of their proposed actions by accounting for the combined impacts of past, present, and future projects on a particular resource. See, e.g., 40 C.F.R. § 1508.7 (2016) (defining “cumulative impact” in the Council on Environmental Quality regulations that implement NEPA). While these provisions aimed at ameliorating aggregate harm have met only moderate success, the point is that Congress at least recognized that addressing indi-

Despite evolutions in scientific thinking, the implementation of the two major federal environmental laws most directly impacting the entry of chemicals and pesticide to the marketplace—the Toxic Substances Control Act (TSCA)⁴ and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)⁵—have largely ignored issues of cumulative risk. With some limited exceptions, chemicals and pesticides are regulated on a chemical-by-chemical basis instead of based on real-world exposures. And though legal scholars have long agreed that chemical regulation was broken under TSCA,⁶ cumulative impacts—the heart of public health concerns—had been virtually absent from proposals to reform TSCA.⁷

This is not to say that both the old and new legal frameworks are incapable of addressing cumulative risk or that Congress did not appreciate the need to do so. In fact, Congress recognized that cumulative exposures to chemicals lie at the heart of public health risks when it enacted TSCA forty years ago.⁸ And in the separate realm of pesticide legislation, Congress amended FIFRA twenty years ago to address aggregate

vidual dischargers or emitters would not necessarily ensure that the aggregate levels of pollution were sufficient to protect public health.

4. 15 U.S.C. §§ 2601–2629 (2012).

5. 7 U.S.C. §§ 136–136y (2012).

6. For a sampling of the critiques leveled against the TSCA, see 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, 495–506 (2014) (discussing the TSCA’s “[p]oor [t]rack [r]ecord”); Noah Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817, 1825–31 (2009) (discussing the “TSCA’s [t]roubles”). For a similar set of criticisms aimed at FIFRA, see Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA’s Implementation of the Food Quality Protection Act*, 53 ADMIN. L. REV. 103, 110–20 (2001).

7. See, e.g., John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721 (2008) (laying out principles for reform without proposing a regulatory approach aimed directly at cumulative risk).

8. See H.R. REP. NO. 94-1679, at 61 (1976) (Conf. Rep.) (“Oftentimes an unreasonable risk will be presented because of the interrelationship or cumulative impact of a number of different substances or mixtures. The conferees intend that the Administrator have authority to protect health and the environment in such situations.”); see also H.R. REP. NO. 94-1341, at 33 (1976) (“Because of the multiple avenues by which humans and the environment are exposed to a substance or mixture and because substances and mixtures do not occur in the environment in isolation, risks may result from complex interactions or because of cumulative effects.”).

risks of pesticides in the limited areas of food residues.⁹ This amendment, in fact, inspired the U.S. Environmental Protection Agency (EPA) to develop a framework for cumulative risk assessment, touting its importance to understanding how chemicals proliferation impacts human health.¹⁰

One should be careful, however, not to conflate regulatory potential or nonbinding frameworks with regulatory action. In fact, while there is some regulatory potential in the area of cumulative risk assessment, that promise is yet untapped. To date, cumulative risk exists only at the regulatory fringe. Without a concerted effort to bring the issues to the forefront, the trend toward a myopic, chemical-by-chemical analysis of the risks is likely to continue. In 2016, President Obama signed chemical reform legislation in law: the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“new Act” or “Chemical Safety Act”). That Act, like its predecessor, is largely silent on how and whether to integrate concerns about cumulative risk into the new framework.

How can this be? It is, after all, no secret that we live in a world full of chemicals. Not infrequently, the popular press runs a feature article reminding us that “chemicals are everywhere,”¹¹ that chemicals commonly used in consumer products

9. The Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (2012) (amended FIFRA by setting a safety limit on pesticide residues on food for the first time in history); *see also* 21 U.S.C. § 346a (2012). Those safety limits are supposed to be set after evaluating the aggregate exposure to individual pesticides. *Id.* While this sounds promising, the FQPA is limited in scope, leaving chemicals in consumer products unaddressed as well as some of the most widely applied pesticides. In addition, the implementation of the FQPA’s mandates on aggregate exposure have been criticized as unsuccessful. *See also infra* Part III.B.

10. U.S. ENVTL. PROT. AGENCY, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT, U.S. (2003), https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf [hereinafter EPA, FRAMEWORK] (“[C]umulative risk assessment may be the best tool available to address certain questions dealing with multiple-stressor impacts.”).

11. *See, e.g.*, Elizabeth Grossman, *Untested Chemicals Are Everywhere, Thanks to a 39-Year-Old US Law. Will the Senate Finally Act?*, THE GUARDIAN (Feb. 13, 2015), <https://www.theguardian.com/lifeandstyle/2015/feb/13/us-senate-toxic-chemicals-law-health-safety> (“Toxics ‘are still shockingly common in our food and everyday objects.”); Nicholas Kristof, *Contaminating Our Bodies with Everyday Products*, N.Y. TIMES (Nov. 28, 2015), <https://nytimes.com/2015/11/29/opinion/sunday/contaminating-our-bodies-with-everyday-products.html> (“In recent weeks, two major medical organizations have issued independent warnings about toxic chemicals in products all around us.”); David S. Martin, *5 Toxics that Are Everywhere: Protect Yourself*, CNN (May 31, 2010), <http://www.cnn.com/2010/HEALTH/05/31/chemical.dangers> (“A growing body

are not as safe as once thought,¹² that some chemicals now have background levels in the ambient environment,¹³ and that others are found in elevated levels of our children's bloodstreams.¹⁴ Those paying attention are forced to grapple with the idea that babies come "pre-polluted" with endocrine disruptors,¹⁵ or that our waters are contaminated with microbeads from personal care products.¹⁶

It is also no secret that for decades the major federal chemicals and pesticide laws in the U.S. have left the toggle switch open, allowing tens of thousands of chemicals to enter the market (and consequently the environment) with little assurance of safety and almost no consideration of the collective consequenc-

of research is linking five chemicals—among the most common in the world—to a host of ailments, including cancer, sexual problems and behavioral issues. . . . In short, every room in almost every house in the United States is likely to contain at least one of these chemicals, many of which did not exist a century ago."); Daniel Neides, *Everyday Toxins Poison Our Best Intentions: Words on Wellness*, CLEVELAND.COM (May 6, 2016), http://www.cleveland.com/lyndhurst-south-euclid/index.ssf/2016/05/everyday_toxins_poison_our_bes.html ("The problem we now face is the incredible toxic load forced upon us every day.").

12. Nathaniel Rich, *The Lawyer Who Became DuPont's Worst Nightmare*, N.Y. TIMES MAG. (Jan. 6, 2016), <https://www.nytimes.com/2016/01/10/magazine/the-lawyer-who-became-duponts-worst-nightmare.html> (discussing how the toxicity of PFOA, a chemical used in products like teflon, was known and yet covered up by DuPont and has since found its way into drinking water supplies from Pennsylvania to Washington); see also Sharon Lerner, *The Teflon Toxin: DuPont and the Chemistry of Deception*, INTERCEPT (Aug. 11, 2015), <https://theintercept.com/2015/08/11/dupont-chemistry-deception> (discussing DuPont's PFOA scandal).

13. See DEPT HEALTH & HUMAN SERVS. & CTR. FOR DISEASE CONTROL & PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: EXECUTIVE SUMMARY 1 (2009) (describing its extensive biomonitoring program to understand exposures to "environmental chemicals," which are defined as a "chemical compound or chemical element present in air, water, food, soil, dust, or other environmental media, such as consumer products").

14. See *id.* at 3 (reporting the widespread presence of commonly used industrial chemicals like fire retardants, BPA, and PFOA in the blood and urine samples of study participants).

15. Kristof, *supra* note 11; see also Sara Goodman, *Test Finds More than 200 Chemicals in Newborn Umbilical Cord Blood*, SCI. AM. (Dec. 2, 2009), <https://www.scientificamerican.com/article/newborn-babies-chemicals-exposure-bpa> (reporting on a study from the Environmental Working Group that tested umbilical cord blood from newborns and found traces of 200 chemicals in their blood, including traces of twenty-one pesticides).

16. Rachel Abrams, *Fighting Pollution from Microbeads Used in Soaps and Creams*, N.Y. TIMES (May 22, 2015), <https://www.nytimes.com/2015/05/23/business/energy-environment/california-takes-step-to-ban-microbeads-used-in-soaps-and-creams.html>.

es. Over 85,000¹⁷ chemicals are manufactured and distributed in the United States; in addition, over 20,000 formulations of about 675 active pesticide ingredients are sprayed on our food, lawns, homes, and commercial offices.¹⁸ For many of these chemicals, little is known by way of safety or public health consequences.¹⁹

Still, at the moment when we should recognize the daunting collective action problem before us, at the moment when assessing cumulative risk and regulating to reduce that risk seem the logical next step, a curious piece of advice has become a common refrain: individual vigilance. Again and again we are told that we can protect ourselves, our families, and unborn babies by becoming informed consumers.²⁰ We are lured by the promise that as individual non-experts we can arm ourselves with the tool of information and live a healthy life. Debra Lynn

17. See *About the TSCA Chemical Substance Inventory*, *supra* note 1 (“The Inventory was initially published in 1979, and a second version, containing about 62,000 chemical substances, was published in 1982. The TSCA Inventory has continued to grow since then, and now lists about 85,000 chemicals.”).

18. McGarity, *supra* note 6, at 110. Europeans fare no better in the quest to avoid chemicals in everyday life. A survey of British females by deodorant-maker Bionsea revealed that the average UK woman wears 515 chemicals a day. Paul Casciato, *Average UK Woman Wears 515 Chemicals a Day*, REUTERS (Nov. 19, 2009), <http://www.reuters.com/article/us-britain-cosmetics-idUSTRE5AI3M820091119>. In addition, Danish researchers concluded that the total amounts of endocrine disruptors absorbed by two-year-old children constitute a risk for both anti-androgenic disruptions and estrogen-like disruptions of their sexual development. See KATHE TØNNING ET AL., SURVEY AND HEALTH ASSESSMENT OF THE EXPOSURE OF 2-YEAR-OLDS TO CHEMICAL SUBSTANCES IN CONSUMER PRODUCTS: SURVEY OF CHEMICAL SUBSTANCES IN CONSUMER PRODUCTS, DANISH ENVTL. PROT. AGENCY, NO. 102, at 40 (2009), <http://www2.mst.dk/udgiv/publications/2009/978-87-92548-81-8/pdf/978-87-92548-82-5.pdf>.

19. See Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law To Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1623–24 (2004) (“Despite the enormous growth in environmental law and regulation since the 1970s, much of the scientific information needed to ensure environmental protection is still missing. . . . Scientific knowledge is insufficient to identify, much less test for, a variety of invisible hazards associated with household products Ignorance prevails in spite of elaborate licensing requirements that purport to protect the public health and environment from these hazards.”).

20. See, e.g., MIKE ADAMS, FOOD FORENSICS: HIDDEN TOXINS LURKING IN YOUR FOOD AND HOW YOU CAN AVOID THEM FOR LIFELONG HEALTH (2016); DEBRA LYNN DADD, TOXIC FREE: HOW TO PROTECT YOUR HEALTH AND HOME FROM THE CHEMICALS THAT ARE MAKING YOU SICK (2011) (“There is no longer any question that consumer products contain toxic chemicals harmful to our families. But how do we protect ourselves, and where do we start?”).

Dadd, dubbed the Queen of Green by the *New York Times*,²¹ begins her latest book on how to avoid toxins in the home by saying “I speak to you not as a doctor, scientist, or toxicologist, but as an educated consumer.”²²

Perhaps because an alternative message is too overwhelming to accept, we continue to pair the reality that “there are 80,000 synthetic chemicals in commerce today” with “the good news about what is in our control, the steps we can take to help our bodies remove our toxic burden—and what we can do to avoid it in the first place.”²³ In one *New York Times* article about the omnipresence of endocrine disruptors and the long-term reproductive impacts that pre-natal exposure can have on babies when they become adults, we are given this helpful advice:

For now, experts say the best approach is for people to try to protect themselves. Especially for women who are pregnant or may become pregnant, and for young children, try to eat organic, reduce the use of plastics, touch cash register receipts as little as possible, try to avoid flame-retardant couches.²⁴

Admittedly, this message of individual vigilance does bear intuitive appeal. After all, the message implies that individuals have control over their own toxic risk profiles. At least for those with means, time, education, and cultural support, there might be some comfort in thinking that public health implications

21. *About Toxic Free*, PENGUIN RANDOM HOUSE, <http://www.penguinrandomhouse.com/books/308971/toxic-free-by-debra-lynn-dadd/9781585428700> (last visited Apr. 24, 2017).

22. DADD, *supra* note 20, at iii.

23. *Promotional Materials for Toxin Toxout*, GOOGLEPLAY, https://play.google.com/store/books/details?id=1W5-AgAAQBAJ&source=productsearch&utm_source=HA_Desktop_US&utm_medium=SEM&utm_campaign=PLA&pcampaignid=MKTAD0930B01&gl=US&gclid=CNGiiIGa38wCFUaWfgodTM0A-Q&gclsrc=ds (last visited Apr. 24, 2017); see BRUCE LAURIE & RICK SMITH, TOXIN TOXOUT: GETTING HARMFUL CHEMICALS OUT OF OUR BODIES AND OUR WORLD (2014); see also RICK SMITH & BRUCE LAURIE, SLOW DEATH BY RUBBER DUCK: THE SECRET DANGER OF EVERYDAY THINGS (2011); GILLIAN DEACON, THERE'S LEAD IN YOUR LIPSTICK: TOXINS IN OUR EVERYDAY BODY CARE AND HOW TO AVOID THEM (2011).

24. Kristof, *supra* note 11. Similar pieces of advice for pregnant women can be found lurking in the blogosphere. See, e.g., Attached Mama, *Book To Help Reduce Toxin Exposure During Pregnancy*, ECO BABY STEPS (July 26, 2014), <http://www.ecobabysteps.com/2014/07/26/book-to-help-reduce-toxin-exposure-during-pregnancy> (“During your pregnancy, the developing fetus is far more vulnerable to toxins than you are as an adult. You are your baby’s protection, so protect your own environment to give your baby the best possible start.”).

from chemicals and pesticide proliferation can be self-managed and avoided through some self-determination and zeal.

This sense of security, even for those who can afford it, is in the end a comforting but false fantasy. Individuals lack basic information required to understand risk of chronic, cumulative, and long-term toxic exposure in their daily lives. Even if individuals had complete information, most lack the expertise to assess the cumulative or synergistic risk from multiple sources. And even in the fantastical world where individuals could accurately assess risk, chemicals proliferation has given way to an environment where some risks simply cannot be avoided.

In the face of this broken landscape, it is time for a paradigm shift—one where cumulative risk moves from regulatory fringe to center stage; one where legal frameworks directly address cumulative risk and stop feeding the fallacy that labeling, information disclosure, or consumer choice can address the central issues of the chemicals age. More specifically, regulatory safety standards need to consider the public health implications not from any single chemical but from the combination of multiple chemicals with common mechanisms of toxicity. It is the potential for combined and synergistic harm that needs attention. In fact, so important is this need that the failure to systematize the considerations of cumulative risk may amount to “arbitrary and capricious” decision-making.²⁵

To be clear, there are ample guidelines and aspirational frameworks written by regulators to develop tools for cumulative risk assessment. And there is great work being done by toxicologists to enhance the efficiency and effectiveness of cumulative risk assessment models. But without meaningful regulatory hooks, these tools will sit upon the shelf of good intentions or buried in the drawer of difficult problems. This Article seeks to change that by showing why understanding cumulative risk, though difficult, is necessary.

This Article proceeds in four parts. Part I describes how cumulative risk assessments tackle the real-world exposure problems that lie at the heart of public health. It shows how risk science has evolved and why policy, not science, lags behind. Part II then examines why key public health concerns

25. See *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983) (suggesting that an agency's decision is “arbitrary and capricious” if it fails to consider all the important factors).

cannot be answered through information disclosure or consumer choice models alone.

Having established that regulatory drivers are needed, Part III begins to examine how to move forward. It does so by looking backward and examining how TSCA and FIFRA have failed historically to provide this critical public health focus despite room in their statutory frameworks. It explores both theoretical and implementation gaps, showing how gaps in the legal frameworks are strikingly disconnected from the risk science literature. Importantly, understanding these gaps will provide critical insights for how to avoid similar pitfalls under the newly enacted Chemical Safety Act.

Finally, Part IV offers a path forward by suggesting where current regulatory frameworks could support a cumulative risk lens. In particular, Part IV considers how the existing safety standards under the newly reformed Chemicals Safety Act and FIFRA—both of which center on a threshold of “unreasonable risk”—can internalize issues of cumulative risk. In the end, it may well be that assessing cumulative risk is not only permissible under the regulatory frameworks, but also indispensable to rational decision-making.

Because TSCA has been recently amended, and because the EPA is required to develop new risk evaluation regulations to implement those amendments, the timing is right for adopting a fresh and deliberate approach to making a home for cumulative risk in the future of chemicals legislation. In addition, the newfound attention on the chemicals legislation affords an opportunity to align the regulatory approaches under FIFRA and the reformed TSCA to redouble efforts to regulate on the basis of cumulative risk. To that end, this Article concludes by sketching a path forward and offering a home for cumulative risk under the existing regulatory framework.

I. THE POTENTIAL OF CUMULATIVE RISK ASSESSMENT

Placing cumulative risk at the center regulatory framework is key to protecting public health in the chemicals age. To appreciate why this is so, this Part examines how risk science is evolving to address issues of cumulative exposure; it explores the promise of cumulative risk assessments as well as the complexities. Ultimately, this Part concludes that policy, not science, has been the more substantial barrier to adopting a cumulative risk lens to public health protection.

A. ASSESSING REAL WORLD EXPOSURES

The U.S. EPA has conventionally approached risk assessments by evaluating a single pollutant in a single exposure medium.²⁶ For example, the agency might evaluate the risks posed by DDT when inhaled through the air separately from the risks of DDT when ingested through drinking water. Risks posed by particulate matter when inhaled through the air would be yet another inquiry. The result is that population-level effects of additive or synergistic exposure to multiple pollutants through multiple channels (air, water, soil, consumer products, pesticides) are not well-studied. In short, evaluating chemical safety under TSCA, or pesticide safety under FIFRA, is conducted product by product.²⁷

This ad hoc, piecemeal approach has downsides. Most notably, single-stressor risk assessments do not reflect the real world, where hazards do not exist independently of one another.²⁸ Rather, in the real world, communities are simultaneously exposed to multiple stressors via multiple exposure pathways.²⁹ It is only by combining the knowledge of multiple stressors that one can begin to paint an accurate picture of pollutant loading that any given community faces over time. For example, a cumulative risk assessment initiated in Baltimore evaluated 175 chemicals emitted into the air from more than 125 facilities in an effort to identify effective prevention efforts to improve community health.³⁰

Scientists, regulators, and Congress have at various levels recognized the wisdom of adopting a cumulative risk lens. For its part, Congress recognized the importance of moving away from single-chemical, single-pathway risk assessment when it

26. The National Research Council's original blueprint for risk assessment, published in 1983, took this single-chemical approach. NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 3 (1983), <https://www.nap.edu/read/366>.

27. EPA, FRAMEWORK, *supra* note 10, at 1 ("The focus of the EPA strategy to control pollution (and the risk assessment methodology being used to partially support decisions) gradually leaned toward assessing and controlling the individual chemicals.")

28. See, e.g., Gallagher et al., *supra* note 2, at 698 ("[P]opulations are exposed simultaneously to multiple stressors via multiple exposure routes and pathways.")

29. The EPA defines a "stressor" as "any physical, chemical, or biological entity that can induce an adverse response. A stressor may also be the lack of an essential entity, such as a habitat." EPA, FRAMEWORK, *supra* note 10, at 74.

30. See Gallagher et al., *supra* note 2, at 699 tbl.1 & 700-01.

adopted the Food Quality Protection Act (FQPA) in 1996.³¹ While the FQPA is limited in scope and has been roundly criticized in its implementation,³² it is one of the few examples where Congress has directly required some form of cumulative risk assessment for chemicals regulation. It is also a good example of why regulatory drivers are needed to encourage the development and use of cumulative risk assessments.

In the wake of the passage of FQPA there was a flurry of activity by regulators to study and develop tools for assessing risk from multiple stressors. This regulatory mandate, in combination with a series of environmental justice lawsuits brought under Title VI of the Civil Rights Act, prompted the EPA to develop cumulative risk models for broader application.³³ The EPA published the result of that work in the Framework for Cumulative Risk Assessment (Framework), which describes best practices for conducting cumulative risk assessments.³⁴

Though not binding,³⁵ the Framework evidences the EPA's recognition that cumulative risk assessments are important tools for advancing the public health goals of various environmental laws: in the preface, the EPA announced that "[a]ssessing cumulative risk through complex exposures is one of the Agency's high priorities" and is "germane and of great interest to all program and regional offices."³⁶ A similar sentiment is reflected in the National Research Council's 2009 Report, which shifted away from a traditional single-chemical paradigm and warned that risk assessments are themselves at risk of becoming irrelevant unless they start accounting for

31. Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified at 7 U.S.C. §§ 136-136y).

32. See, e.g., McGarity, *supra* note 6, at 147-202 (criticizing the implementation of certain FQPA provisions).

33. See EPA, FRAMEWORK, *supra* note 10, at x-xii (noting in several places the FQPA and its mandates related to cumulative risk assessment).

34. See *id.* at x ("[T]his framework is intended to identify the basic elements of the cumulative risk assessment process.").

35. See *id.* at xvii (noting that the Framework "is neither a procedural guide nor a regulatory requirement within EPA, and it is expected to evolve with experience"); see also *id.* at xvii-xx ("Nothing in this report should be interpreted as mandating that a cumulative risk assessment be conducted. . . . Rather, it is an information document."). In fact, the Framework includes aspects of risk assessment that are "outside of the EPA's current legislative mandates . . ." *Id.* at xviii. The Framework is largely aspirational and "will serve as a foundation for developing future guidelines." *Id.* at xvii.

36. *Id.* at xi.

cumulative impacts.³⁷ The risk assessment literature also reflects a call by some academics and scientists to expand the use of cumulative risk assessments. As one epidemiologist observed:

[T]here is a growing mismatch between the broader, real-world questions being asked by decision makers and important stakeholders, and the narrow, limited answers provided by conventional risk assessments. To rectify this situation, traditional chemical-by-chemical risk assessments must expand to incorporate consideration of combined health effects from exposure to a diverse array of environmental agents such as people encounter during their normal daily routines.³⁸

To appreciate why assessing cumulative risk is key to addressing public health, it helps to begin with a detailed understanding of what cumulative risk assessment is and how it has been used. To that end, the Framework defines cumulative risk to mean “[t]he combined risks from aggregate exposures to multiple agents or stressors.”³⁹ Several key features of cumulative risk assessment are housed in this definition.

First, cumulative risk assessments do not simply catalog descriptions of all the stressors and associated risks that impact a defined population.⁴⁰ Rather, cumulative risk assess-

37. See also Gallagher et al., *supra* note 2, at 697 (“CRAs are meant to increase the relevance of risk assessments, providing decision makers with information based on real world exposure scenarios that improve the characterization of actual risks and hazards.”).

38. 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 (2012) (citations omitted).

39. EPA, FRAMEWORK, *supra* note 10, at 72. Stressors go beyond chemicals—they can include low income, depressed community property values, limited access to healthcare, psychosocial stress, and other non-chemical stressors. See Ari S. Lewis et al., *Non-Chemical Stressors and Cumulative Risk Assessment: An Overview of Current Initiatives and Potential Air Pollutant Interactions*, 8 INT’L J. ENVTL. RES. & PUB. HEALTH 2020, 2023 (2011). These nonchemical stressors are important to CRA initiated as part of environmental justice efforts. Examples of physical stressors include radiation, noise, vibration, odor, temperature, and humidity. *Id.* at 2031. Biological stressors include pathogenic agents like bacterial or viral agents. *Id.*

40. See EPA, FRAMEWORK, *supra* note 10, at xvii–xx (“[A]n assessment that covers a number of chemicals or other stressors but that merely lists each chemical with a corresponding risk without consideration of the other chemicals present is not an assessment of cumulative risk under this definition.”); see also *id.* at 47 (“Nonchemical stressors . . . can also interact with chemicals to change the risks either that would cause separately. For example, chemicals such as toluene can damage the auditory system and have been shown to potentiate the effects of a physical stressor, noise, on hearing loss.”).

ments study how various stressors interact with one another and impact the given population when considered in combination. This means studying whether the impacts are additive or synergistic. Additive means determining which chemicals operate by similar modes of action—e.g., which ones are endocrine disruptors—and then determining whether the total risk can be calculated by adding up the individual risks posed by each of the chemicals over all identifiable exposure pathways.⁴¹ Synergistic interactions are more complicated. Assessing synergistic interactions means determining whether two or more stressors combine such that the combination of stressors is worse than the impact of the individual stressors simply added together.⁴² In some cases, the individual stressors may have no discernable effect except in combination with other stressors.⁴³

Second, stressors need not be chemical; they can also be physical, biological, or social.⁴⁴ For example, assessing the risk of living near an airport would evaluate the impacts of air pollution (chemical stressor) and noise (non-chemical stressor), both of which potentially affect hypertension.⁴⁵ In addition, risk scientists recognize that “[s]tressful social environments may make a population that is already subject to chemical stressors even more sensitive to unhealthy environment exposures.”⁴⁶ Understanding how nonchemical stressors combine with chem-

41. See *id.* at 8 (description of synergism).

42. See Ken Sexton & Dale Hattis, *Assessing Cumulative Health Risks from Exposure to Environmental Mixtures—Three Fundamental Questions*, 115 ENVTL. HEALTH PERSP. 825, 825 (2007) (explaining that “exposure to noise and toluene results in higher risk of hearing loss than from either stressor alone” and that “exposure to polycyclic aromatic hydrocarbons and ultraviolet radiation increases toxicity to aquatic organisms”).

43. See NAT’L RESEARCH COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 342 (1993) (explaining that synergistic effects include situations where “two compounds, innocuous by themselves, might interact chemically even at low doses to form a new substance that is toxic”); see also Lewis et al., *supra* note 39, at 2038 (“A complication of defining the [mode of action] of non-chemical stressors (e.g. [socioeconomic status]) remains their lack of a biological link to disease, that is, [socioeconomic status] does not cause illness, but rather certain aspects associated with [socioeconomic status] appear to contribute to disease.”).

44. See EPA, FRAMEWORK, *supra* note 10, at xvii–xx.

45. Lewis et al., *supra* note 39, at 2033.

46. DEVON C. PAYNE-STURGES & LAWRENCE MARTIN, CUMULATIVE RISK WEBINAR SERIES: WHAT WE LEARNED 1 (2014), <https://www.epa.gov/sites/production/files/2015-10/documents/cra-webinar-summary.pdf> (summarizing a series of webinars presented during 2012 and 2013 designed to “examine and stimulate discussion of topical issues important to advancing cumulative risk”).

ical stressors to impact vulnerable subpopulations is becoming a particularly important tool in the area of environmental justice advocacy.⁴⁷

Third, perhaps the most important conceptual feature of cumulative risk assessments is their focus on population-level analysis. This focus makes cumulative risk assessments useful to decision-makers who are wrestling with questions of public health or ecological health. In this way, a population-level risk analysis fits well with the public health mission of many environmental statutes. For example, the Clean Air Act announces up front its purpose “to protect and enhance the quality of the Nation’s air resources so as to promote the public health and welfare.”⁴⁸ This purpose stems from the congressionally stated finding that “the growth in the amount and complexity of air pollution brought about by urbanization, industrial development, and the increasing use of motor vehicles, has resulted in mounting dangers to the public health and welfare.”⁴⁹ The Clean Water Act, RCRA, and OSHA similarly declare broad public health purposes as the driving force for the legislation.⁵⁰ Even TSCA, despite its failings,⁵¹ is rooted in concerns about public health implications of chemicals proliferation. To that end, TSCA begins with the congressional finding that “human beings and the environment are being exposed each year to a large number of chemical substances and mixtures.”⁵² Certainly a risk assessment tool that considers the cumulative impact of these many chemicals is relevant to the core questions of risk and public safety. In fact, the EPA has similarly acknowledged the challenge of assessing the cumulative effects from chemicals and pesticide proliferation:

As of August 1, 2001, there were 19,533 pesticide products on the market and 79,120 existing chemicals on the Toxic Substance Control Act inventory. Each year, a number of chemicals are added. Assessing

47. See NAT’L ENVTL. JUST. ADVISORY COUNCIL, ENSURING RISK REDUCTION IN COMMUNITIES WITH MULTIPLE STRESSORS: ENVIRONMENTAL JUSTICE AND CUMULATIVE RISKS/IMPACTS 1 (2004), <https://www.epa.gov/sites/production/files/2015-04/documents/ensuringriskreductionnejac.pdf>.

48. Clean Air Act, 42 U.S.C. § 7401(b)(1) (2012).

49. *Id.* § 7401(a)(2).

50. See Clean Water Act, 33 U.S.C. § 1251(a) (2012); Resource Conservation and Recovery Act, 42 U.S.C. § 6902(a) (2012); Occupational Health and Safety Act of 1970, 29 U.S.C. § 651(b) (2012).

51. See *supra* note 6; see also Kristen Ekey, Note, *Tick Toxic: The Failure To Clean up TSCA Poisons Public Health and Threatens Chemical Innovation*, 38 WM. & MARY ENVTL. L. & POL’Y REV. 169, 169 (2013).

52. Toxic Substances Control Act of 1976, 15 U.S.C. § 2601(a)(1) (2012).

the cumulative effect of these chemicals will be a great challenge to the field of risk assessment and to the Agency.⁵³

Certainly a risk assessment tool that considers the cumulative impact of these chemicals is relevant to core questions of risk and public health.⁵⁴ Not only is the tool relevant, but it is versatile. Cumulative risk assessments can be used to address a variety of public and ecological health issues at the national, regional, or community level. They can be used to assess single exposure routes or multiple exposure routes. They can be used to study a single adverse outcome or understand relative risk between different health concerns (e.g., cancer, neurological, endocrinal). They can evaluate multiple exposure routes where the chemicals lead to similar adverse outcomes via different modes of action. They can even help assess chemical and nonchemical stressors that impact a more localized community and account for genetic vulnerabilities in certain subpopulations.⁵⁵

The idea that cumulative risk is highly relevant to a broad range of public health concerns is reflected in several case studies that the EPA collected and commissioned during its development of the Framework. These case studies highlight the current capability of performing cumulative risk assessments, demonstrating their usefulness in addressing a variety of public and ecological health issues at the national, regional, or community level.

In one nationwide study, the EPA examined the health effects from 177 hazardous air pollutants, including mixtures of pollutants.⁵⁶ The study considered cancer risks and non-cancer hazards (e.g., respiratory or neurological effects). By relying on

53. EPA, FRAMEWORK, *supra* note 10, at xii (citations omitted).

54. *See, e.g.*, Sexton, *supra* note 38 (“Over the past 35 years, the vast majority of risk assessments conducted by EPA have concentrated narrowly on individual chemical agents, distinct sources or source categories, and single exposure pathways, environmental media, routes of exposure, and health endpoints. It is becoming apparent, however, that a more holistic approach is necessary if risk assessment is to remain a relevant and reliable decision-making tool.” (citations omitted)).

55. EPA, FRAMEWORK, *supra* note 10, at 41 (“Cumulative risk assessments may be uniquely suited to addressing the issues related to vulnerability.”) To address environmental justice concerns, some researchers have worked to develop cumulative risk assessment methodologies that incorporate nonchemical stressors into the overall understanding of health risks faced by certain vulnerable communities. *See, e.g.*, Lewis et al., *supra* note 39, at 2020.

56. *See* Gallagher et al., *supra* note 2, at 702–03 (describing the National-Scale Air Toxics Assessment (NATA)).

atmospheric dispersion models and human activity pattern data, the EPA was able to identify which pollutants and sources posed the greatest relative risk. Importantly, this study was able to draw on existing, facility-specific data sets that had been systematically collected through air-monitoring requirements routinely included in permits issued under Title V of the Clean Air Act.⁵⁷ Studies like these can help the agency set regulatory priorities for reducing community exposures.⁵⁸ Understanding cumulative risk for local communities can also be useful when evaluating permitting decisions or facility siting proposals.

While the air toxins studies demonstrate the use of cumulative risk assessments on various spatial scales, and while they underscore the usefulness of having systematized data sets, they deal primarily with a single exposure route (namely inhalation). Real-world scenarios for chemical exposure from consumer products, by contrast, will likely require assessments that are sensitive to multiple exposure routes like dermal contact, inhalation, and ingestion. Fortunately, other case studies focused on assessing risks from groups or classes of chemicals have undertaken this challenge. Those studies have developed methods for assessing combined impacts from multiple exposure routes and for multiple chemicals leading to similar adverse outcomes.

For example, in response to regulatory requirements under the FQPA, the EPA studied the health risks posed by multiple pathways of exposure to the organophosphorus class of pesticides (also known as “organophosphates” or “OPs”).⁵⁹ These pesticides operate through a common mode of action and lead to similar adverse outcomes. In particular, organophosphates cause a common neurotoxic effect—they all inhibit cholinesterase.⁶⁰ Practically speaking, cholinesterase inhibition operates

57. *Id.* at 703 (discussing the Regional Air Impact Modeling Initiative (RAIMI) Pilot).

58. *Id.*

59. Examples of organophosphates include acephate, bensulide, DDVP, disulfoton, malathion, naled, Tetrachlorvinphos, and trichlorfon. See ENVTL. PROT. AGENCY, ORGANOPHOSPHORUS CUMULATIVE RISK ASSESSMENT 4 (2006), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2006-0618-0002&disposition=attachment&contentType=pdf> [hereinafter EPA, OP CRA].

60. The EPA explains the process:

OPs share the ability to bind to and phosphorylate the enzyme acetylcholinesterase in both the central (brain) and peripheral nerv-

as a nerve gas—acute exposure can cause death and some studies have suggested that chronic, low-level exposure can cause neurological disorders such as ADHD.⁶¹ The EPA’s cumulative risk assessment studied the combined risk from multiple pathways including food, drinking water, and residential exposures. Because the EPA was examining risks from more than one chemical, and from more than one pathway, the EPA used the relative potency factor (RPF) method to determine the combined risk associated with exposure to organophosphates. As explained by the EPA in its assessment:

Briefly, the RPF approach uses an index chemical as the point of reference for comparing the toxicity of the OP pesticides. Relative potency factors (RPFs) are calculated as the ratio of the toxic potency of a given chemical to that of the index chemical. RPFs are used to convert exposures of all chemicals in the group into exposure equivalents of the index chemical.⁶²

ous systems. When acetylcholinesterase is inhibited, acetylcholine accumulates and cholinergic toxicity results due to continuous stimulation of cholinergic receptors throughout the central and peripheral nervous systems which innervate virtually every organ in the body.

Id. at 3.

61. For a popular account of acute and chronic risks of organophosphates, see Ker Than, *Organophosphates: A Common but Deadly Pesticide*, NAT’L GEOGRAPHIC (July 18, 2013), <http://news.nationalgeographic.com/news/2013/07/130718-organophosphates-pesticides-indian-food-poisoning>. For studies discussing impacts from chronic exposure, see Maryse F. Bouchard et al., *Attention-Deficit/Hyperactivity Disorder and Urinary Metabolites of Organophosphate Pesticides*, 125 PEDIATRICS e1270, e1270–71 (2010); Amy R. Marks et al., *Organophosphate Pesticide Exposure and Attention in Young Mexican-American Children: The CHAMACOS Study*, 118 ENVTL. HEALTH PERSP. 1768 (2010) (examining Mexican-American children living in agricultural regions of California and concluding that prenatal and early childhood exposure to organophosphates can increase the risks of neurological disorders).

62. EPA, OP CRA, *supra* note 59. For the EPA’s cumulative risk assessment for the class of pesticides known as organophosphates, the EPA chose methamidophos as the reference chemical and then determined the relative potency of other organophosphates with respect to methamidophos. For example, malathion, an organophosphate used in mosquito control programs and sometimes found in lice-killing shampoo, was determined by EPA to be 0.0003 as potent as methamidophos through oral exposure, 0.015 as potent through dermal exposure, and 0.003 as potent through inhalation. By calculating these relative potencies, over multiple exposure routes, the EPA can add exposure risks from a class of chemicals that are otherwise varied in their toxic potentials. For a table of the relative potency factors, see *id.* at 51 tbl.I.B-5. Other similar methods have been used for assessing the impact of dioxin-like compounds. In December 2010 the EPA published the results of a cumulative risk assessment that examined the health impacts from exposure to “dioxin-like compounds” found in multiple environmental media. DLCs include 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated bi-

Because several chemicals were being assessed over multiple exposure pathways, the EPA used behavioral and environmental factors to develop a “probabilistic exposure assessment” in order to calculate the distribution of exposures from the various routes.⁶³ In the end, the EPA was able to compare the hazards posed from different pathways and identify specific organophosphates that posed the greatest hazard. In other words, the cumulative risk assessment allowed the EPA to assess overall safety from a class of compounds with similar mechanisms of toxicity and use that assessment to set regulatory priorities.⁶⁴

Recall that the OP study addressed impacts from multiple chemicals with a common mode of action. This means the chemicals cause a common toxic effect by operating through a similar “sequence of major biochemical events.”⁶⁵ A slightly different and more complex problem is raised when chemicals lead to similar adverse outcomes (e.g., cancer) but operate via different modes of action. The EPA tackled that issue in an evaluation of risk due to disinfection byproducts in chlorinated drinking water. In that instance there had been “[s]ome positive epidemiological and toxicological studies suggest[ing] reproductive and developmental effects and cancer are associated with consumption of chlorinated drinking water.”⁶⁶ The study was designed to assess multiple exposure routes, including dermal, oral, and inhalation. Because the chemicals studied did not necessarily operate via the same mode of action, the study tested the viability of a new method—the “cumulative relative po-

phenyls (PCBs). Having determined that these compounds were additive in their effect and operated through similar modes of toxicity, the EPA determined the toxic equivalency factor (TEF) for these compounds relative to TCDD. In doing so, the EPA would be able to determine the cumulative impact of these compounds when added together. The TEF methodology is appropriate for compounds with additive toxicity. U.S. ENVTL. PROT. AGENCY, RECOMMENDED TOXICITY EQUIVALENCE FACTORS (TEFs) FOR HUMAN HEALTH RISK ASSESSMENTS OF 2,3,7,8-TETRACHLORODIBENZO-P-DIOXIN AND DIOXIN-LIKE COMPOUNDS (2010), <https://www.epa.gov/sites/production/files/2013-09/documents/tefs-for-dioxin-epa-00-r-10-005-final.pdf> [hereinafter RECOMMENDED TOXICITY].

63. EPA, OP CRA, *supra*, note 58, at 9.

64. See Gallagher et al., *supra* note 2, at 702.

65. See EPA, OP CRA, *supra* note 59, at 3.

66. Linda K. Teuschler et al., *A Feasibility Study of Cumulative Risk Assessment Methods for Drinking Water Disinfection By-Product Mixtures*, 67 J. TOXICOLOGY & ENVTL. HEALTH 755, 755 (2004).

tency factor (CRPF) method”—to assess overall risk.⁶⁷ These methods for addressing common adverse outcomes as opposed to common mechanisms of toxicity have paved the way for cumulative risk assessments of chemicals like phthalates that are commonly found across a range of consumer products.⁶⁸

Together these examples demonstrate that the questions that cumulative risk assessments are meant to answer line up strikingly well with the real-world public health concerns that lie at the heart of chemicals and pesticide proliferation. This suggests a simple truth: if legislators and regulators are serious about addressing public health concerns, they need to move cumulative risk from the regulatory fringe and place it at the center of their efforts to set regulatory priorities.

B. THE CHALLENGES OF CUMULATIVE RISK ASSESSMENT

Given the natural fit between cumulative risk assessments and public health implications of chemicals and pesticide proliferation, one might ask why cumulative risk assessments have not taken a more prominent role in driving regulatory decisions. There are at least two reasons why cumulative risk assessments exist largely at the regulatory fringe. The first reason turns on technical and informational challenges to risk characterization. The second reason stems from the relatively few regulatory provisions that require risk management decisions to turn on cumulative risk characterization.

It is difficult to say which one of these challenges has to be tackled first—will the technical and informational gaps diminish if regulatory decision-making is required to turn on issues

67. The CRPF method is described by Teuschler et al.:

The CRPF approach is a new method that combines the principles of dose addition and response addition into one method to assess mixtures risk for multiple route exposures. (Using two subclasses, Sets A and C, Figure 2 illustrates how the CRPF approach estimates risk from exposure to the mixture.) The CRPF approach uses information on MOA to assign chemicals to common MOA subclasses. These subclasses differ with respect to MOA, but the toxicological endpoint (or outcome) is the same. For each subclass, an index chemical (a mixture component with high-quality dose-response data that acts [or is judged to act] through the same MOA as the other members of the subclass for the effect and route of concern) is selected, and *Index Chemical Equivalent Doses (ICED)* are calculated using the relative potency factor (RPF) approach.

Id. at 759 (citations omitted). As with the methods used to assess combined risk from organophosphates, the CRPF method makes the assumption of additivity. *Id.*

68. See *infra* Part I.B.1.

of cumulative risk? Or, would more regulatory drivers exist if cumulative risk assessments were easy to come by? To solve this chicken and egg problem, this Section examines the challenges to regulating cumulative risk. Ultimately, this Section concludes that a regulatory driver is necessary to making cumulative risk assessments relevant to risk management decisions. The technical challenges are complex but not insurmountable. Much progress has been made in developing methods, tools, and databases to facilitate cumulative risk characterization by regulators, communities, and professionals. For that work to translate into meaningful public health protection, however, a regulatory driver is needed.

1. Complexity in Risk Characterization

It is no secret that preparing a cumulative risk assessment is difficult.⁶⁹ Risk characterization for multiple chemicals over multiple exposure pathways requires researchers to properly model and synthesize several data sets. This process can pose both technical challenges (e.g., developing models to match the complexity of real world scenarios) and informational challenges (e.g., obtaining the information needed to run the models). Challenges include issues related to combining risk, fate and transport, timing of exposures, informational gaps, and compounding uncertainty.

a. *Combining Risk*

Some of the difficulty in assessing cumulative risk comes from the technical challenges of not only evaluating the health impacts of individual stressors but also developing ways to add up the risk.⁷⁰ To do this, researchers have to understand how chemicals interact in a mixture. In some situations, individual risks can be added to determine the joint risk. But in other situations, individual risks operate synergistically such that the sum is worse than the parts. Often the EPA will simplify the cumulative risk assessment by assuming additivity, because the understanding of synergistic interaction is still fairly undeveloped. In its cumulative risk assessment for organophosphate pesticides, for example, the EPA made a simplifying assump-

69. EPA, FRAMEWORK, *supra* note 10, at 8 (explaining that assessing multiple-stressor cumulative risk is “considerably more complex methodologically and computationally than for . . . aggregate risk assessments or single-effect cumulative risk assessments”).

70. EPA, FRAMEWORK, *supra* note 10, at 2.

tion based on available data that doses from the studied pesticides could be added once their relative toxicity was calculated.⁷¹ The EPA made this assumption while acknowledging “it is very difficult to prove dose additivity at human exposure levels” and “studies available on individual chemicals were usually not designed to address the issue of dose additivity.”⁷² The challenge of addressing synergistic interactions between chemicals was an issue that the EPA flagged in its 2003 Framework as well.⁷³

b. Fate and Transport

Because the goal of cumulative risk assessments is ultimately to model real-world exposure scenarios, understanding what happens to chemicals when released into the environment is an expected part of the assessment process. These “fate and transport” aspects of chemical assessment include considerations of bioaccumulation and metabolites. Bioaccumulating chemicals do not metabolize; that is, they do not breakdown over time. Rather, they are stored in the fatty tissue of humans and animals and persist in the environment for a long time. Chemicals like PCBs and other dioxin-like compounds are notorious for their persistence in the environment and bioaccumulation.⁷⁴ This bioaccumulating behavior prompted the EPA to study the kind of cumulative risk model that would be appropriate for these dioxin-like compounds.⁷⁵ Similarly, international regulatory agencies like Health Canada have identified bioaccumulation as a point of uncertainty in evaluating cumulative risk from phthalates.⁷⁶ Importantly, the bioaccu-

71. EPA, OP CRA, *supra* note 59, at 135.

72. *Id.*

73. EPA, FRAMEWORK, *supra* note 10, at xii.

74. See, e.g., Angelika Beyer & Marek Biziuk, *Environmental Fate and Global Distribution of Polychlorinated Biphenyls*, 201 REV. ENVTL. CONTAMINATION & TOXICOLOGY 137, 153 (2009) (“The intrinsic properties of PCBs, such as high environmental persistence, resistance to metabolism in organisms, and tendency to accumulate in lipids have contributed to their ubiquity in environmental media and have induced concern for their toxic effects after prolonged exposure.”).

75. RECOMMENDED TOXICITY, *supra* note 62, at ii.

76. Health Canada acknowledged that “[a] lack of empirical data on bioaccumulation for some phthalates also presents some uncertainty in the estimates of internal exposure concentrations.” HEALTH CAN. & ENV’T CAN., PROPOSED APPROACH FOR CUMULATIVE RISK ASSESSMENT OF CERTAIN PHTHALATES UNDER THE CHEMICALS MANAGEMENT PLAN 65 (2015), http://www.ec.gc.ca/ese-ees/723C9007-1CBE-427D-BC20-755F25013B53/Approach_

mulating nature of some chemicals means that the public health risks they pose can outlive their marketplace presence. For example, even though PCBs have long since been banned, they continue to impact ecological and human health.⁷⁷

The issues presented by metabolites are slightly different. Metabolites, or daughter products, are the chemical compounds that are formed when parent chemicals break down in the environment. These metabolites can be significant potential sources of toxicity. In its organophosphates study, for example, the EPA acknowledged that once organophosphates are released into the environment they can transform into other chemicals called oxons and that those oxons “may be more toxic than the parent [organophosphate].”⁷⁸ Similarly, when the EPA conducted a cumulative risk assessment for atrazine, a widely used and suspected endocrine-disrupting pesticide, the EPA also studied key metabolites. Notably, the metabolites are recognized as toxicologically equivalent to the commercially produced parent pesticide: “DEA, DIA, and DACT are all considered toxicologically equivalent (equipotent) to atrazine. All are key metabolites that occur in drinking water and have been included in this cumulative risk assessment.”⁷⁹ While at that time the EPA

Phthalates%20(CRA)_EN.pdf. Phthalates are a class of chemicals used in many consumer products “that have been associated with effects on the development of the reproductive system of male laboratory animals.” COMM. ON THE HEALTH RISKS OF PHTHALATES, NAT’L RES. COUNCIL, PHTHALATES AND CUMULATIVE RISK ASSESSMENT: THE TASK AHEAD (2008). The potential for exposure from phthalates from multiple consumer products (including such as cosmetics, medical devices, children’s toys, and building materials) prompted the National Academy of Sciences to call for a cumulative risk assessment in 2008. *Id.*

77. See WASH. DEPT OF ECOLOGY, PUB. NO. 14-04-035, POLYCHLORINATED BIPHENYLS (PCBS) IN GENERAL CONSUMER PRODUCTS 2 (2014), <https://fortress.wa.gov/ecy/publications/documents/1404035.pdf> (“Current levels of PCBs in Washington stem from cycling of PCBs in the environment, continuing releases from historic uses, and releases of newly generated PCBs [as by-products].”); Beyer & Biziuk, *supra* note 74, at 137.

78. EPA, OP CRA, *supra* note 59, at 11.

79. HEALTH EFFECTS DIV., OFFICE PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, CUMULATIVE RISK FROM TRIAZINE PESTICIDES 32 (2006), <http://oehha.ca.gov/media/downloads/crn/triazinecumulativerisk2006.pdf>. Based on that cumulative risk assessment, the EPA concluded that “there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable subgroups of consumers from aggregate exposure (from food, drinking water, and non-occupational sources) to cumulative residues of atrazine and the other chlorinated triazine pesticides.” Memorandum from Diane Sherman et al., Chem. Review Manager, Office of Pesticide Programs, to Robert McNally et al., Branch Chief, Office of Pesticide

concluded that atrazine exposure met federal safety standards, the EPA has recently published a refined ecological risk assessment that concludes atrazine poses significant ecological risk for “mammals, birds, reptiles, plants and plant communities across the country.”⁸⁰ That assessment reiterates that some of atrazine’s metabolites are of “equal potency” to atrazine.⁸¹

c. Timing of Exposures

In addition to fate and transport issues, assessing cumulative risk is made more complicated by the time-related aspects of exposure. As the EPA explained in its Framework: “Because some chemicals may have the ability to affect an organism’s response to other chemicals, consideration of the time sequence of exposure may take on an additional layer of complexity in multiple-chemical cumulative risk assessments.”⁸² In other words, timing of exposures to various chemicals may matter because exposure to one chemical may make an individual or community more susceptible to a later in time exposure to a second chemical. In single stressor assessments, by contrast, the timing of doses relative to one another is less important (although it may be important to consider timing relative to childhood developmental stages).

d. Information Gaps and Compounding Uncertainties

In addition to the technical challenges that experts face in developing theoretical models to reflect real-world exposure scenarios, there is one more obstacle to contend with: informational challenges. Even if researchers are confident in the theoretical models—e.g., choosing additive interactions over synergistic—the confidence in the ultimate assessment will be a function of the quality of the data inputs to the theoretical models. To that end, risk assessments require not just knowledge of chemical behavior (e.g., mode of action, whether

Programs 2 (Apr. 6, 2006), https://archive.epa.gov/pesticides/reregistration/web/pdf/atrazine_combined_docs.pdf.

80. FRANK T. FARRUGIA ET AL., U.S. ENVTL. PROT. AGENCY, REFINED ECOLOGICAL RISK ASSESSMENT FOR ATRAZINE 2 (2016), <http://chicagotonight.wttw.com/sites/default/files/article/file-attachments/EPA-HQ-OPP-2013-0266-0315.pdf>.

81. *Id.* at 23 (“Atrazine, simazine, propazine, and the 3 chlorinated degradates common to these compounds all exhibit neuroendocrine effects seen across mammals and can alter hormone levels in rats that may result in developmental and reproductive consequences.”).

82. EPA, FRAMEWORK, *supra* note 10, at 37.

interactions are additive) but also an understanding of dose to the average member of a population (e.g., exposure pathways, how frequently people are exposed, concentrations at which exposed).⁸³

Characterizing the dose-response relationship often requires researchers to make certain assumptions about human activity. It also requires understanding how chemical concentrations in the environment or in consumer products translate into doses. The national-scale air toxic assessment, for example, used atmospheric deposition models and human activity pattern data to estimate the frequency, duration, and magnitude of exposure.⁸⁴ In another, more regionally focused air toxics study, the EPA used air emissions data from federal and state regulatory databases and permit applications to estimate risks on the neighborhood level.⁸⁵ Similarly, to understand exposure probabilities, the researchers in the water study used data regarding concentrations of disinfection byproducts in water as well as human activity and water use patterns.⁸⁶ To get a sense of the assumptions involved, consider that the estimations of human patterns in the National Air Toxics Assessment were complicated by the fact that people move around from location to location, which may have differing air quality.⁸⁷ Also, people breathe at different rates depending on activity levels. “For these reasons, the average concentration of a pollutant that people breathe (i.e., exposure concentration) may be significantly higher or lower than the concentration at a fixed location (i.e., ambient concentration).”⁸⁸

Though complex, these case studies demonstrate that quantifying risks through cumulative risk assessments is more feasible when regulatory frameworks like the Clean Air Act or the Safe Drinking Water Act systematize the collection of data regarding chemical concentrations in the environment (e.g., air emissions data or water concentration data). When exposure results from chemicals contained in multiple consumer prod-

83. *Id.* at 38 (“Estimating exposure is a key step in determining potential health risk.”).

84. Gallagher et al., *supra* note 28, at 703.

85. *Id.*

86. *Id.* at 702.

87. *Id.* at 58.

88. See *Overview: The 4 Steps*, U.S. ENVTL. PROTECTION AGENCY, <https://archive.epa.gov/airtoxics/nata/web/html/4steps.html> (last updated Feb. 21, 2016).

ucts, informational challenges may be more substantial because there may be additional uncertainty regarding how contact with a chemical translates into dose. For example, how much of the PFOA in Teflon-coated cookware makes its way into a given person's body when that person uses the cookware on average ten times per week? Or how much of the BPA from a water bottle leaches in the water that an individual then drinks?

In order to fully appreciate the informational challenges that confront cumulative risk assessments, consider that cumulative risk assessments require the same knowledge as otherwise needed for single stressor risk assessments, and then some.⁸⁹ This means that whatever data gap issues plague a regulator's understanding of individual chemicals are not avoided, but potentially compounded, in cumulative risk assessments.⁹⁰ The information gap for chemicals has been well documented.⁹¹ If cumulative risk assessments were to take a

89. See EPA, FRAMEWORK, *supra* note 10, at 44 (discussing how single stressor studies can "provide informative qualitative information for multistressor assessments" but that "further consideration" is needed before exposure assessments for single stressors can be used in cumulative risk assessments).

90. *Id.* at 32 ("Large data gaps make risk and hazard assessment of environmentally relevant chemical exposures highly uncertain even for single agents. Expanded assessments that address cumulative risk considerations (e.g. mixtures, developmental toxicity, nonchemical agents) are a better match for real-world circumstances but require acknowledgement of even more uncertainty."); see also *id.* at 36 (explaining that information challenges are even greater for nonchemical stressors).

91. For a detailed discussion of the profound information gap that plagues toxic chemicals, see Wagner, *supra* note 19, at 1619 ("One of the most significant problems facing environmental law is the dearth of scientific information available to assess the impact of industrial activities on public health and the environment."). Similar observations have been made in the cumulative risk assessment literature. See EPA, FRAMEWORK, *supra* note 10, at 47 ("Toxicity and interaction data that cover the full range of exposures for the exposure-response relationship for mixture of interest is usually impossible to obtain because of limits on budgets and other resources."); see also Sarah Alves et al., *U.S. EPA Authority To Use Cumulative Risk Assessments in Environmental Decision-Making*, 9 INT'L J. ENVTL. RES. & PUB. HEALTH 1997, 2001 (2012) ("[I]n real life, information is usually limited on one or more of these key data needed for risk assessment calculations." (quoting *Risk Assessment: About Risk Assessment*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/risk/about-risk-assessment> (last visited Apr. 24, 2017))); Ken Sexton & Dale Hattis, *Assessing Cumulative Health Risks from Exposure to Environmental Mixtures—Three Fundamental Questions*, 115 ENVTL. HEALTH PERSPS. 825, 825 (2007) ("Although there is an expanding body of work on cumulative exposures and combined effects on people . . . adequate and appropriate data are rarely available to conduct a rigorous assessment of cumulative risk.").

more prominent role in the regulation of chemicals and pesticides, the informational problems that exist today would need to be addressed before substantial progress could be made for cumulative risk assessments. In the meantime, for some cumulative risk assessments, qualitative analysis may need to substitute for quantification if the data sets are not available.

Taken together, these individual technical and informational challenges may result in one of the most difficult political challenges standing between cumulative risk assessments and their more widespread use in risk management decisions. That is, at each step along the way—assessing individual risk, determining the mechanism for adding together the risk, deciding how to treat the timing of exposures, identifying vulnerabilities from nonchemical or genetic stressors, accounting for metabolites, relying on qualitative assessments when data is unavailable—uncertainty is introduced to the overall assessment.

Notably, uncertainty need not be a bar to regulation. To supplement the federal regime, California adopted legislation to address chemicals regulation.⁹² In addition to imposing a disclosure requirement, Proposition 65 prohibits businesses from discharging toxic chemicals into drinking water supplies.⁹³ Because liability turns on specified risk levels, the statute contains a number of provisions addressing how risk from chemicals exposure ought to be calculated.⁹⁴ To account for uncertainty in assessing cumulative risk, for example, Proposition 65 makes conservative assumptions, e.g., setting the exposure level for reproductive toxicants at one thousand times the actual exposure level.⁹⁵

92. Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HCS CODE §§ 25249.5–26217 (2016).

93. *Id.* § 25249.5.

94. Michael W. Graf, *Regulating Pesticide Pollution in California Under the 1986 Safe Drinking Water and Toxic Exposure Act (Proposition 65)*, 28 *ECOLOGICAL L.Q.* 663, 671–73 (2001).

95. *Id.* at 673. As Michael Graf has explained:

Proposition 65 assumes a *lifetime exposure* at the level of chemical concentration in the relevant environmental medium (such as air or water). For reproductive toxicants, which may pose an acute risk dependent on the amount of a single dose, Proposition 65 assumes an exposure at *one thousand (1,000) times the actual exposure level*. These conservative statutory assumptions assure that discharges or exposures are assessed in a preventative manner, in effect taking into account—albeit in an approximate fashion—the cumulative effect of the different sources of toxic chemicals to which persons will be exposed.

Id.

While uncertainty in risk assessment is not a bar to regulation, and while even the act of asking cumulative risk questions advances public health missions, uncertainty does open up regulators to delay through litigation challenges and rule-making ossification. Ultimately, the appetite for regulating in the face of uncertainty, both from regulators and legislators, will have much influence over how useful cumulative risk assessments can ultimately be in risk management decisions.

Part IV will take up the discussion of how legal frameworks can be structured to protect public health in the face of uncertainties in cumulative risk assessment. In particular, regulating on the basis of cumulative risk would require statutory frameworks that anticipate uncertainty and reflect a precautionary approach to chemicals or pesticide proliferation, either by shifting the burden of proving safety to firms or crafting safety standards that allow regulation when cumulative risks “may” be unreasonable to public health.

2. The Need for a Regulatory Driver

So far, an examination of the promise and challenges of cumulative risk assessment appears to present a dilemma of sorts: on the one hand, assessing cumulative risk is highly relevant to answering key questions about public health; on the other hand, it is difficult. As it turns out, however, the fact that cumulative risk assessments are complex does not justify keeping them on the regulatory fringe. It may well be true that the science could not support a regulatory focus on cumulative risk assessment in the 1970s and 1980s, when many environmental statutes were adopted. That is no longer true.

Today, agency scientists, academics, and professionals are devoting resources to develop better methods and tools for undertaking cumulative risk assessments.⁹⁶ Most notably, the U.S. EPA has initiated a research program called the Cumulative Communities Research Program.⁹⁷ This program develops

96. See generally Valerie G. Zartarian & Bradley D. Schultz, *The EPA's Human Exposure Research Program for Assessing Cumulative Risk in Communities*, 20 J. EXPOSURE SCI. & ENVTL. EPIDEMIOLOGY 351 (2010) (describing various tools being developed to facilitate cumulative risk assessments).

97. See Timothy M. Barzyk et al., *Tools Available to Communities for Conducting Cumulative Exposure and Risk Assessments*, 20 J. EXPOSURE SCI. & ENVTL. EPIDEMIOLOGY 371 (2010); Myriam Medina-Vera et al., *An Overview of Measurement Method Tools Available to Communities Conducting Exposure and Cumulative Risk Assessment*, 20 J. EXPOSURE SCI. & ENVTL. EPIDEMIOLOGY 359 (2010). A companion program—the EPA Community Action for a Re-

a broad range of tools, including fact sheets, web portals, exposure models, databases, and sampling methods to advance cumulative risk science.⁹⁸ For example, several web-based GIS mapping tools to help regulators, communities, and professionals identify locations of regulated facilities, brownfields, superfund sites, waste management facilities, and more.⁹⁹ One web-site was developed by federal, state and tribal agencies to provide access to national air quality information.¹⁰⁰ In addition to mapping tools, the EPA has developed several informational databases on everything from chemical toxicity data to national radiation data, to water pollutant discharge data, to hazardous air pollutant data.¹⁰¹ Many of these tools and databases are publicly available.

There are also guidance documents available on a variety of topics meant to advance community understanding of public health and environmental risk. For example, there are documents providing advice on how to reduce asbestos exposure, how to identify sources of outdoor air pollution, how to apply principles of risk assessment to air toxins, how to become involved in the superfund assessment process. More specific to cumulative risk assessments, the EPA has published frameworks for ecological risk assessment, risk assessment guidelines on chemical mixtures and developmental toxicity, and guidance documents on issues like cumulative risk planning and scoping.¹⁰²

Not least, the EPA has devoted resources to developing exposure models for cumulative risk.¹⁰³ One model is aimed specifically at quantifying the “potential inhalation, dermal and ingestion dose rates resulting from chemicals released from

newed Environment (CARE)—provides funding and technical assistance to community groups to address concerns related to public health risks. *Id.* In addition to the CARE program, the EPA’s National Center for Environmental Research (NCER) is also funding research “to develop methods and strategies for assessing the combined effects of chemical, physical, biological and social stressors while factoring in population vulnerabilities.” PAYNE-STURGES & MARTIN, *supra* note 46.

98. See Barzyk, *supra* note 97, at 372.

99. *Id.* at 373.

100. *Id.* at 374.

101. *Id.* at 380.

102. EPA, FRAMEWORK, *supra* note 10, at 5 (providing table of guidelines and guidance documents published by the EPA to advance cumulative risk science).

103. Barzyk, *supra* note 97.

consumer products.”¹⁰⁴ Another examines dietary exposure to pesticide through chemical residues on food. The models can get fairly specific—like modeling exposure to wood preservatives from outdoor playgrounds. Some models even tackle the time-related aspects of cumulative risk modeling.¹⁰⁵ Other tools address population vulnerability and nonchemical stressors.¹⁰⁶ Still others look at child-specific issues of aggregate exposure.¹⁰⁷ Notably, states like California are breaking ground on these issues as well. To that end, the California Environmental Protection Agency (Cal. EPA) has been a trailblazer in efforts to develop a screening method to identify and rank communities that are most affected by cumulative risk from chemical and nonchemical stressors.¹⁰⁸

With advances in research on biomarkers, nonchemical stressors, genomics, and data analysis, there are many tools, models and databases available for cumulative risk analysis. Together this body of research may inspire an optimist to observe that technical and informational challenges to cumulative risk assessment, while difficult, are increasingly solvable. And given the evolutions in science to provide better tools for assessing cumulative risk, one might expect cumulative risk as-

104. *E-FAST-Exposure and Fate Assessment Screening Tool Version 2014*, ENVTL. PROTECTION AGENCY, <https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014> (last visited Apr. 24, 2017).

105. EPA, FRAMEWORK, *supra* note 10, at 40.

106. See PAYNE-STURGES & MARTIN, *supra* note 46, at 2 (discussing in generalities the Cumulative Environmental Vulnerability Analysis (CEVA) and the California EPA’s CalEnviroScreen models). See generally Teresa Chahine et al., *Modeling Joint Exposures and Health Outcomes for Cumulative Risk Assessment: The Case of Radon and Smoking*, 8 INT’L J. ENVTL. RES. & PUB. HEALTH 3688 (2011) (examining residential radon levels to make generalizations about chemical and non-chemical stressors).

107. See generally Paloma I. Beamer, *Relative Pesticide and Exposure Route Contribution to Aggregate and Cumulative Dose in Young Farmworker Children*, 9 INT’L J. ENVTL. RES. & PUB. HEALTH 73 (2012) (utilizing the Child-Specific Aggregate Cumulative Human Exposure and Dose framework to quantify exposure in young farmworker children).

108. Laura Meehan August, *Methodological Considerations in Screening for Cumulative Environmental Health Impacts: Lessons Learned from a Pilot Study in California*, 9 INT’L J. ENVTL. RES. PUB. HEALTH 3069, 3070 (2012); Ganlin Huang & Jonathan K. London, *Cumulative Environmental Vulnerability and Environmental Justice in California’s San Joaquin Valley*, 9 INT’L J. ENVTL. RES. PUB. HEALTH 1593, 1594 (2012); James L. Sadd, *Playing It Safe: Assessing Cumulative Impact and Social Vulnerability Through an Environmental Justice Screening Method in the South Coast Air Basin, California*, 8 INT’L J. ENVTL. RES. PUB. HEALTH 1441, 1454–56 (2011).

assessment to have become more of a driver in environmental and public health regulation. This has not been the case.

Despite progress on the technical side, and with the possible exception of state-led efforts in California, risk assessment practice has “lagged behind the science.”¹⁰⁹ Within EPA program offices, there is no agency-wide policy for considering cumulative risks when making environmental decisions.¹¹⁰ To be sure, there have been statements of support, urging the importance of cumulative risk assessments. There have also been guidance documents in support of efforts to assess cumulative risk. And yet, cumulative risk assessments exist largely in the context of voluntary and informational measures. The EPA’s framework on cumulative risk assessment is “[n]either a procedural guide nor a regulatory requirement.”¹¹¹ The risk assessment literature more often speaks in terms of developing tools to “empower communities with information” than to meet regulatory requirements.¹¹² To that end, the EPA developed a web-based tool, the Community-Focused Exposure and Risk Screening Tool (C-FERST), which is meant to be a “one-stop shopping tool” that makes exposure models, information databases, and guidance documents available in the same place.¹¹³

Of course, no part of this critique is meant to suggest that community empowerment is ill-advised. Rather this serves to highlight the fact that regulatory frameworks are not featured prominently as the endpoint for risk characterization efforts. Indeed, there is a separation between risk assessment efforts

109. Margaret M. MacDonell et al., *Cumulative Risk Assessment Toolbox: Methods and Approaches for the Practitioner*, J. TOXICOLOGY, 2013, at 1, 2 <http://dx.doi.org/10.1155/2013/310904> (“Despite the increase in relevant analyses and reports, the translation of a more fully integrated approach to practice has lagged behind the science. With various groups and individual community members unaware of available tools that could be used to assess cumulative risk, explicit applications have been relatively modest.”).

110. Alves, *supra* note 91, at 1997; *see also id.* (“Some EPA offices make decisions as if they do not have the authority to use cumulative risk assessments.”).

111. MacDonell, *supra* note 109.

112. Zartarian & Schultz, *supra* note 96, at 357; *see also* Barzyk, *supra* note 97 (“Community-based risk assessments have been gaining momentum as community groups become involved in identifying, prioritizing, and mitigating their environmental concerns.”).

113. Pamela R.D. Williams et al., *Cumulative Risk Assessment (CRA): Transforming the Way We Assess Health Risks*, 46 ENVTL. SCI. & TECH. 10868, 10871 (2012), <http://pub.acs.org/doi/abs/10.1021/es3025353> (describing C-FERST as a “flagship tool”).

and risk management decisions.¹¹⁴ The Center for Disease Control (CDC) has been conducting a series of biomonitoring studies since 1999, whereby the CDC measures various chemicals in people's blood and urine to assess the levels of chemical absorption across the general population.¹¹⁵ The results of these CDC assessments highlight that while individual products or chemicals might not raise safety concerns, the collective exposure may be quite alarming. And yet, the CDC reports are informational only; they do not provide regulatory recommendations.¹¹⁶ Similarly, some cumulative risk assessments undertaken by the EPA, like the dioxin assessment, emphasize that the work is not binding.

Ultimately these observations point to a simple assertion: for cumulative risk assessment to move from regulatory fringe, there need to be regulatory drivers. The problem with taking a cumulative risk focus to public health regulation is not a barrier of science, but policy. In fact, while the science has evolved, the legal frameworks have remained stagnant. The Food Quality Protection Act (FQPA) is one of the few examples of a regulatory command that puts issues of cumulative risk at the center of public health standards.¹¹⁷ Not surprisingly, much of the recent work that has been done on cumulative risks of chemicals or pesticides has cited the FQPA mandates as the impetus for that work.¹¹⁸ Outside of limited legal contexts, however, cumulative risk assessments have assumed only an ad hoc, informational role. In fact, relative to the number of questions that regularly emerge regarding exposure to chemicals in all aspects

114. P. Calow & V.E. Forbes, *Making the Relationship Between Risk Assessment and Risk Management More Intimate*, 47 ENVTL. SCI. & TECH. 8095, 8096 (2013).

115. See U.S. DEP'T HEALTH & HUMAN SERVS. & CTR. FOR DISEASE CONTROL, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS 1 (2009), <https://www.cdc.gov/exposurereport/pdf/fourthreport.pdf>. The CDC released its Fourth National Report on Human Exposure to Environmental Chemicals in 2009 and provided updates to its tables in 2015. See generally U.S. DEP'T HEALTH & HUM. SERVS. & CTR. FOR DISEASE CONTROL, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS, UPDATED TABLES (2015), https://www.cdc.gov/biomonitoring/pdf/FourthReport_UpdatedTables_Feb2015.pdf.

116. See *National Report on Human Exposure to Environmental Chemicals: Frequently Asked Questions*, CTRS. FOR DISEASE CONTROL, <https://www.cdc.gov/exposurereport/faq.html> (last visited Apr. 24, 2017).

117. See U.S. ENVTL. PROT. AGENCY, FRAMEWORK FOR CUMULATIVE RISK ASSESSMENT app. E (2003).

118. See, e.g., Beamer, *supra* note 107, at 73.

of daily life, very little work has been done to find answers from a cumulative risk perspective. And when that work has been done, it does not always have an obvious or prominent home in the risk management decisions.

II. THE NECESSITY OF REGULATING CUMULATIVE RISK

So far, this Article has examined why cumulative risk assessments are a good fit for addressing population-level risks posed by chemicals and pesticide proliferation. To understand why regulating cumulative risk is not just a good idea but also necessary to protecting public health, consider the alternative: when regulatory frameworks ignore issues of cumulative risk, or when chemicals and pesticide regulations are weak, individuals are left to assess and manage their own risk from countless consumer products and environmental sources.

This is precisely the situation that existing legal frameworks have created. In fact, an important backdrop to the story of failed chemicals regulation in the United States may be the promotion of the idea that individual consumers are the masters of their own fate. For example, there is no shortage of helpful hints from the blogosphere, books, news articles, or NGOs on how to protect ourselves in a world laced with chemicals. In one article, the *Washington Post* provides tips for avoiding toxic bisphenol-S, which is the chemical sometimes used to replace the controversial bisphenol-A in BPA-free products.¹¹⁹ Among the long list of items to avoid, we find “tissue paper and toilet paper.”¹²⁰ From the reporters at CNN we are told to avoid shampoo with fragrances.¹²¹ From the Environmental Working Group we are told to buy organic whenever possible.¹²² Of

119. Amy Ellis Nutt, *How To Avoid Products with Toxic Biphenol-S*, WASH. POST (Jan. 13, 2015), <https://www.washingtonpost.com/news/to-your-health/wp/2015/01/13/how-to-avoid-products-with-toxic-bisphenol-s>. Also on the list are hard plastic sports bottles, plastic food storage containers, food wrap, hard and flexible packaging, deli containers, plastic bags, baby bottle components (nipple, ring, liner, etc.), plastic dinnerware and plates, non-stick cookware, plastic cleaning products, thermal receipt paper, and canned foods and drinks. *Id.*

120. *Id.*

121. See Martin, *supra* note 11.

122. *Frequently Asked Questions About Produce and Pesticides: Should We Eat More Fruits and Vegetables? What About Pesticide Residues?*, ENVTL. WORKING GROUP, https://www.ewg.org/foodnews/faq.php#question_8 (last visited Apr. 24, 2017).

course this helpful advice usually comes with the caveat that “it is nearly impossible to not be exposed to plastic in the course of a day.”¹²³

When the problems of chemicals and pesticide proliferation are viewed from a public health lens, it may seem obvious to some that individuals cannot manage the fallout on their own.¹²⁴ At the same time, disclosure regulation has found traction in many areas of regulatory decision-making and certainly has appeal from a freedom of choice perspective. Some reflection on the scholarly discourse surrounding disclosure regulation is, therefore, warranted. To that end, this Part begins by considering the general support for and criticisms of disclosure as a regulatory tool. After surveying the existing discourse rules, this Part goes on to explain why, when viewed with an appreciation for cumulative risk, disclosure is a nonsensical approach to chemicals and pesticide regulation. In the end, the inability of individuals to manage their own risk from the multitude of chemical and pesticides that are encountered in daily life is not just an argument against relying on information disclosure; it is an argument for directly addressing public health concerns by regulating cumulative risk.

A. DISCLOSURE REGULATION AS A GOVERNANCE TOOL

Disclosure regulation relies on the dissemination of information to the public as a means of facilitating consumer choice and ultimately allowing public pressure to encourage self-regulatory corporate behavior. This governance tool has deep and wide roots in American regulatory regimes.¹²⁵ In what Pro-

123. Nutt, *supra* note 119.

124. Non-experts would understandably have difficulty sorting out conflicting scientific reports and counter-narratives from industry groups. See David Heath, *Contesting the Science of Smoking*, THE ATLANTIC (May 4, 2016), <http://www.theatlantic.com/politics/archive/2016/05/low-tar-cigarettes/481116> (comparing the strategies used by the chemicals industry with those used by tobacco industry in manufacturing doubt with respect to health data). See generally NAOMI ORESKES & ERIK CONWAY, *MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING* (2010); *MERCHANTS OF DOUBT*, <http://www.merchantsofdoubt.org> (last visited Apr. 24, 2017) (“The troubling story of how a cadre of influential scientists have clouded public understanding of scientific facts to advance a political and economic agenda.”).

125. Cass R. Sunstein, *Informational Regulation and Informational Standing: Akins and Beyond*, 147 U. PA. L. REV. 613, 619 (1999) (“[M]any statutes and regulations now require the disclosure or even the production of information.”).

fessors Omri Ben-Shahar and Carl Schnieder have since called the “Disclosure Empire,”¹²⁶ information disclosure requirements have played a role in myriad legal frameworks from financial regulations to fuel efficiency standards, and pension plans to college promotional brochures.¹²⁷ Professor Cass Sunstein has likewise observed that “[t]raditionally, information production and disclosure have been considered an appropriate regulatory response to market failures that stem from asymmetric or inadequate information.”¹²⁸

The idea that government should reduce regulatory burdens and encourage freedom of choice for the public has also found traction in Executive Order 13563, issued by the Obama administration: “Where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.”¹²⁹

Among legal scholars, the support for information disclosure runs the gamut from using disclosure as a complement to substantive regulation to relying on disclosure as a substitute for substantive regulation. Professor Cass Sunstein argues “from the standpoint of efficiency, information remedies can be better than either command-and-control regulation or reliance on unregulated markets alone.”¹³⁰ The information, he explains, allows citizens to oversee and assess government regulation. In this way, “[a] well-functioning system of deliberative democracy requires a certain degree of information.”¹³¹ Similarly, Professors Kip Viscusi and Ted Gayer have advocated disclosure laws

126. Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 665 (2011) (“The great paradox of the Disclosure Empire is that even as it grows, so also grows the evidence that mandated disclosure repeatedly fails to accomplish its ends.”).

127. See, e.g., Cass R. Sunstein, *Empirically Informed Regulation*, 78 U. CHI. L. REV. 1349, 1366–67 (2011); see also Jacob Alderice, *The Informed Student-Consumer: Regulating For-Profit Colleges by Disclosure*, 50 HARV. C.R.—C.L. L. REV. 215, 247 (2015) (discussing the role of information disclosure in the regulation of for-profit colleges); Lauren E. Willis, *When Nudges Fail: Slippery Defaults*, 80 U. CHI. L. REV. 1155, 1224 (2013).

128. Sunstein, *supra* note 127 (describing the various areas in which disclosure regulation has been used).

129. Exec. Order No. 13563, 76 Fed. Reg. 3821, 3822 (Jan. 21, 2011); see also *id.* at 3821 (including information disclosure as one an example of an appropriate regulatory tool).

130. Sunstein, *supra* note 125, at 625.

131. *Id.*

as a cost effective regulatory approach that respects the different risk tolerances among various individuals: “hazard warnings potentially can work through the market by providing consumers and workers with needed information” and “permit[ting] people to make choices consistent with their own risk-cost balancing rather than being subject to uniform regulatory standards that almost invariably fail to recognize such differences in individuals’ willingness to bear risk.”¹³² In a rhetorical twist, Professor Katherine Renshaw argues that information disclosure is beneficial because it “can demonstrate regulatory failings and thus has the potential to shift political and grassroots support towards developing stronger ex ante controls.”¹³³

Within the particular area of environmental regulation, disclosure as a regulatory driver has at times been celebrated as well.¹³⁴ As Professor David Case has observed, “Advocates of informational regulation argue that public distribution of information can lead to self-regulatory improvement in the environmental performance of business and industry.”¹³⁵ Most frequently, the Toxic Release Inventory (TRI) has been held out as an example of how information disclosure regimes can result in desired behavioral shifts.¹³⁶

132. W. Kip Viscusi & Ted Gayer, *Safety at Any Price?*, 25 CATO. REV. BUS. & GOVT: REG. 54, 60 (2002); see also CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE 152 (2005) (urging that government regulation should respect the fact the people have various appetites and tolerances for risk). *But cf.* Cass R. Sunstein & Lucia A. Reisch, *Automatically Green: Behavioral Economics and Environmental Protection*, 38 HARV. ENVTL. L. REV. 127, 127–57 (2014) (arguing for the use of default rules to preserve consumer choice while encouraging “greener choices”).

133. Katherine Renshaw, *Sounding Alarms: Does Informational Regulation Help or Hinder Environmentalism?*, 14 N.Y.U. ENVTL. L.J. 654, 658 (2006).

134. See David Case, *The Law and Economics of Environmental Information as Regulation*, 31 ENVTL. L. REV. 10773, 10773 (2007) (“[I]nformation disclosure has emerged as a key component of strategies to promote more effective, less costly alternatives to command-and-control regulation. A number of consensus-building forums, expert panels, and policy reports argue that public distribution of information can serve as an effective policy tool for driving improvements in environmental performance.”).

135. David W. Case, *The Lost Generation: Environmental Regulatory Reform in the Era of Congressional Abdication*, 25 DUKE ENVTL. L. & POL’Y F. 49, 76–78 (2014).

136. *Id.* at 77. (“The perception that informational regulatory strategies can successfully create conditions leading to desirable self-regulatory environmental behavior is largely fueled by the relative success of the Toxics Release Inventory (TRI).”); see also Bradley C. Karkkainen, *Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a*

The TRI, created by the Emergency Planning and Community Right to Know Act (EPCRA) in 1986, requires manufacturing facilities to submit annual data to the EPA on the amount of certain chemicals released into the air, water, or land.¹³⁷ The EPA compiles that information into the TRI, which is publically available and has been used by media outlets and groups like the Environmental Defense to generate facility “Scorecards.”¹³⁸ The public pressure generated by the TRI has been credited for a forty percent reduction in the covered chemicals.¹³⁹

Even famously progressive states like California have made information disclosure the centerpiece of chemical regulation laws adopted to supplement the federal regime. For example, California Proposition 65 prohibits manufacturers from exposing any person to carcinogens or reproductive toxins without providing a clear and reasonable warning.¹⁴⁰ The labels are generally generic, typically some version of “WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm.”¹⁴¹ While there have been some benefits of the infor-

New Paradigm?, 89 GEO. L.J. 257, 261–62 (2001); Sunstein, *supra* note 127, at 1384 (“Available evidence indicates that the TRI has had beneficial effects, helping to spur reductions in toxic releases throughout the United States.”). Outside the TRI context, information disclosure as an approach to environmental problems has found cabined support as well. See Sarah E. Light, *NEPA’s Footprint: Information Disclosure as a Quasi-Carbon Tax on Agencies*, 87 TUL. L. REV. 511, 519 (2013) (“Accurate information can promote and facilitate better technology-based direct regulation, more tailored health-based regulations, improved market approaches through the identification of negative or positive externalities, and social norms that promote environmental goals and aspirations.”).

137. Case, *supra* note 135, at 77.

138. Case, *supra* note 134, at 10775.

139. *Id.*; see also Case, *supra* note 135, at 77; Archon Fung & Dara O’Rourke, *Reinventing Environmental Regulation from the Grassroots, Explaining and Expanding the Success of the Toxics Release Inventory*, 25 ENVTL. MGMT. 115, 120–21 (2000) (surveying how citizen groups use TRI data and finding that “85% of respondents reported that they used it to exert public pressure on facilities and 58% reported that targeted facilities eventually pursued source reduction efforts”).

140. CAL. HEALTH & SAFETY CODE § 25249.6 (West 2016), *preempted by* People v. Tri-Union Seafoods, L.L.C., No. CGC-01-402975, 2006 WL 1544384 (Cal. Super. Ct. May 11, 2006) (“No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . .”).

141. Michael Barsa, Note, *California’s Proposition 65 and the Limits of Information Economics*, 49 STAN. L. REV. 1223, 1228 (1997) (quoting CAL. CODE REGS. tit. 22. § 12601(b)(4)(D) (1991)).

mation law in terms of incentives on manufacturers to design safer products in order to avoid warning labels,¹⁴² California Proposition 65 leaves members of the public to decipher warning signs posted in parking lots, banks, apartment complexes,¹⁴³ and even Disneyland.¹⁴⁴

Not all of the attention on information disclosure within environmental law has been positive, however. Margot Pollans writes about consumer decisions in response to food labeling and argues that “[p]rovision of information might be counter-productive or ineffectual, particularly if consumer bias or lack of knowledge prevents proper interpretation.”¹⁴⁵ Evaluating future risk proves especially problematic in the usefulness of labeling, she argues.¹⁴⁶ California Proposition 65 and its efforts to influence chemicals safety through disclosure requirements has drawn strong criticism¹⁴⁷ on the grounds that the required warnings are too vague,¹⁴⁸ tend to overstate the risk,¹⁴⁹ and are

142. *Id.* at 1226, 1238 (arguing that the regulatory regime is successful in terms of raising the consciousness of manufacturers and motivating change in order to avoid undesired warning labels, instead of defending California Proposition 65 on the basis that it effectively communicates risk); Michael W. Graf, *Regulating Pesticide Pollution in California Under the 1986 Safe Drinking Water and Toxic Exposure Act (Proposition 65)*, 28 *ECOLOGY L.Q.* 663, 665–66 (2001) (describing California Proposition 65 as furthering the public’s right to know about toxic chemical exposure and arguing for a similar disclosure regime to supplement pesticide regulation).

143. See Brendan Borrell, *Are Proposition 65 Warnings Healthful or Hurtful?*, *L.A. TIMES* (Nov. 2, 2009), <http://www.latimes.com/health/la-he-pro-con2-2009nov02-story.html>.

144. See *Disneyland Attractions Contain High Levels of Lead, Environmental Group Alleges*, *HUFFINGTON POST* (Dec. 23, 2011), http://www.huffingtonpost.com/2011/10/23/disneyland-attractions-lead-contamination_n_1023825.html.

145. Margot J. Pollans, *Bundling Public and Private Goods: The Market for Sustainable Organics*, 85 *N.Y.U. L. REV.* 621, 636–37 (2010).

146. *Id.*

147. For a thorough critique of the myriad ways California Proposition 65 fails to provide effective warnings, see Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California’s Proposition 65*, 23 *ECOLOGY L.Q.* 303, 327 (1996).

148. *Id.* at 327 (“Warnings also fail to identify the specific chemicals causing an exposure.”); see also *id.* (“The warnings also fail to convey other useful information for informed decisionmaking, such as the means of exposure (inhalation, ingestion, or absorption), or information about steps that can be taken to reduce exposures.”).

149. W. KIP VISCUSI, *PRODUCT-RISK LABELING: A FEDERAL RESPONSIBILITY* 61–69 (1993); Lars Noah, *The Imperative To Warn: Disentangling the “Right To Know” from the “Need To Know” About Consumer Product Hazards*, 11 *YALE J. ON REG.* 293, 298–339 (1994).

so commonplace that they are simply ignored by consumers.¹⁵⁰ Even the celebrated TRI has been criticized on the grounds that it “omits many environmentally significant chemicals[,] . . . focuses on sources that account for a small fraction of releases[,] and] . . . fails to note distinctions between more and less risky pollutants or modes of release.”¹⁵¹

Scholars outside the area of toxin regulation are likewise speaking out against disclosure and notice as viable approaches to solve collective action problems. For example, in the privacy space, Professor Daniel J. Solove argues that “[t]here are too many entities collecting and using personal data to make it feasible for people to manage their privacy separately with each entity.”¹⁵² These and other structural problems limit the effectiveness of privacy self-management and suggest that managing personal data is a collective action problem that calls for a more coordinated and deliberate regulatory approach.

Professors Omri Ben-Shahar and Carl Schneider argue more globally that mandatory disclosure simply does not work. They argue that the sheer volume of disclosures bombarding individuals under current regulatory regimes makes meaningful digestion of that information unreasonable:

Mandated disclosure is a regulatory response to the problems of non-specialists facing unfamiliar and complex decisions. It is broadly, almost indiscriminately, used. But it fails to achieve its goals because unfamiliar and complex decisions are much harder than disclosurite ideology assumes. Giving consumers information about such decisions cannot equip them to make the truly informed decisions that disclosurites desire. Mandated disclosure is a fundamental failure that cannot be fundamentally fixed.¹⁵³

Ben-Shahar and Schneider further explain that the “clutter of information” faced by individuals by myriad disclosures across many subjects (home loan, privacy disclosure, medical care,

150. Rechtschaffen, *supra* note 147, at 355 (discussing the “overwarning” problem with California Proposition 65); *see also id.* (arguing that the volume of warnings has diminished the effectiveness of Proposition 65 as a public awareness tool (citing Peter H. Weiner, *Enforcement of Proposition 65: Unclear and Unreasonable?*, PROP 65 NEWS, Feb. 1992, at 8)).

151. William F. Pederson, *Regulation and Information Disclosure: Parallel Universes and Beyond*, 25 HARV. ENVTL. L. REV. 151, 152 (2001).

152. Daniel J. Solove, *Introduction: Privacy Self-Management and the Consent Dilemma*, 126 HARV. L. REV. 1880, 1881 (2013).

153. OMRI BEN-SHAHAR & CARL E. SCHNEIDER, MORE THAN YOU WANTED TO KNOW: THE FAILURE OF MANDATED DISCLOSURE 12 (2014); *see also* Omri Ben-Shahar & Carl E. Schneider, *The Failed Reign of Mandated Disclosure*, REG BLOG (June 15, 2015), <http://www.regblog.org/2015/06/15/ben-shahar-schneider-failed-disclosure> (discussing the authors’ findings in their book).

products labeling) creates an “accumulation problem” and dilutes the attention or cognitive understanding that individuals can devote to any single disclosure.¹⁵⁴

Beyond its ineffectiveness, Ben-Shahar and Schneider urge that mandatory disclosure may be affirmatively doing harm by allowing legislators to skirt hard regulatory choices under the guise of this “benign” regulatory approach.¹⁵⁵ Professors Ryan Bubb and Richard H. Pildes similarly argue that the focus of behavioral economics on preserving consumer choice has led to the endorsement of disclosure regulation even when it might not be optimal form a social welfare perspective.¹⁵⁶ They argue that the field of law “fails to take its own behavioral insights seriously enough” and, as a result, those who subscribe to the behavioral law and economics paragraph “often artificially and wrongly exclude[] more traditional regulatory tools, such as direct mandates, from [their] analysis of policy options.”¹⁵⁷

B. A CRITIQUE OF DISCLOSURE AS A GOVERNANCE TOOL FOR CHEMICALS REGULATION

While much of the scholarly discourse on information disclosure has focused on the wisdom of disclosure as an *express* regulatory choice, Professor Catherine A. O’Neill has explained that even environmental statutes with directed mandates can be unwittingly transformed into disclosure regimes.¹⁵⁸ For an

154. Ben-Shahar & Schneider, *supra* note 126, at 686–90; *see also* Karen Bradshaw Schultz, *Information Flooding*, 48 IND. L. REV. 755 (2015) (explaining that a major problem of disclosure regulation is “information flooding,” the phenomenon of presenting consumers with too much information to process).

155. Ben-Shahar & Schneider, *supra* note 126, at 689–90.

156. Ryan Bubb & Richard H. Pildes, *How Behavioral Economics Trims Its Sails and Why*, 127 HARV. L. REV. 1593 (2014).

157. *Id.* at 1638, 1597. Professors Bubb and Pildes use fuel-economy standards to illustrate their point that truncated behavioral economic analyses can overlook more optimal regulatory choices: “The upshot of this analysis is that incorporating insights from behavioral economics into policy analysis of the pollution-externality problem might turn out to justify traditional command-and-control approaches, rather than more modest disclosure nudges.” *Id.* at 1676. Critics of Bubb and Pildes argue economists are not trimming the sails, but merely being appropriately cautious. *See, e.g.*, Quinn Curtis et al., *Tacking in Shifting Winds: A Short Response to Bubb and Pildes*, 127 HARV. L. REV. F. 204, 204 (2014) (“[C]hoicepreserving approaches into policymaking may reflect the recognition of uncertainty” and may simply be a “rationally cautious approach to navigating unknown and potentially treacherous policymaking seas . . .”).

158. O’Neill, *supra* note 132, at 276 (“Government decision makers have increasingly come to rely on risk avoidance as a form of risk regulation.”).

example of regulators choosing disclosure over pollution reduction, consider that the EPA uses fish consumption advisories to warn people against consuming mercury-contaminated fish from substantial portions of waters of the United States.¹⁵⁹ Some of these advisories, though touted as temporary, have been in place since the 1970s.¹⁶⁰ By the same token, until recently there have been no federal standards limiting mercury emissions from the nation's largest emitter—power plants.¹⁶¹

As another example, “ozone alerts” show how risk regulation can devolve into risk avoidance under even our most well-regarded statutes like the Clean Air Act.¹⁶² In particular, the Clean Air Act requires states to ensure compliance with National Ambient Air Quality Standards (NAAQS) for six criteria pollutants including ozone.¹⁶³ Despite the regulatory mandate to reduce risk, over 160 million people live in areas that do not meet the ozone safety standard.¹⁶⁴ In the face of the regulatory failure, agencies have turned to risk avoidance, using ozone alerts to encourage individuals to stay indoors on days when ozone levels are unsafe.¹⁶⁵ According to Professor O'Neill, “Agencies have allowed ozone alerts to supplant risk reduction, moreover, despite evidence that the number of individuals who suffer from asthma and other respiratory ailments triggered by exposure to ground-level ozone has continued to climb.”¹⁶⁶

As Part III explains, TSCA and FIFRA follow this model identified by Professor O'Neill, where the implementation of the statutes has exacerbated theoretical gaps and resulted in a regulatory scheme that operates largely as a risk avoidance framework. Because TSCA and FIFRA function like a *laissez-faire* disclosure regime, it is worth considering why that approach is unacceptable. To that end, this Part extends the work of scholars who have critically examined information disclosure

159. *Id.* at 278–83.

160. See, e.g., John Tilden et al., *Health Advisories for Consumers of Great Lakes Sport Fish: Is the Message Being Received?*, 105 ENVTL. HEALTH PERSP. 1360, 1360 (1997) (noting that Great Lakes fish advisories were first issued in the 1970s for PCB contamination).

161. See *Basic Information About Mercury and Air Toxics Standards*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/mats/basic-information-about-mercury-and-air-toxics-standards> (last visited Apr. 24, 2017).

162. O'Neill, *supra* note 132, at 290.

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.* at 291.

in other contexts. It advances three reasons to reject a laissez-faire, disclosure-based approach to chemicals and pesticide regulation: First, setting information gaps aside, individuals cannot assess cumulative risk. Second, even if they could, the pervasiveness of chemicals in the ambient environment means individuals cannot opt out of the risk. Third, because not all individuals are similarly situated, government action is necessary to avoid disparate impacts to vulnerable populations. In the end, the reasons for rejecting a disclosure regime are also the reasons for ensuring cumulative risk is assessed and used as a metric for reducing overall risk.

1. Individuals Cannot Assess Cumulative Risk

Cumulative risk assessments are too complex for non-experts to sort out. Risk scientists know this.¹⁶⁷ In one research paper, the authors discuss in great detail the various tools available to communities for assessing cumulative risk.¹⁶⁸ The real illumination comes at the end when the authors emphasize that analyzing cumulative risk requires technical expertise at every level, from finding the relevant information to using exposure models to interpreting the results: “the compilation of information from different tools . . . can be very challenging,” “mining and analyzing information may be challenging without technical training,” “[e]xposure models often require a high level of technical expertise,” and “their results can also be difficult to interpret without a working knowledge of exposure assessments.”¹⁶⁹

Similarly, the EPA emphasized the technocratic nature of cumulative risk assessments in its study of organophosphates: “Interpretation of the risk estimates presented in this updated OP CRA depends upon the synthesis and processing of a vast body of data on hazard and exposures and no single value in the assessment should be used to independently arrive at the interpretation of the risk estimates or results.”¹⁷⁰ And if one can use length as a proxy for complexity, consider that the update to which the EPA was referring spanned 522 pages of text, tables, figures, and appendices.¹⁷¹

167. See *infra* Part I.B.1 (discussing technical challenges in assessing cumulative risk).

168. Barzyk et al., *supra* note 97, at 378–81.

169. *Id.* at 382–83.

170. EPA, OP CRA, *supra* note 59, at 12 (emphasis omitted).

171. *Id.*

This and other cumulative risk assessments that have been completed illustrate why these issues cannot be undertaken by the individual and/or chalked up to consumer choice issues. Consider the EPA's study on disinfection byproducts in water, which highlights the various pieces of information that researchers have to pull together to arrive at a cumulative risk assessment: (1) identifying classes of chemicals that lead to the same adverse outcome requires understanding something about the health impacts and toxicological characteristics of individual chemicals; (2) choosing a model for how these chemicals interact when mixed together requires knowing whether impacts from individual chemicals are additive or whether there are synergistic interactions from the mixtures; and (3) developing an overall risk characterization requires understanding how the population is exposed and in what doses.¹⁷²

The idea that individuals can assess risk is further complicated by the lack of information regarding the health impacts of many chemicals to which individuals are exposed. The information deficit that plagues chemical regulation in the United States is well known.¹⁷³ This information gap makes risk assessment for even individual chemicals or products challenging, never mind the task of synthesizing risk across several products or common chemicals.¹⁷⁴ Of course, the information gap does not go away by asking regulators or manufacturers to undertake cumulative risk assessments. That said, matching the responsibility for assessment with actors capable of producing or requiring that information is far more likely to address information gaps. To that end, individuals are in the worst position for acquiring the needed information or generating leverage to demand its production.¹⁷⁵

On one level, individuals may be unable to assess cumulative risk because of too little information. On another level, the problem may be too much information, with the irrelevant obscuring the relevant or the good obscuring the bad. Professor Karen Bradshaw Schultz has written about the phenomenon

172. See Teuschler et al., *supra* note 66, at 756–57.

173. Wagner, *supra* note 19, at 1624.

174. *Id.*

175. For one reason why individuals may fare poorly in eliciting information about chemical toxicity, see Peter S. Menell, *Structuring a Market-Oriented Federal Eco-Information Policy*, 54 MD. L. REV. 1435, 1445 (1995) (“The unregulated market may fail to provide adequate information about environmental impacts of consumer choice because it is difficult to appropriate sufficient return for generating such information.”).

where firms, nongovernmental organizations, agencies, and political parties alike strategically inundate the marketplace with information to influence consumers.¹⁷⁶ This flood of information serves to overwhelm and confuse consumers, further undermining the workability of disclosure regulation or reliance on consumer choice models of risk management.¹⁷⁷

Whatever the case may be—too little information or too much—the bottom line is that even with just-right knowledge, cumulative risk assessments require some expert knowledge on issues of risk exposure and toxicology. The many facets of knowledge that are required to assess cumulative risk underscores the absurdity of the “individual vigilance” strategy for dealing with issues of chemical and pesticide proliferation. Indeed, even if individuals were capable of such risk assessment, it would be economically inefficient to suggest that individuals should be responsible. Doing so forces each individual, even those without specialized training in risk assessment or toxicology to behave as experts. This approach is duplicative and requires individuals to unnecessarily divert energy and resources away from more productive societal contributions.

2. Individuals Cannot Opt out of Risk

Even if individuals could assess cumulative risk, and even if informational problems were alleviated, there is another fundamental reason why issues of cumulative risk need governmental response: individuals cannot opt out of exposure to toxins. Chemicals and pesticides are so ubiquitous in the ambient environment that individuals have no ability to avoid exposure no matter the degree of vigilance deployed. The existing regulatory regime—which for decades has left open the toggle switch for chemicals entering the marketplace and environment—has created public health externalities that require collective regulatory action to resolve.

As an example of how consumer products can wreak public health havoc, consider that companies like DuPont that have little to gain from disclosing health risks from widespread products. In 2016, the *New York Times Magazine* ran a feature article on the rising public health concerns from a chemical called perfluorooctanoic acid, or PFOA.¹⁷⁸ Invented by 3M in

176. Schultz, *supra* note 154, at 757–62.

177. *Id.*

178. Rich, *supra* note 12.

1947, PFOA has been used in a wide range of products for its non-stick, stain-proofing, and water-proofing properties.¹⁷⁹ From Teflon coating in frying pans to Scotchguard furniture protectants,¹⁸⁰ these convenience products were sold under the banner of improving quality of life—no more scrubbing pans or furniture to get the stains out. As it turns out, the health risks from PFOA exposure are potentially significant; in 2011 government scientists released findings of a “probable link” between PFOA and “kidney cancer, testicular cancer, thyroid disease, high cholesterol, pre-eclampsia and ulcerative colitis.”¹⁸¹

DuPont, which has purchased PFOA for its use in Teflon since 1951, has conducted private medical studies of PFOA for four decades.¹⁸² By the early 1990s, results from these studies raised enough suspicions to cause DuPont and 3M to consider less-toxic alternatives to PFOA.¹⁸³ DuPont opted against those alternatives and against sharing its concerns about PFOA with the EPA or the public.¹⁸⁴ In the meantime, PFOA continued to enter the marketplace and drinking water.¹⁸⁵ By the time the regulatory agencies and public had enough information to start asking public health questions, PFOA had become commonplace in the ambient environment.¹⁸⁶ A study by the Environmental Working Group in 2015 showed that ninety-four water systems across twenty-four states had PFOA levels exceeding the safety threshold approximated by an earlier report from researchers at the Harvard School of Public Health.¹⁸⁷ In the water districts closest to DuPont’s Washington Works plant in Parkersburg, West Virginia, earlier tests had shown that public and private water source “were tainted with levels of PFOA higher than DuPont’s own internal safety standard.”¹⁸⁸

Open questions remain as to what exposure levels cause harm. But as public health questions are sorted out, there is at least one unfortunate certainty—individuals concerned about PFOA can stop buying products with Teflon but they cannot

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*

avoid exposure to PFOA. In fact, DuPont stopped manufacturing PFOA in 2013, but PFOA is still present in the environment.¹⁸⁹ As the *New York Times Magazine* reported, “Where scientists have tested for the presence of PFOA in the world, they have found it.”¹⁹⁰ How much comfort is the idea of “individual vigilance” and “consumer choice” when PFOA has been detected in American blood banks since 1976?¹⁹¹

[I]f you are a sentient being reading this article in 2016, you already have PFOA in your blood. It is in your parents’ blood, your children’s blood, your lover’s blood. How did it get there? Through the air, through your diet, through your use of nonstick cookware, through your umbilical cord. Or you might have drunk tainted water.¹⁹²

While PFOA is not manufactured anymore, substitute chemicals that are also part of the fluorochemicals family have yet to undergo safety testing.¹⁹³ A group of scientists and other professionals from around the globe signed the “Madrid Statement” in May 2015 expressing concern about the replacement chemicals.¹⁹⁴

Unfortunately, this story is not an outlier.¹⁹⁵ As another example of how chemicals exposure is not always a choice, consider children that are exposed to pesticide through drift in rural communities. In 2009, Earthjustice submitted a petition to the EPA on behalf of the United Farmworkers and other non-governmental organizations.¹⁹⁶ The petition asked the EPA to

189. *Id.*

190. *Id.*

191. “The EPA was particularly alarmed to learn that PFOA had been detected in American blood banks, something 3M and DuPont had known as early as 1976. By 2003 the average concentration of PFOA in the blood of an adult American was four to five parts per billion.” *Id.*

192. *Id.*

193. “Under the 1976 Toxic Substances Control Act, the EPA can test chemicals only when it has been provided evidence of harm. This arrangement, which largely allows chemical companies to regulate themselves, is the reason that the EPA has restricted only five chemicals, out of tens of thousands on the market, in the last 40 years.” *Id.*

194. See Arlene Blum et al., *The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)*, 123 ENVTL. HEALTH PERSP. A107 (2015), <http://ehp.niehs.nih.gov/1509934>.

195. Consider, for example, that in 1999 the U.S. Geological Survey found that “96 percent of all fish analyzed in major rivers and streams contained residues of one or more pesticides at detectable levels.” ENVTL. & HUMAN HEALTH, INC., RISKS FROM LAWN CARE PESTICIDES: INCLUDING INADEQUATE PACKAGING AND LABELING 8 (2003), http://www.ehhi.org/reports/lcpesticides/lawnpest_full.pdf.

196. Pesticides in the Air – Kids at Risk: Petition to EPA To Protect Children from Pesticide Drift, Pesticide Action Network v. U.S. Env’tl. Prot. Agen-

“expeditiously evaluate the exposure of children to pesticide drift and impose safeguards to ensure that children are protected from aggregate pesticide exposures, including pesticide drift.”¹⁹⁷ In support of concerns about drift exposure, the petition submitted evidence from several air monitoring studies conducted near rural elementary schools in states nationwide. For example:

In 2007, an air monitoring study conducted near the Southwoods Elementary School in Hastings, Florida, detected four pesticides—endosulfan, diazinon, trifluralin, and chlorothalonil. At least one pesticide was found in each of the 39 samples, with three or four of the pesticides detected in 74% of samples, sometimes at levels exceeding levels of concern based on end points selected by the EPA as appropriate for assessing inhalation risk. Exposure to these four chemicals is associated with a wide range of adverse health effects—endosulfan interferes with hormones and was linked to autism in an epidemiological study, diazinon is neurotoxic, and trifluralin and chlorothalonil are rated by the EPA as “possible” and “probable” carcinogens, respectively.¹⁹⁸

The Petition also cited other air monitoring reports,¹⁹⁹ as well as a number of epidemiological studies linking pesticide drift to health effects.²⁰⁰ To protect children from drift, the petition argued that the “EPA should impose no-spray buffer zones for dangerous drift-prone pesticides around homes, schools, parks, daycare centers, and other places where children congregate.”²⁰¹

cy, No. 13-72616 (W.D. Wash. Oct. 13, 2009), <https://www.farmworkerjustice.org/sites/default/files/Petition%20-%20Pesticides%20in%20the%20Air%20-%20Kids%20at%20Risk.pdf> [hereinafter Pesticides in the Air].

197. *Id.* at 1.

198. *Id.* at 9 (footnotes omitted).

199. *See, e.g., id.* at 9 (“In 2004, a study by scientists from the University of Washington and Washington State University on the organophosphate methamidophos determined that pesticide volatilization drift ‘could be a potentially high percentage of inhalation exposure.’” (quoting Jaya Ramaprasad et al., *The Washington Aerial Spray Drift Study: Assessment of Off-Target Organophosphorus Insecticide Atmospheric Movement by Plant Surface Volatilization*, 38 *ATMOSPHERIC ENVT.* 5703, 5703–13 (2004))).

200. *See id.* at 8 (“[A] growing number of epidemiological studies link pesticide drift to specific adverse health effects in humans, including autism spectrum disorders, Parkinson’s disease, and childhood acute lymphoblastic leukemia.” (footnote omitted) (citing Sadie Costello et al., *Parkinson’s Disease and Residential Exposure to Maneb and Paraquat from Agricultural Applications in the Central Valley of California*, 169 *AM. J. EPIDEMIOLOGY* 919, 919 (2009))); Eric M. Roberts et al., *Maternal Residence near Agricultural Pesticide Applications and Autism Spectrum Disorders Among Children in the California Central Valley*, 115 *ENVTL. HEALTH PERSP.* 1482 (2007); Rudolph P. Rull et al., *Residential Proximity to Agricultural Pesticide Applications and Childhood Acute Lymphoblastic Leukemia*, 109 *ENVTL. RES.* 891 (2009).

201. Pesticides in the Air, *supra* note 196, at 4.

The EPA responded to the petition in 2014, sharing the petitioners' concerns that "the risks from drift and volatilization must be accounted for, for both children and adults, and that action must be taken to mitigate those risks."²⁰² While acknowledging that drift risks are important and had not been systematically taken into account by the agency, the EPA denied the request to take interim safety measures of implementing spray buffers around areas where children are likely to be present and subject to drift.²⁰³ In response, Earthjustice noted its disappointment, which can best be summed up with its observation that "[a]cknowledging risk does not, on its own, reduce risk."²⁰⁴

To date, the EPA's responses to problems of drift have been limited to developing assessment tools, improving produce labels, and implementing a voluntary "Pesticide Drift Reduction Technology" program to encourage the use of safer spray equipment.²⁰⁵ In the meantime, while voluntary disclosure efforts characterize the EPA's regulatory agenda, children and rural families are left with little ability to avoid drift exposure.

In addition to illustrating the difficulty of opting out of chemical exposure, the example of pesticide drift also underscores the broader point of this Article: protecting public health requires risk reduction, not just assessment, acknowledgement or disclosure. In particular, regulatory drivers should trigger risk reduction mandates based on understandings of cumulative risk.

For one last example on the pervasiveness of certain chemicals in the ambient environment and the growing inability to opt out of exposure, consider methyl tert-butyl ether (MTBE). MTBE is a gasoline additive, used as an anti-knocking agent and to reduce carbon monoxide emissions since the 1980s.²⁰⁶

202. Letter from Martha Monell, Acting Dir., Office of Pesticide Programs, to Erik Nicholson et al., Nat'l Vice President, United Farm Workers (Mar. 31, 2014), http://www.panna.org/sites/default/files/petition%20response%20transmittal%20letter%203_31_14.pdf [hereinafter EPA Letter].

203. *Id.*

204. Written Objections to EPA's Response to Pesticides in the Air — Kids at Risk: Petition to EPA To Protect Children from Pesticide Drift, Pesticide Action Network v. U.S. Env'tl. Prot. Agency, No. 13-72616, at 11 (W.D. Wash. May 28, 2014), <http://earthjustice.org/sites/default/files/files/2743writtenobjections5-28-14.pdf>.

205. See *What EPA Is Doing To Reduce Pesticide Drift*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/reducing-pesticide-drift/what-epa-doing-reduce-pesticide-drift> (last visited Apr. 24, 2017).

206. See *National Biomonitoring Program: Biomonitoring Summary*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/biomonitoring/>

Perhaps best known for causing persistent groundwater contamination,²⁰⁷ MTBE has also been a poster child for the failings of TSCA.²⁰⁸ More specifically, ARCO began manufacturing MTBE in 1979.²⁰⁹ Under the watch of TSCA, it went to market without toxicity testing.²¹⁰ After MTBE became widely used, after it had contaminated groundwater and entered the ambient air through vehicle emissions, after the industry had begun to learn more about the toxicity of MTBE—only then did the regulators begin to ask questions about risk.²¹¹ Today there remains uncertainty over the health risks of MTBE exposure. The EPA at one time recognized MTBE as a “potential human carcinogen” at high doses.²¹² Little is known about health impacts from long-term, chronic exposure.²¹³

Concerned about its susceptibility to contaminate groundwater, states like California and New York have banned MTBE.²¹⁴ Because of these bans, concerns about liability, and policy changes set in motion in the Energy Policy Act of 2005, many companies have switched from using MTBE to ethanol in

MTBE_BiomonitoringSummary.html [hereinafter *Biomonitoring Summary*] (last visited Apr. 24, 2017).

207. Professor Thomas O. McGarity has written about the history and lessons learned from the “MBTE fiasco.” Thomas O. McGarity, *MBTE: A Precautionary Tale*, 28 HARV. ENVTL. L. REV. 281 (2004).

208. See, e.g., Bernard Goldstein, *MTBE: A Poster Child for Exposure Assessment as Central to Effective TSCA Reform*, 20 J. EXPOSURE SCI. & ENVTL. EPIDEMIOLOGY 229, 229–30 (2010), <http://www.nature.com/jes/journal/v20/n3/full/jes201017a.html>.

209. McGarity, *supra* note 207, at 297.

210. *Id.*

211. *Id.* at 298–300.

212. *Methyl Tertiary Butyl Ether (MTBE) Overview*, U.S. ENVTL. PROTECTION AGENCY, <https://archive.epa.gov/mtbe/web/html/faq.html> [hereinafter *MTBE Overview*] (last visited Apr. 24, 2017); see also Kathleen M. Burns & Ronald L. Melnick, *MBTE: Recent Carcinogenicity Studies*, 18 INT’L J. OCCUPATIONAL & ENVTL. HEALTH 66, 68 (2012), <http://www.sciencecorps.org/Cancer%20evidence%20MTBE%202012.pdf> (“With substantial evidence of genotoxicity now available, it is entirely plausible that MTBE would cause cancer in multiple organs.”); McGarity, *supra* note 207, at 288 (noting EPA has classified MTBE as a potential human carcinogen).

213. See McGarity, *supra* note 207 at 288 (“On the whole, though, there is a dearth of health effects data on MTBE—a worrisome fact given that it has been more than twenty years since its introduction into gasoline on a broad basis.”); see also *MTBE Overview*, *supra* note 212. (“[R]esearchers have limited data about what the health effects may be if a person swallows (ingests) MTBE.”).

214. McGarity, *supra* note 207, at 282 n.4.

their gasoline formulations.²¹⁵ According to the EPA, MTBE has not been used in significant quantities since 2005.²¹⁶

Still, despite the industry's move away from MTBE, the chemical lives on in our bloodstreams. According to 2009 CDC biomonitoring results, MBTE is found in human blood.²¹⁷ In particular, "[c]ommuters in urban areas with high vehicular traffic had median blood MTBE blood levels that were more than tenfold higher than those in the U.S. general population."²¹⁸ The CDC, like the EPA, cannot say what this means in terms of health impacts.²¹⁹

MBTE has been a poster child for the enduring problems that are created when chemicals are allowed to enter the marketplace without understanding the health and ecological risks. But it is also a good example of how the shortcomings of TSCA constrain consumer choice. In other words, when chemicals enter the marketplace, they inevitably enter the environment. And depending on the quantities at which they are produced, those chemicals become part of the background world in which we live. Exposure moves beyond the realm of consumer choice. These constraints on consumer choice can be significant. In its Framework on Cumulative Risk Assessments, for example, the EPA recognizes that chemical exposure from the ambient environment are generally important and relevant considerations when assessing public health harms.²²⁰

These examples of chemical risk from the ambient environment underscore how the regulation of chemicals and pesticides before they enter the marketplace is an obvious step to protecting public health. They also point to the simple fact that avoiding exposure to chemicals and pesticides is not an issue of consumer choice, but rather a matter of government regulation in response to a collective action problem. Finally, these examples demonstrate why relying on disclosure and consumer-

215. *MTBE Overview*, *supra* note 212.

216. *Id.*

217. *Biomonitoring Summary*, *supra* note 206 ("Levels of MTBE in blood reflect recent exposure.").

218. *Id.*

219. *Id.* ("Human health effects from MTBE at low environmental doses or at biomonitored levels from low environmental exposures are unknown.").

220. See EPA, *FRAMEWORK*, *supra* note 10, at 98 ("Because cumulative risk assessments are population based, exposures due to naturally occurring background concentrations should typically be considered important.") Naturally occurring means from the environment or part of background from anthropogenic sources.

generated pressure on firms to explore green chemistry comes too late in the equation, after costly damage has already been done. On that point, bear in mind that none of these examples even scratch the surface of ecological harms that may be resulting from our decades-long experiment with chemical proliferation. To state concerns about human health, for example, says nothing about the bees or other ecological resources serving valuable functions within the human-ecological community.²²¹

3. Private Burdens Are Not Evenly Distributed

Not all citizens are equally situated to assess risk and make choices to avoid it. As scholars like Professor Catherine A. O'Neill have documented, the poor, uneducated are more likely to suffer from chronic toxic exposure.²²² Risk scientists and the National Environmental Justice Advisory Council have likewise studied the disproportionate burdens of chemical and pesticide exposure on vulnerable communities.²²³ Even some statutory frameworks, like the Clean Air Act, recognize that additional regulatory measures are sometimes warranted to adequately protect sensitive or vulnerable populations.²²⁴ Dis-

221. For a popular press primer on the concerns about pesticides and bees, see Jennifer S. Holland, *The Plight of the Honeybee*, NAT'L GEOGRAPHIC NEWS (May 10, 2013), <http://news.nationalgeographic.com/news/2013/13/130510-honeybee-bee-science-european-union-pesticides-colony-collapse-epa-science>; Alex Morris, *What Is Killing America's Bees and What Does It Mean for Us?*, ROLLINGSTONE (Aug. 18, 2015), <http://www.rollingstone.com/politics/news/what-is-killing-americas-bees-and-what-does-it-mean-for-us-20150818?page=2>.

222. See Catherine A. O'Neill, *Mercury, Risk, and Justice*, 34 ENVTL. L. REP. 11070 (2004) [hereinafter O'Neill, *Mercury, Risk, and Justice*] (explaining how the EPA's Clean Air Mercury Rule leaves those most exposed to undertake risk avoidance); Catherine A. O'Neill, *Risk Avoidance, Cultural Discrimination, and Environmental Justice for Indigenous Peoples*, 30 ECOLOGY L.Q. 1 (2003).

223. See, e.g., Peter L. deFur et al., *Vulnerability as a Function of Individual and Group Resources in Cumulative Risk Assessment*, 115 ENVTL. HEALTH PERSP. 817, 819 (2007) ("The evidence suggests a pattern of disproportionate exposures to environmental risks among communities of color and the poor, with racial differences often persisting across economic strata."); NAT'L ENVTL. JUSTICE ADVISORY COUNCIL, ENSURING RISK REDUCTION IN COMMUNITIES WITH MULTIPLE STRESSORS: ENVIRONMENTAL JUSTICE AND CUMULATIVE RISKS/IMPACTS 1-2 (2004) [hereinafter NEJAC 2004 REPORT] (describing a "matrix of physical, chemical, biological, social, and cultural factors which result in certain communities and sub-populations being more susceptible to environmental toxins, being more exposed, or having compromised ability to cope with and/or recover from such exposure").

224. See Lewis et al., *supra* note 39, at 2025 ("The consideration of vulnerable or sensitive populations in human health risk assessments is not new. . . . [The] EPA is mandated under the Clean Air Act to provide a margin of safety

parate and disproportionate impacts of chemical exposure are yet further reasons why chemicals regulation that leaves the toggle switch open and masks ineffectiveness with labeling requirements is an inappropriate governmental response.

The cumulative risk literature is particularly useful in highlighting the many factors that contribute to disproportionate impacts on low-income, minority, or other vulnerable communities. The EPA 2003 Framework on Cumulative Risk Assessment describes four properties of vulnerability: exposure, susceptibility, preparedness, and responsiveness.²²⁵

Looking first at exposure, consider that for vulnerable communities exposure is not just an issue of absolute risk. It is also an issue of relative risk. As the environmental justice movement has recognized for some time, vulnerable populations bear the brunt of toxic exposures because of geographic proximity to polluting facilities. Cancer Alley in Louisiana is a popular image.²²⁶ In addition to intensely concentrated pockets of industry in low-income urban communities, issues of differential exposure arise in rural communities as well. The disproportionate impact of pesticide use on farmworkers and their families is one example.²²⁷ For Native American tribal communities, issues of differential exposure most often arise in the context of mercury exposure from fish consumption.²²⁸

Turning next to susceptibility, consider that, even in the face of similar levels of exposure some populations are more likely to suffer harm do to synergistic interactions with nonchemical stressors. A growing body of evidence suggests that social, physical, and other nonchemical stressors can exacerbate the health impacts of chemical pollutants.²²⁹ For example, poor nutrition, noise, obesity, or psychosocial stress can

to protect sensitive sub-populations by considering vulnerability and susceptibility factors in its health assessments.”).

225. EPA, FRAMEWORK, *supra* note 10, at 39–41.

226. Cancer Alley is the nickname given to an eighty-five-mile corridor that stretches from Baton Rouge to New Orleans and supports over 150 industrial plants and refineries. For an example of popular news coverage of the area, see Trymaine Lee, *Cancer Alley: Big Industry, Big Problems*, MSNBC, <http://www.msnbc.com/interactives/geography-of-poverty/se.html> (last visited Apr. 24, 2017).

227. See Beamer, *supra* note 107.

228. See O’Neill, *Mercury, Risk and Justice*, *supra* note 222, at 11071.

229. Lewis et al., *supra* note 39, at 2021 (“Researchers have identified disparities for numerous health outcomes among disadvantaged populations and hypothesize that exposures to combinations of non-chemical and chemical stressors contribute to these disparities . . .”).

impact a body's ability to recover from harmful exposures.²³⁰ There are reasons, therefore, to be especially concerned about the exposure of vulnerable populations to toxins.

Finally, on the issue of preparedness and responsiveness, consider that not everyone is equally capable of reducing risk. Not every family has the means to buy organic foods or move to a neighborhood with cleaner water. As the literature reflects, access to health care, income levels, unemployment, and family mobility may impact preparedness and responsiveness to chemicals exposure.²³¹ In other words, when it comes to toxicological risk assessment, having the information to assess cumulative risk, the bandwidth to think about it, or the means to make different choices are all separate matters. In that way, both the preparedness and responsiveness properties of the EPA framework speak directly to notions of choice and opt-out ability discussed throughout this Article.²³² In the face of claims for individual vigilance or calls for "freedom of choice" within regulatory frameworks, it is worth thinking about the degree to which vulnerable communities are able to avoid chemicals exposure or mitigate situational susceptibility.

In the end, addressing these disparate impacts is a classic role of government. The Office of the President has long recognized the responsibility of federal agencies to take special care in ensuring their activities do not result in "disproportionately high and adverse human health or environmental effects" on certain vulnerable populations.²³³ In particular, Executive Order 12898 directs each federal agency to make "environmental justice part of its mission."²³⁴

230. deFur et al., *supra* note 223 ("Illness may also compromise the capacity to cope and recover from the adverse effects of environmental exposures.") According to one study, "[v]ulnerability to cumulative risk exposure among primary school children is higher among those with negative emotionality (fearfulness, irritability, startle responses)." *Id.* at 820 (citing Liliana J. Lengua, *The Contribution of Emotionality and Self-Regulation to the Understanding of Children's Response to Multiple Risk*, 73 CHILD DEV. 144 (2002)). On the flip side, "[a]mong adults, optimism appears to offer protection against a wide range of physical and psychologically threatening conditions." *Id.* (citing Michael F. Scheier & Michael W. Bridges, *Person Variables and Health: Personality Predispositions and Acute Psychological States as Shared Determinants for Disease*, 57 PSYCHOSOMATIC MED. 255 (1995)).

231. EPA, FRAMEWORK, *supra* note 10, at 41.

232. *Id.*

233. *E.g.*, Exec. Order No. 12898, 59 Fed. Reg. 7629 (Feb. 16, 1994).

234. *Id.* § 1-101.

For its part, the EPA has recognized that the cumulative risk lens can help answer that call, acknowledging that “[c]umulative risk assessments may be uniquely situated to addressing the issues related to vulnerability.”²³⁵ In a similar vein, the National Environmental Justice Advisory Council (NEJAC), upon request from the EPA’s Office of Environmental Justice, prepared a report addressing the long- and short-term actions the agency should take in ensuring environmental justice for all communities. Cumulative risk assessment was at the center of the NEJAC’s recommendations for how to “institutionalize a bias for action within [the] EPA.”²³⁶

Several state agencies have made the connection between cumulative risk assessments and addressing environmental justice concerns. States like California and Texas are developing screening methods or setting legislative directives to use cumulative risk as a means of setting regulatory priorities among communities in need of risk-reduction resources.²³⁷ The Texas Water Code, for example, directs the state agency to “protect the public from cumulative risks in areas of concentrated operations” and “give priority to monitoring and enforcement in areas in which regulated facilities are concentrated.”²³⁸

At the federal level, these acknowledgments and recommendations need to be put to action. As Part III discusses, the regulatory framework is still too weak to take the widespread support for cumulative risk assessment and make it a trigger for risk-reducing action. Without that action, the disparate impacts will continue to manifest, the disclosure fallacy will continue to give false hope to individuals that risk can be avoided, and real risk-reduction efforts will be buried in the drawer of good intentions.

Understanding the historical support for disclosure regulation in the United States across a range of issues, and examin-

235. EPA, FRAMEWORK, *supra* note 10, at 41.

236. NEJAC 2004 REPORT, *supra* note 223, at 3; *id.* at ii (“[T]he EPA’s Framework for Cumulative Risk Assessment represents a profound advancement in the kinds of thinking that will help communities and tribes address their concerns.”); *id.* at 15 (incorporating the EPA’s Cumulative Risk Framework into a model that is “sensitive to the ‘real life’ context of communities and tribes suffering environmental injustice”).

237. See, e.g., TEX. WATER CODE ANN. § 5.130 (West 2016).

238. *Id.* § 5.130(1)–(2).

ing why addressing chemicals and pesticide regulation through information disclosure is a fool's errand, helps underscore two fundamental points: First, addressing public health concerns related to chemical and pesticide proliferation requires gatekeeping before chemicals enter the marketplace. Leaving the toggle switch open and hoping individuals can avoid risk if given appropriate information is not an acceptable approach; hope is not a regulatory strategy. Second, not only is gatekeeping necessary, but any meaningful gatekeeping should systematically address issues of cumulative risk.

III. THE HISTORY AND FAILURE TO REGULATE CUMULATIVE RISK

The first two Parts of this Article have laid the groundwork for understanding why cumulative risk assessments are necessary to chemical and pesticide regulation and how risk science has evolved to make regulation on this basis feasible. This Part turns to the history of chemical and pesticide regulation in the United States. It tells a story of how assessing cumulative risk has had little regulatory backing or success despite theoretical promise. In particular, TSCA and FIFRA—the two pieces of federal legislation most directly charged with regulating toxin input into the marketplace for the past several decades—have largely failed to address the cumulative risk aspects of chemical and pesticide proliferation.

While some of these failings derive from structural flaws in the statutes, many of the failings result from implementation gaps. Regulators have the room under both statutes to address cumulative risk. In fact, Congress has in varying degrees recognized that cumulative risk is an important piece of the public health picture in the chemical age. In some cases, the gaps in implementation are the function of flaws in the underlying statutory structure. In others, regulators have failed to exercise that authority. In still others, court decisions have impeded meaningful regulation.

Understanding the implementation gaps that have plagued TSCA and FIFRA provides the necessary context for Part IV, which examines how the recently adopted chemicals reform legislation—signed into law by President Obama on June 22, 2016—can be implemented to avoid similar pitfalls. Importantly, the new Act contains the same safety threshold as TSCA for allowing chemicals to enter the marketplace—chemicals must not pose an “unreasonable risk.” This, too, is the basic thresh-

old for approving pesticide registrations under FIFRA. Appreciating how this safety threshold has functioned under TSCA and FIFRA is necessary to exploring how it might function in the future to bring cumulative risk more to the forefront in public health protection.

As a preliminary observation, note that much of the legal scholarship separates out the discussion of FIFRA from TSCA, perhaps because the statutes have different political landscapes and policies that drive their implementation. This Article tackles both frameworks in a single discussion because both contribute to the overall public health concerns. Pesticides are in fact chemicals designed to cause harm to living organisms.²³⁹ From a public health perspective, then, the human body and the environment do not make distinctions between chemicals and pesticides to reflect policy. When examining the public health challenges of the chemicals age, therefore, chemical and pesticide regulation need to be considered together.

A. TSCA: PROMISE UNDELIVERED

The story of TSCA can be understood as a tragic disconnect of what it could have been and what it became. TSCA was enacted in 1976 to address a growing concern with chemical proliferation in the U.S. marketplace.²⁴⁰ In particular, there were over 61,000 chemicals in existence at the time TSCA was adopted and very little was known about their toxin profiles.²⁴¹ Despite several other pieces of landmark environmental legislation passed in the 1970s, none had addressed toxic substances at the point at which they entered the market.²⁴² Rather, statutes like the Clean Air Act or Clean Water Act dealt with pollutants and other toxins at the point of emission or discharge. TSCA by contrast was intended to deal with chemical regulation head on, and as such was heralded by then-EPA

239. FIFRA defines “pesticide” as “any substance or mixture of substances intended for preventing, *destroying*, repelling, or mitigating any pest.” 7 U.S.C. § 136(u) (2012) (emphasis added).

240. See Presidential Statement on Signing S.3149 (Oct. 12, 1976) (“This toxic substances control legislation provides broad authority to regulate any of the tens of thousands of chemicals in commerce. Only a few of these chemicals have been tested for their long-term effects on human health or the environment.”).

241. 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, 340 (2010).

242. *Id.*

Administrator Russell Train as “one of the most important pieces of ‘preventative medicine legislation’ ever passed by Congress.”²⁴³

Importantly, when it adopted TSCA, Congress was fully aware of the public health concerns associated with cumulative exposures. Speaking to the basis for the legislation, congressional records reflect the view that:

[i]ntelligent standards for regulating exposures to a chemical in the workplace, the home or elsewhere in the environment cannot be set unless the full extent of human or environmental exposure is considered. The importance of considering the cumulative impact of all sources of exposure and the synergistic effects resulting from exposure to a number of chemicals in regulating hazardous chemicals was pointed out by the National Academy of Sciences²⁴⁴

This broad level of concern for cumulative and synergistic impacts was not just lip service. The Conference Report expressly contemplates that these types of impacts would be considered in TSCA’s safety standard. Recall that for both new and existing chemicals the EPA also had authority to take action and ban existing chemicals that present “an unreasonable risk of injury to health or the environment.”²⁴⁵ In its discussion of § 6 of the Act, the Conference Report emphasizes that “[o]ftentimes an unreasonable risk will be presented because of the interrelationship or cumulative impact of a number of different substances or mixtures. The conferees intend that the Administrator have authority to protect health and the environment in such situations.”²⁴⁶

The statutory language bears out that intent. In other words, there was room within this language for the EPA to have considered cumulative risk as part of the safety threshold analysis. To that end, the Act requires the EPA to regulate substances that present an “unreasonable risk of injury to health or the environment.”²⁴⁷ In making a finding of “unreasonable risk” the EPA is required to “consider all relevant factors” including “magnitude of human exposure” and “magni-

243. *Id.* at 336–37 (quoting Press Release, U.S. Evtl. Prot. Agency, Train Sees New Toxic Substances Law as “Preventive Medicine” (Oct. 21, 1976), <https://archive.epa.gov/epa/aboutepa/train-sees-new-toxic-substances-law-preventive-medicine.html>).

244. See H.R. REP. NO. 94-1341, at 6 (1976).

245. 15 U.S.C. § 2605(a)(1) (2012).

246. See H.R. REP. NO. 94-1679, at 61 (1976) (Conf. Rep.).

247. See, e.g., 15 U.S.C. §§ 2604(f), 2605(a) (2012).

tude of environmental exposure.²⁴⁸ The term “environment” is broadly defined to include water, air, and land.²⁴⁹ The term “chemical substance” is also broadly defined to include “any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature.”²⁵⁰ The breadth of language certainly suggests that the fate and transport of a chemical substance to humans, to the environment, and through the environment were relevant factors in assessing safety. Indeed, given the importance of cumulative risk to the protection of public health on issues of chemicals proliferation, one may wonder how agency decisions based only on a siloed analysis of individual risks could survive arbitrary and capricious review.²⁵¹

Though the implementation of TSCA would eventually tell a much different story, one in which the Act failed to live up to its promise of public health protection, several aspects of TSCA made it deserving of advanced praise at the time of its passage. Moreover, many of TSCA’s tools could certainly have been useful in the service of assessing cumulative risk. To start, TSCA created a national inventory and required all existing and new chemicals to be listed on the inventory. It thus aspired to organize vast amounts of information about what chemicals are manufactured, distributed and sold in the United States.²⁵² The inventory includes over 84,000 chemicals.²⁵³

In theory, the Act did more than just create a database of existing information. It had the potential to create information. TSCA gave the EPA the authority to require testing of new and existing chemicals where data regarding toxicity is deficient.²⁵⁴ In particular, § 2603(a) required testing if the manufacture, distribution, or use of the chemical may present an “unreasonable risk of injury” and if there is “insufficient data and experience” to determine the effect of the substance on health.²⁵⁵ Be-

248. *Id.* § 2604(b)(4)(A)(ii).

249. *Id.* § 2602(5).

250. *Id.* § 2602(2)(A).

251. For a more detailed discussion on this point, see *infra* Part IV.

252. 15 U.S.C. § 2607(b) (2012).

253. *About the TSCA Chemical Substance Inventory*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory> (last updated Sept. 14, 2016) (describing the TSCA Inventory, where the EPA is trying to ascertain how many chemicals are actually being produced today).

254. 15 U.S.C. §§ 2603(a), 2604(b) (2012).

255. *Id.* § 2603(a). Manufacturers proposing to make and distribute new

cause the Act defines “chemical” broadly,²⁵⁶ the information-gathering and information-generating potential of the Act was substantial.²⁵⁷ As compared to other regulatory approaches that came before, TSCA provided a “means for discovering adverse effects on health and environment before manufacture of new chemical substances.”²⁵⁸ And because “unreasonable risk” was broad enough to include issues of cumulative risk, one could imagine a world where TSCA’s testing provisions might have extended to questions of cumulative impacts.

Given its broad jurisdictional reach, legislators in 1976 may reasonably have believed that the Act would help the EPA get a handle on the potential chemical exposure for the public at large. On paper, the Act had potential and in broad strokes contained elements necessary for success. It contained provisions permitting the EPA to gather and organize data about tens of thousands of chemicals. It allowed the EPA to require additional testing to fill information gaps. It authorized the ban of chemicals that pose dangers to health and the environment. And it addressed both new and existing chemicals, defined broadly to maximize regulatory potential. With the theoretical tools provided by Congress through TSCA, one can imagine how the Council on Environmental Quality, in 1977, celebrated TSCA as a law that “empowers the federal government to control and even to stop production or use of chemical substances

chemicals were required to submit to the EPA a pre-manufacture notice (PMN) along with basic information on chemical properties, uses, production levels, and expected exposures. *Id.* § 2604(a)–(e). The EPA reviewed the information and had the authority to require additional chemical testing if it believed that the product may pose a threat to health or the environment. *Id.* § 2603(a). The EPA could then refuse to allow the manufacture of the chemical if it presents an unreasonable risk of injury. *Id.* § 2604(f). In theory, the EPA served as a check on the manufacture of all new chemicals.

256. The Act defines “chemical substance” to include “any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical.” *Id.* § 2602(2). The Act, however, does not apply to chemicals regulated under other statutes, which includes pesticides, tobacco, nuclear material, alcohol, food, drugs, and cosmetics. *Id.* § 2602(2)(B).

257. In its first year, TSCA regulated over 61,000 existing chemicals. *See* CONG. RESEARCH SERV., THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES 3 (2008).

258. *See* Markell, *supra* note 241, at 345 (quoting S. REP. NO. 94-698 (1976), which also notes that under other statutes, “the Government regulator’s only response to chemical dangers is to impose restrictions after manufacture begins”).

that may present an unreasonable risk of injury to health or environment.”²⁵⁹

But despite TSCA’s hype and aspirational goals, the statute turned out to be a total failure in assessing chemical risk or protecting the public from chemicals proliferation. The Act, as implemented, did little more than organize incomplete data and shift risk-management decisions to the individual consumer. While the many failures of TSCA have been well documented,²⁶⁰ less discussed is the Act’s failure to systematically address cumulative risk or how that failure to fully assess public health risks compounded other structural flaws. And yet, it may well be that TSCA’s failure to expressly tackle cumulative risk lies at the root of its ineffectiveness. In fact, at least three of TSCA’s well-known shortcomings can be traced in some fashion to the failure of Congress or the EPA to expressly adopt a cumulative risk lens.

First, the structure of TSCA largely left the toggle switch open by allowing new chemicals to enter the market place unless the EPA could show “unreasonable risk.” In fact, despite giving the EPA authority to require testing or ban chemicals, TSCA allowed the EPA to exercise that authority only after the EPA determined that a chemical substance presented an unreasonable risk. Since risk is not necessarily apparent without testing and adequate information, this threshold created a bit of a chicken and egg issue for the EPA. In the end, thousands of chemicals entered commerce with no assurance of safety.

Had Congress more directly tackled chemicals proliferation as a collective action problem, perhaps the compounding nature of approving each additional chemical would have been more appropriately appreciated as part of a portfolio of exposures rather than as individual, incremental, and independent actions. To that end, the more cabined the analysis, often the more insignificant individual actions have seemed. By contrast, a frank recognition of the public health concerns associated with chemicals proliferation—one that more deeply appreciated the complexity of the problems created by an open toggle switch—might have led to a more precautionary approach. For example, the European Union’s chemical legislation—REACH²⁶¹—elected

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

260. See *supra* note 6 for a sampling of the literature.

261. REACH stands for “Registration, Evaluation, and Authorization of Chemicals.” Sachs, *supra* note 6, at 1819.

for precaution when it required manufacturers to demonstrate safety before chemicals are approved for distribution and sale.²⁶² The United States Congress has come around to this precaution in the newly adopted Lautenberg Chemical Safety Act, which similarly requires the EPA to make a finding of safety before a new chemical is approved for market distribution.²⁶³ As Part IV discusses, this change will be important in shaping a new place for cumulative risk in the regulatory framework.

In addition to leaving the toggle switch open by placing the burden on the EPA to show that a chemical was unsafe, TSCA made it too difficult to close that toggle switch even if the EPA identified an “unreasonable risk.” This second major failing of TSCA resulted from both structural hurdles within the statute and implementation gaps imposed by courts. It is also one that could have been alleviated with a cumulative risk perspective.

Structurally, TSCA limited the regulatory choices available to the EPA if the agency could show “unreasonable risk.” To that end, TSCA set forth seven enumerated options and required the EPA to choose the least burdensome regulatory method necessary to protect adequately against risk.²⁶⁴ While chemical bans or use restrictions were options, three of the seven regulatory choices focused on information management. Those choices included regulating by marking with warnings or instructions, imposing recordkeeping requirements, or requiring manufacturers “to give notice of [the unreasonable risk of injury] to distributors . . . and, to the extent reasonably ascer-

262. *See id.* (“REACH is the first major chemical regulatory regime in the world to shift the burden of proof on chemical safety from government to manufacturers, and it requires safety testing for thousands of chemicals on which there is limited or non-existent toxicity data in the United States.”). This is not to suggest that REACH or the Chemical Safety Act adopted burden-shifting frameworks because those statutes are otherwise directly targeting issues of cumulative risk. In fact, somewhat ironically, REACH has been criticized for taking an individualized approach to chemicals at the same time that it has been held out as an example of precaution on its burden-shifting framework. *See* Denis A. Sarigiannis & Ute Hansen, *Considering the Cumulative Risk of Mixtures of Chemicals – A Challenge for Policy Makers*, 11 ENVTL. HEALTH SUPPL. 1 (2012).

263. *See* H.R. 2576 § 5(g) (2016) (“If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, then . . . the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use . . .”).

264. 15 U.S.C. § 2605(a) (2012).

tainable, to other[s]” and “to give public notice” of such risk of injury, and to replace or repurchase the chemical from the people who have been so warned if they elect.²⁶⁵ Because TSCA required the EPA to choose the least burdensome method necessary, even when the EPA made a finding of “unreasonable risk of injury,” the Act placed a presumption in favor of regulatory avoidance, namely regulation through information disclosure. In doing so, the Act expressly made it more difficult for the EPA to choose public health protection through actual, substantive gatekeeping (e.g., chemical bans or use restrictions).

There is no better example of this presumption in favor of avoidance than the Fifth Circuit’s decision in *Corrosion Proof Fittings v. EPA*, where the court famously rejected the EPA’s rule banning asbestos upon concluding that the agency failed to consider the least burdensome alternatives to a complete ban. This ruling came in response to ten years and thousands of pages of documentation regarding the dangers posed by asbestos.²⁶⁶ The Fifth Circuit’s ruling reflects, in part, the structural flaws of TSCA. At the same time, the Fifth Circuit’s ruling may have generated an unnecessarily high hurdle to chemicals regulation, one not reflected in congressional intent. To that end, despite the significant study and documentation by the EPA on the risks posed by asbestos, the court separately ruled that the EPA had failed to provide substantial evidence of an “unreasonable risk of injury.”²⁶⁷ Ordinarily, the substantial evidence standard for reviewing an agency’s factual determination is not considered a high evidentiary hurdle,²⁶⁸ but in the context of TSCA review the court concluded that the EPA’s ten-year study of the impact of asbestos on human health and its accompanying in-depth analysis of this known carcinogen were not enough to warrant regulation under TSCA. Tellingly, the court cau-

265. *Id.*

266. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

267. *Id.*

268. *See, e.g.*, *Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951) (setting out the standard for “substantial evidence” review of factual determinations made through formal adjudication under the APA); *Ass’n of Data Processing Serv. Orgs. v. Bd. of Governors of the Fed. Reserve Sys.*, 745 F.2d 677, 684 (D.C. Cir. 1984) (“We have noted on several occasions that the distinction between the substantial evidence test and the arbitrary or capricious test is ‘largely semantic.’”); *cf. Corrosion Proof Fittings*, 947 F.2d at 1213 (“Contrary to the EPA’s assertions, the arbitrary and capricious standard found in the APA and the substantial evidence standard found in TSCA are different standards, even in the context of an informal rulemaking.”).

tioned that “Congress did not enact TSCA as a zero-risk statute.”²⁶⁹

After that decision, the EPA effectively concluded that § 6 is largely unenforceable. Rather than continue to pursue its authority to restrict or ban chemicals, the EPA turned to voluntary approaches to address risks.²⁷⁰ Notwithstanding the hype, the words offered by Russell Train in 1976 upon adoption of TSCA are as true today as they were forty years ago: “Most Americans had no idea, until relatively recently, that they were living so dangerously. . . . They had no idea that, without their knowledge or consent, they were often engaging in a grim game of chemical roulette whose result they would not know until many years later.”²⁷¹

It is worth noting that the EPA might have alleviated the shortcomings of TSCA had it routinely considered cumulative risks as part of the safety inquiry. If a finding of “unreasonable risk” were based in part on cumulative exposures, the EPA might also have reasonably discounted regulatory choices rooted in information disclosure. In addition, by fully assessing public health risks from cumulative exposures the EPA may have stood a better chance at educating the courts on the public health need for chemicals regulation. When viewed as a necessary tool for addressing a collective action problem, rather than as a limit on marketplace activity, courts may have been more amenable to an “unreasonable risk” threshold that would have

269. *Corrosion Proof Fittings*, 947 F.2d at 1215.

270. In 2011, as part of an educational series sponsored by the Environmental Law Institute, the EPA’s Director of the Office of Pollution Prevention and Toxics explained that:

[T]he Agency has only successfully invoked § 6 five times since 1976. The most ambitious attempt to use § 6 was in the 1980s, when there was an attempt to ban most uses of asbestos, a known human carcinogen. That attempt was overturned in litigation that resulted in additional burdens on Agency action under TSCA. Since the early 1990s, the Agency has not used the provision of TSCA that allows us to address unreasonable risks from existing chemicals. Given the difficulties of using some of TSCA’s regulatory tools, the Agency has pursued various voluntary and stewardship approaches to address risks from chemicals.

Wendy Cleland-Hamnett, Dir., EPA Office of Pollution Prevention and Toxics, Panel Discussion at the Environmental Law Institute, *TSCA Reform: The Standard of Safety* (July 21, 2011), in 41 ENVTL. L. REP. NEWS & ANALYSIS 11081, 11083 (2011); see also Angela J. Levin & Maria V. Souder, *In a World Without Congressional Reform: A New (Old) Role for EPA Under TSCA Section 6*, 29 NAT. RESOURCES & ENV’T 12 (2015) (summarizing TSCA’s poor track record).

271. Russell Train, Former Administrator, U.S. EPA 1973–1977.

reduced collective risk over time. This is an example of how, in the end, the fact that cumulative risk has been a blind spot in the implementation of TSCA may have weakened its effectiveness on multiple levels and exacerbated structural flaws.

In light of the many shortcomings of TSCA, the collection of criticisms of TSCA found political traction and spurred Congress to action and a new Act—the Frank R. Lautenberg Chemical Safety for the 21st Century Act—was signed into law by President Obama on June 22, 2016. This new Act replaces TSCA as the new chemical regulatory regime for the U.S. markets. Part IV explains how that new legislation eliminates some of TSCA’s shortcomings and how it can be implemented to more fully embrace issues of cumulative risk than its predecessor.

B. FIFRA: MORE PROMISES UNDELIVERED

While TSCA regulates chemical substances, it is a gap-filler statute; it regulates where other statutes do not. One major class of chemicals to which TSCA does not apply is pesticides.²⁷² Similarly, the Chemical Safety Act will not modify pesticides regulation. Rather, the EPA will continue to regulate pesticides under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Unlike TSCA, FIFRA has not been the recent target of any major reform efforts. But that is not to say that FIFRA takes a particularly strong approach to the protection of public health from chemicals exposure. Like TSCA, FIFRA suffers from heavy reliance on information disclosure as the primary vehicle for pesticide regulation. And, like TSCA, the combination of statutory mandates and incentives created by FIFRA have resulted in relatively little gatekeeping despite theoretical promise. So while FIFRA in theory more directly tackles issues of aggregate exposure, the implementation gaps that plague FIFRA leave substantial room for improvement.

A bit of FIFRA’s history helps explain where the gaps in this area of regulation have been and where they continue to be. The origins of FIFRA are quite telling. When it was enacted

272. See 15 U.S.C. § 2602(2)(B)(ii) (2012) (excluding from TSCA regulation chemicals that are “manufactured, processed, or distributed in commerce for use as a pesticide”). In addition, TSCA does not apply to foods, food additives, cosmetics, and drugs that are regulated by the Federal Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act. See *id.* § 2602(2)(B)(vi).

in 1947, FIFRA was a licensing and labeling law.²⁷³ Like the law that it replaced (the 1910 Federal Insecticide Act), FIFRA “protected farmers and consumers against fraudulent products” by promoting labeling uniformity and honesty.²⁷⁴ In short, it sought to ensure that pesticides actually killed pests.²⁷⁵ Written under the heavy influence of industry,²⁷⁶ FIFRA generally allowed for the quick registration of pesticides with few regulatory or informational requirements.²⁷⁷ To complete the picture, consider that FIFRA was administered by the USDA, an agency widely accepted to serve the interests of the agricultural lobby and chemical industry.²⁷⁸

As originally enacted, FIFRA did little to address public health-related concerns. The use of pesticides was rampant (over 300 million pounds of pesticides were produced in 1950),²⁷⁹ and yet, health consequences of eating foods sprayed with chemicals did not enter the regulatory picture until 1954. At that time, Congress amended the Food Drug and Cosmetic Act to create a program for setting safety limits for pesticide residues in food.²⁸⁰ However, the laws continued to overlook a

273. Stephen D. Otero, *The Case Against FIFRA Preemption: Reconciling Cipollone's Preemption Approach with Both the Supremacy Clause and Basic Notions of Federalism*, 36 WM. & MARY L. REV. 783, 785 (1995).

274. Pamela A. Finegan, *FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?*, 6 PACE ENVTL. L. REV. 615, 623 (1989) (citing S. REP. NO. 346 (1988)).

275. Anthony J. Nownes, *Interest Groups and the Regulation of Pesticides: Congress, Coalitions, and Closure*, 24 POL'Y SCI. 1, 2 (1991) (“The goal of [FIFRA] was to ensure that a pesticide was able to kill the pests that the manufacturer purported it did.”).

276. See Christopher J. Bosso, *Transforming Adversaries into Collaborators: Interest Groups and the Regulation of Pesticides*, 21 POL'Y SCI. 3, 5 (1988) (“The 1947 Act emerged out of close cooperation among members of the House Committee on Agriculture, USDA officials, and representatives of the major pesticides manufacturers—a classic ‘iron triangle’ in the words of subgovernment theorists.”); see also Albert H. Meyerhoff, *Frightening Tale of Dinoseb Is Rule, Not Exception, in the World of Pesticides*, L.A. TIMES (July 25, 1988), http://articles.latimes.com/1988-07-25/local/me-4548_1_dinoseb-ban (“FIFRA, written largely by and for the agrichemical industry, has not been seriously amended in 16 years and is severely flawed.”).

277. See Finegan, *supra* note 274, at 616 (examining a GAO report from 1986 that concluded pesticides registered before 1972 underwent inadequate testing).

278. See *id.* at 619 (“During the 1940s, the farm bloc seized power and increased its support of the United States Department of Agriculture (USDA) with new programs and increased budgetary support.”).

279. See *id.* at 619.

280. *Id.* at 622 (explaining that the FDA implemented the safety limits be-

host of other public health and environmental concerns associated with prolific pesticide use, including farm worker safety,²⁸¹ groundwater contamination,²⁸² and public parks.

By the early 1970s, Rachel Carson had famously spotlighted the risks of pesticides to humans and the environment in her book *Silent Spring*,²⁸³ and public concerns grew forceful enough to bring about substantial congressional change.²⁸⁴ It was in reaction to public pressure that Congress adopted major amendments to FIFRA in 1972. The authority for implementing FIFRA was transferred to the EPA, a newly created agency.²⁸⁵

Along with the transfer of power came a number of new provisions more directly addressing public health and the environment. For the first time, the EPA was given authority to reject the registration of pesticides that posed an “unreasonable adverse risk” to the environment.²⁸⁶ The EPA was also given authority to cancel registrations of existing pesticides, albeit with a rather large caveat: the EPA was required to indemnify manufacturers, distributors and retailers for unused product if registrations were cancelled.²⁸⁷ Issues of cumulative exposure were not directly addressed.

Despite the 1972 amendments, FIFRA continued to draw criticisms from public health and environmental advocates.²⁸⁸ By the mid-1980s criticisms to FIFRA bore a striking resemblance to some of the current criticisms of TSCA. Concerns in-

cause the EPA was not created until 1970).

281. See, e.g., U.S. GOV'T ACCOUNTING OFFICE, GAO/RCED-00-40, PESTICIDES: IMPROVEMENTS NEEDED TO ENSURE THE SAFETY OF FARMWORKERS AND THEIR CHILDREN (2000).

282. See Finegan, *supra* note 274, at 625 (citing 1987 congressional hearings for the claim that the EPA had detected groundwater contamination from pesticides in twenty-four states).

283. RACHEL CARSON, *SILENT SPRING* (1962).

284. See Bosso, *supra* note 276, at 4.

285. See Reorganization Plan No. 3 of 1970 § 2(a)(4), 35 Fed. Reg. 15623 (Oct. 6, 1970).

286. 7 U.S.C. § 136a(a) (2012).

287. *EPA History: FIFRA Amendments of 1988*, U.S. ENVTL. PROTECTION AGENCY, <https://archive.epa.gov/aboutepa/epa-history-fifra-amendments-1988> (last visited Apr. 24, 2017); see also Nownes, *supra* note 275, at 10–11 (describing the indemnification provisions and the structural barriers they raised to regulation).

288. See Finegan, *supra* note 274, at 625 (explaining that among the general public, pesticide residues was the number one consumer concern in a 1988 poll conducted by the Food Marketing Institute.).

cluded the completeness and adequacy of scientific data available to the EPA when evaluating new pesticides for public safety;²⁸⁹ the large number of existing pesticides that continued to be used despite little knowledge regarding public health impacts;²⁹⁰ the disincentives that agency indemnification created to cancelling pesticide registrations;²⁹¹ and the fact that “pesticides were innocent until proven guilty.”²⁹² There were many attempts to change the status quo but with little success. As one prominent political scientist remarked in the late 1980s: “To resolve a policy battle that all agree only perpetuates an unacceptable status quo may require yet another scandal or unfortunate incident.”²⁹³

It was not until 1993, when the National Academy of Sciences released a report on the vulnerability of infants and children to pesticide residues on food that Congress was again motivated to pay attention.²⁹⁴ That report, *Pesticides in the Diets of Infants and Children*, concluded that approaches used by the EPA to set pesticide tolerance levels insufficiently protected infants and children. The report made several recommendations, including that the EPA determine tolerances based on health, not agricultural cost-benefit; that the EPA develop toxicity studies evaluating neurological, immune and reproductive vulnerabilities of infants and children; and that the EPA include a safety factor when data is inadequate to evaluate toxicological

289. See Richard M. Dowd, *FIFRA Update*, 17 ENVTL. SCI. & TECH. 415A (1983).

290. As the *L.A. Times* reported in 1988: “FIFRA, written largely by and for the agricultural industry, has not been seriously amended in 16 years and is severely flawed. Thus, under its provisions, hundreds of ‘old,’ largely untested, pesticides continue to be used. (Ninety percent of the 2.6 billion pounds of pesticides used annually in the United States have never been adequately tested for chronic health effects like cancer, birth defects and nerve damage, according to the National Academy of Sciences.)” Meyerhoff, *supra* note 276; see also Finegan, *supra* note 274, at 617 (explaining that while the 1972 FIFRA amendments required the EPA to reregister the 35,000 pesticide products in existence at the time, fourteen years later the EPA had “completed review of only five active ingredients” out of 600 in need of review).

291. Finegan, *supra* note 274, at 634 (providing for statistics on how much cancelling pesticides cost the EPA in the late 1980s).

292. Nownes, *supra* note 275, at 8.

293. Bosso, *supra* note 276, at 18.

294. NAT’L RESEARCH COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN (1993); see also Kristina Thayer & Jane Houlihan, *Pesticides, Human Health, and the Food Quality Protection Act*, 28 WM. & MARY ENVTL. L. & POLY REV. 257 (2004) (detailing Congress’s efforts to pass the Food Quality Protection Act).

risk to infants and children.²⁹⁵ Most notably, the report recommended that the EPA consider risks from exposure to “multiple pesticides with a common toxic effect.”²⁹⁶ Moreover, the risks should be calculated by considering the total exposure from both dietary and non-dietary routes.²⁹⁷

Ultimately, in 1996 Congress responded to public concerns and enacted the Food Quality Protection Act (FQPA).²⁹⁸ Under that Act, the EPA must set a maximum residue, or tolerance, limit before a specific pesticide can be used on a food crop.²⁹⁹ The tolerance limit is the amount of pesticide residue allowed to remain in or on each treated food commodity. In setting tolerances, the EPA must make a finding that the tolerance is “safe.” A tolerance is defined as “safe” if there is a “reasonable certainty that no harm will result from *aggregate exposure* to the pesticide residue.”³⁰⁰ These aggregate exposure assessments must specifically account for the particular vulnerability of infants and children.³⁰¹

By passing the FQPA, Congress directly addressed issues of aggregate exposure. In this way, FIFRA and the history of

295. See NAT'L RESEARCH COUNCIL, *supra* note 294, at 9.

296. *Id.* at 11.

297. *Id.*

298. Food Quality Protection Act of 1996, Pub. L. No. 104–170, § 405, 110 Stat. 1513, 1514–35 (1996) (codified as amended at 21 U.S.C. § 346(a)(2000)).

299. The power of the EPA to set such tolerances comes from § 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). *Setting Tolerances for Pesticide Residues in Food*, ENVTL. PROTECTION AGENCY, <https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods> (last visited Apr. 24, 2017); *Summary of the Federal Food, Drug and Cosmetic Act*, ENVTL. PROTECTION AGENCY, <https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> (last visited on Apr. 24, 2017).

300. 21 U.S.C. § 346a(c)(2)(A)(ii) (2012) (emphasis added). Today, the EPA considers multiple factors in setting safety limits, including: (i) the toxicity of the pesticide and its breakdown products; (ii) how much of the pesticide is applied and how often; (iii) how much of the pesticide (i.e., the residue) remains in or on food by the time it is marketed or prepared; (iv) aggregate exposure to the pesticide in foods and from other sources of exposure; and (v) any special risks posed to infants and children. See *Setting Tolerances for Pesticide Residues in Food*, *supra* note 299. It is important to note that some pesticides are exempt from this process. The EPA may grant exemptions in cases where the exemption is found to be safe and the pesticide residues do not pose a dietary risk under reasonably foreseeable circumstances. *Id.* To make this exemption determination, the EPA must review toxicity and exposure data, the same as for tolerance setting. *Id.* In addition, there must be a practical method for detecting and measuring levels of the pesticide residues so regulatory officials can ensure that any residues are at or below the level found to be safe. *Id.*

301. § 346a(c)(2)(A)(ii).

pesticide regulation serve as useful starting points for thinking about issues of common toxicity and cumulative risk more broadly—beyond pesticides and residues. At a minimum, the pre-amendment history of the FQPA shows that scientists have recognized the importance of considering aggregate risk for nearly three decades.

While the safety limits required under FQPA are a step in the right regulatory direction, and while other areas of chemicals regulation could benefit from similar requirements to perform aggregate risk assessments, FIFRA's bright spots have to be put into context of the statute's overall limits. In other words, the fact that the EPA must consider aggregate exposure to pesticide residues on food does not mean that FIFRA, or FQPA, has been successful in addressing public health issues related to pesticide exposure.

Even setting aside the fact that the implementation of FQPA has been described as "disappointing" by some scholars,³⁰² FQPA is limited in scope. Importantly, cumulative risk assessments are more sophisticated tools than the aggregate risk assessments required by the FQPA. Aggregate exposure assessments, in contrast to cumulative risk assessments, simply evaluate a single chemical or pesticide across multiple exposure routes.³⁰³ An aggregate assessment, for instance, might study the impacts of benzene on a given community by studying the combined impact from all sources of benzene. At its core, the aggregate assessment is still single-stressor; it looks only at the impacts of benzene, not benzene as combined with other carcinogens or non-chemical stressors.³⁰⁴ In other words, aggregate risk assessments do not consider how the studied chemical behaves in a matrix of other chemical stressors or what level of risk is posed to a population from the combination of many chemicals through multiple exposure routes over long periods of time. Understanding the difference between cumulative and aggregate risk assessments highlights the limitations

302. See McGarity, *supra* note 6, at 147–202 (detailing FQPA's implementation and the unique problems the EPA faced). Much of the law's promises have gone unfulfilled and continue to be the subject of targeted lawsuits. See Alexandra B. Klass, *Pesticides, Children's Health Policy, and Common Law Tort Claims*, 7 MINN. J.L. SCI. & TECH. 89 (2005).

303. For an explanation of the differences between aggregate assessments and cumulative risk assessments, see EPA, FRAMEWORK, *supra* note 10, at 7.

304. *Id.*

of even current regulatory attempts to move beyond single-stressor, single-pathway assessments.

In addition, the mandates to set safety limits or to consider aggregate risk apply only to pesticide exposure through food residues. These public health protections do not apply to a whole host of other human health and ecological issues associated with pesticide use. As an example of FQPA's limited scope, consider the fact that it does not address farm worker safety,³⁰⁵ nor does it protect families of farmworkers or rural communities from pesticide drift.³⁰⁶

Urbanites fair no better under FIFRA's framework. Consider that over eighty million pounds of pesticide active ingredients are used on U.S. lawns each year.³⁰⁷ By some estimates, pesticides used in homes and on residential lawns rival agricultural use on a per acre basis.³⁰⁸ Unless these pesticides are also licensed for use on foods, they are not tested for chronic or aggregate health effects. For example, MCPP, the third-most heavily used herbicide in the United States, is not approved for food use and therefore has not been assessed for aggregate risk under the FQPA framework.³⁰⁹ Last year, risks to families from pesticide-driven lawn care inspired one county in Maryland to ban homeowners from using pesticides on their lawn.³¹⁰ That this measure regulated private lands was unusual. States like Connecticut have banned the use of certain pesticides on public lands, but have prohibited localities from regulating pesticide use on private lands.³¹¹

305. Cf. Scott Cook, *Farm Children as a "Major Identifiable Subgroup" for Setting Tolerances Under the Food Quality Protection Act of 1996*, 81 TEX. L. REV. 1121 (2003) (arguing that the FQPA should protect farmworkers).

306. See *supra* Part II.B for a discussion of the litigation concerning impacts to farmworkers and children from pesticide drift. See also Petition, *supra* note 196; Cynthia L. Curl et al., *Evaluation of Take-Home Organophosphorus Pesticide Exposure Among Agricultural Workers and Their Children*, 12 ENVTL. HEALTH PERSP. 110 (2002) (discussing the problem of pesticide drift for farmworkers and their families).

307. JOHN WARGO ET AL., RISKS FROM LAWN-CARE PESTICIDES (2003).

308. The U.S. Fish and Wildlife Service, in a report on lawn care and frogs, asserted that "homeowners use up to 10 times more chemical pesticides per acre on their lawns than farmers use on crops." See *id.* at 6.

309. See *id.* at 7.

310. Bill Turque, *MoCo Becomes First Major Locality To Ban Cosmetic Pesticides from Lawns*, WASH. POST (Oct. 6, 2015), https://www.washingtonpost.com/local/md-politics/moco-becomes-first-major-locality-to-ban-cosmetic-pesticides-from-lawns/2015/10/06/ccb5df9a-6c55-11e5-b31c-d80d62b53e28_story.html.

311. Connecticut enacted a law "banning lawn care pesticide applications

Keep in mind that these state-adopted measures, aimed at reducing pesticide exposure by reducing pesticide use, are not driven by the federal regulatory framework. As Professor Wendy Wagner and Lynn Blais have observed, “[T]he actual environmental application and use of . . . pesticides . . . is not regulated at all on the federal level.”³¹² Rather, while FIFRA requires registration and compliance with labeling, the regulation on pesticide use is left to the states.³¹³ Many states have failed to fill that gap.³¹⁴ Because of the impacts of pesticide proliferation on the ambient environment, discussed below, this ad hoc approach is not adequate to address the scope of the problem. As Professor Wagner and Blais have observed, FIFRA’s regulatory gaps have created a “legal blindspot” that leaves environmental threats to children’s health woefully unaddressed.³¹⁵

Together these examples highlight that, outside of the food residue context, FIFRA leaves many potential exposures to pesticides unregulated and unexamined. To be sure, FIFRA does give the EPA authority to ban or restrict the use of pesticides that would cause “unreasonable adverse effects on the environment.”³¹⁶ In fact, FIFRA requires product manufacturers seeking to register pesticides to show that the new pesticide or new use meets this safety standard before pesticides are approved to enter the market.³¹⁷ In theory, this burden-shifting framework sounds good. Indeed, it is adopted by the European Union’s chemicals legislation—REACH—and has been similarly part of the successful effort to reform TSCA.³¹⁸

on the grounds of day care centers, elementary and middle schools (grade 8 and lower) as a result of residents’ concerns about children’s health and the environment.” CONN. DEP’T OF ENVTL. PROT., CONNECTICUT’S LAWN CARE PESTICIDE BAN: INFORMATION FOR SCHOOLS AND DAY CARE CENTERS, [http://www.ct.gov/deep/lib/deep/p2/government/turf_mgt_without_pesticides_final_\(2\).pdf](http://www.ct.gov/deep/lib/deep/p2/government/turf_mgt_without_pesticides_final_(2).pdf).

312. Wendy Wagner & Lynn Blais, *Children’s Health and Environmental Exposure Risks: Information Gaps, Scientific Uncertainty, and Regulatory Reform*, 17 DUKE ENVTL. L. & POL’Y F. 249, 265 (2007).

313. *Id.*

314. *Id.*

315. *See id.*

316. 7 U.S.C. §136a(a).

317. *Id.* § 136a(c)(5)(C); *Envtl. Def. Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 593 (D.C. Cir. 1971) (holding that FIFRA shifts the burden of showing safety from the EPA to the registrant).

318. Frank R. Lautenberg Chemical Safety for the 21st Century Act, 15 U.S.C. § 2604(a) (2016) (amending the registration requirements of TSCA).

FIFRA's bite, however, remains weak despite the fact that it places the burden of showing safety on industry. One reason is that, like TSCA, a finding of "unreasonable adverse effects" must consider environmental, social, and economic costs. By entwining the safety threshold with economic considerations, this standard puts a thumb on the scale of pesticide proliferation and shifts the focus away from longer-term public and ecological health. In particular, the cost-benefit component makes substantive regulation of widely used pesticides difficult given that bans will often carry significant economic costs while social and environmental benefits will be harder to quantify.³¹⁹ In addition, cost-benefit analysis is only as good as the information available to properly value costs and benefits.

Even if FIFRA's measure of "unreasonableness" were tied solely to health risks, the effectiveness of FIFRA's safety standard would still be limited by information gaps. Several scholars have noted the limited toxicity testing available to evaluate pesticide safety. For example, the EPA has been criticized for failing to "require full-scale neurodevelopmental toxicity testing, even for neurotoxic pesticides."³²⁰ The guidelines that do exist fail to adequately consider long-term degenerative effects of pesticide exposure, which is a particular concern for children. Effects on the immune system and endocrine system similarly suffer from lack of information and testing. These information gaps are even more pronounced in older pesticides that were on the market before FIFRA was enacted.³²¹

One of the culprits for FIFRA's information gaps is the EPA's conditional registration authority.³²² Notably, no aggregate risk assessment is required under FQPA for conditional

For a discussion of REACH and a call to reform U.S. law to include similar burden-shifting requirements, see Sachs, *supra* note 6, at 1836.

319. For a detailed examination of the history (and ineffectiveness) of FIFRA in banning pesticides under the current statutory structure, see FREDERICK ROWE DAVIS, *BANNED: A HISTORY OF PESTICIDES AND THE SCIENCE OF TOXICOLOGY* (2014). For a discussion of the systemic problems in valuing regulatory benefits, see Arden Rowell, *The Cost of Time: Haphazard Discounting and the Undervaluation of Regulatory Benefits*, 85 NOTRE DAME L. REV. 1505 (2010).

320. See Wagner & Blais, *supra* note 312, at 266.

321. See *id.*

322. The EPA is allowed to grant conditional registrations for pesticides that are substantially similar to currently registered pesticides, as well as to registrations proposing new uses of current pesticides and pesticides with new active ingredients. 7 U.S.C. § 136a(c)(7)(A) (2012).

registrations.³²³ Moreover, FIFRA's burden-shifting provisions do not apply to the conditional registration process, which by its design allows the EPA to register pesticides without full safety data.³²⁴

Ostensibly, registrants have between one and four years to provide the missing information.³²⁵ Whether this information is actually submitted within the required timeframe, however, is a bit of mystery. A 2013 Government Accountability Office study found major problems with the EPA's method for tracking pesticide registrations.³²⁶ This study was prompted by environmental groups claims that the "EPA had overused conditional registrations" to the point where "conditional registrations represented the majority of active registrations."³²⁷ And based on information collected through Freedom of Information Act requests, the group raised concerns that some 3200 pesticides had been in conditional status since 1995 and 2100 had been in conditional status since 1990.³²⁸ Some of these claims were confirmed when the EPA's Office of Pesticide Programs (OPP) conducted an internal review in 2011 that determined sixty-nine percent of active pesticide registrations were conditionally registered. Keep in mind that conditional registrations represent the pesticides that are being sold and used in the United States without adequate safety data.

The state of conditional registrations is both more complicated and disturbing than the OPP information suggests. When the GAO followed up on these claims in 2013, the GAO uncovered a deeper problem: "OPP lacks a reliable system specifically to track the status of conditional registrations to ensure that additional required data are submitted timely, and that OPP reviews that data."³²⁹ In other words, OPP was not able to say how many of its conditional registrations were subsequently backed by adequate safety data and how many had fallen through the regulatory cracks. Indeed, OPP reported that each

323. See *Nat. Res. Def. Council v. EPA*, 735 F.3d 873 (9th Cir. 2013) (upholding EPA's decision not to conduct an aggregate risk assessment in granting a conditional registration of clothing and textile pesticides containing nanosilver).

324. § 136a(c)(7).

325. U.S. GOV'T ACCOUNTABILITY OFFICE, *EPA SHOULD TAKE STEPS TO IMPROVE ITS OVERSIGHT OF CONDITIONAL REGISTRATIONS* 3 (2013).

326. *Id.*

327. *Id.*

328. *Id.* at 12.

329. *Id.* at 19.

of its twenty product managers used a variety of methods to track information regarding the status of conditional registrations, “including electronic spreadsheets or reminder notices, handwritten notes, and memory.”³³⁰ With this kind of ad hoc approach, mistakes and oversights are bound to arise. Not surprisingly, the GAO Report provides some examples that leave one to question the seriousness with which OPP treats issues of pesticides and the public health:

For example, in the case of a pesticide product containing the active ingredient Foramsulfuron, conditionally registered in November 2002, two required studies on the effects of this pesticide on terrestrial and aquatic plants that were due in December 2004 had not been submitted 10 years after the conditional registration was issued, as determined by OPP’s registration review of this pesticide in 2012. In another case, involving a pesticide product containing the active ingredient Acetamiprid, conditionally registered in March 2002, OPP discovered during its registration review of this pesticide in 2012, about 10 years later, that it had received, but not reviewed, a study related to the effects of this pesticide on honeybees. OPP documents indicate the registrant submitted this study in 2001, even before OPP granted the conditional registration. Acetamiprid belongs to a class of pesticides called neonicotinoids that some beekeepers, environmental groups, and others suspect of having adverse effects on honeybees.³³¹

The summary lesson is troubling: for almost forty years the EPA has been bypassing the safety standard under FIFRA without assurances that information gaps would be closed in any timely fashion, or at all. Needless to say, the EPA’s widespread use of conditional registrations supports the origins of FIFRA as a weak regulatory regime concerned mainly with registration and labeling; one not founded on the expectation of having much teeth in terms of public health protection. Indeed, the EPA’s approach to conditional registrations is a troubling example of Professor Donald Hornstein’s observation that “pesticide regulation is not . . . a body of law that addresses in any strategic way the underlying prevalence of pesticides in American agriculture, nor is it a body of law designed to minimize pesticide use.”³³² Conditional registrations also illustrate a deeper pathological problem with FIFRA—ones where the ad hoc regulatory approach reflects a disregard for the serious public health issues associated with widespread pesticide use.

330. *Id.* at 23.

331. *Id.* at 25.

332. Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. ON REG. 369, 392 (1993), *cited in* Wagner & Blais, *supra* note 312, at 265–66, n.83.

IV. A PATH FORWARD (AND SOME HURDLES)

While this Article is primarily dedicated to the thesis that cumulative risk analysis needs to be at the regulatory forefront, this Part sketches a path forward. In particular, it offers a home—a legal hook—for cumulative risk in the existing statutory landscape: when assessing whether impacts are “unreasonable” under the applicable safety standards, the EPA should make cumulative risk part of that assessment. In fact, one could certainly argue that the EPA must take cumulative risks into account in order to survive judicial review. Though fairly straightforward in terms as matter of legal interpretation, identifying a legal hook is not in itself a solution unless some underlying equitable concerns are addressed. This Part, therefore, concludes by cataloging the practical policy challenges that regulators will have to tame in order for cumulative risk assessments to translate into risk reduction strategies.

A. SAFETY THRESHOLDS AS THE KEYSTONE TO REGULATING CUMULATIVE IMPACTS

The most direct and obvious step toward integrating cumulative risk assessments into the existing regulatory frameworks would be for the EPA to consider cumulative risks as part of regulatory safety thresholds. Both FIFRA and the Chemical Safety Act of 2016 support this approach.

1. “Unreasonable Risk” and the Chemical Safety Act of 2016

Under the Chemical Safety Act of 2016, the EPA has the authority to regulate chemicals that “present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.”³³³ This safety threshold of “unreasonable risk” is similar to the one that governed under TSCA and is broad enough to support the consideration of cumulative risk; indeed, the legislative history of TSCA reflects Congress’s desire to do just that. And in passing the Chemical Safety Act of 2016, there is no indication that Congress intended to take a narrow view or otherwise exclude the consideration of cumulative risk. In fact, the Chemical Safety Act includes several statutory provisions that strengthen the EPA’s authority to restrict chemical use under the new Act.

333. 15 U.S.C. § 2604(a)(3)(A) (2016).

The most obvious way that Congress strengthened the safety threshold is the prohibition against considering “cost or other nonrisk factors” when evaluating safety. By making clear that the safety threshold is a health-based determination, Congress took an express step toward public health protection and signaled its desire to approach chemicals regulation as a public health issue foremost. Because cumulative risk lies at the heart of public health, it stands to reason that the including cumulative risk in the safety assessment would be consistent with Congress’s directive to assess risk on the basis of health.

Notably, the Chemical Safety Act does not abandon considerations of the economic consequences of regulations altogether. Once the EPA determines that a chemical substance presents an unreasonable risk, the EPA must consider, as part its rulemaking, the benefits of the chemical substance and the economic consequences of any proposed restrictions.³³⁴ Unlike TSCA, however, the Chemical Safety Act does not require a formal cost-benefit analysis nor does it require the EPA to make decisions based on that analysis. Rather, the Chemical Safety Act simply directs the EPA to factor economic consequences “to the extent practicable” in the agency’s selection of prohibitions and restrictions.³³⁵ The latitude afforded to the EPA to prescribe restrictions under the Chemical Safety Act, and the Act’s deletion of a cost-based decision model, is further example of Congress’s intent to support health-based determinations under the Act.

In addition, the Chemical Safety Act opens the door for the EPA to consider cumulative risk in safety determinations in another critical regard. Namely, in an attempt to fix TSCA, Congress shifted the burden of proving safety of new chemicals to industry. Now, like FIFRA and the EU’s REACH legislation, a manufacturer can only start making and selling a new chemical under the Chemical Safety Act if the EPA has determined that the new chemical “is not likely to present an unreasonable risk of injury to health or the environment.”³³⁶ Relatedly, the EPA must impose restrictions necessary to protect the public if the new chemical presents or may present an unreasonable risk, if the EPA lacks sufficient information to make a safety determination, or if the chemical is produced in large amounts

334. *Id.* § 2605(c)(2)(A).

335. *Id.* § 2605(c)(2)(B).

336. *Id.* § 2604(a)(3)(A).

and results in large releases or exposures.³³⁷ By contrast, under the old TSCA, manufacturers were generally free to start making and distributing a new chemical unless the EPA determined that the chemical posed an unreasonable risk within the ninety day window.

This burden shift signals a new era of precaution in chemicals regulation and provides the EPA with the opportunity to be more thorough in its risk evaluations. Consider that under the old law, the EPA had ninety days to make a safety determination and the EPA had the burden of proving a new chemical was unsafe. Under those circumstances, the EPA might reasonably have shied away from cumulative risk analysis, both because of the time and because of the uncertainty. After all, when the EPA bore the burden of proof, uncertainties would have undermined the EPA's ability to regulate. In other words, when the EPA had the burden of proving that a chemical presented an unreasonable risk, the EPA may very well have concluded that the dearth of information on issues of cumulative exposure would not permit the EPA to make a determination of "unreasonable risk" on that basis.

Now that the burdens are flipped, the EPA actually has the opposite problem. Whereas uncertainties historically prevented the EPA from barring the manufacture of new chemicals, the EPA cannot reasonably conclude that a new chemical is safe unless uncertainties are resolved and unless more information is known about cumulative risks. In fact, because cumulative risk responds to the actual, real-life risks that chemicals pose, there is no logical reason why the burdens of proving safety should not reflect that full suite of actual risks.³³⁸

There are two final aspects of the Chemical Safety Act of 2016 that support the adoption of a cumulative risk perspective to public health. First, the Act requires the EPA to base its decisions on "the best available science."³³⁹ As risk science evolves to provide a fuller suite of tools and methodologies for assessing cumulative risk, the EPA's obligation to use that science is mandated by this "best science" provision.

Second, the Chemical Safety Act requires the EPA to include certain discussions in its risk evaluations. Notably, the

337. *Id.* § 2604(a)(3)(B).

338. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (setting forth "arbitrary and capricious" factors).

339. 15 U.S.C. § 2625(h) (2016).

EPA is required to “describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration.”³⁴⁰ While this provision stops short of requiring the EPA to conduct a cumulative risk assessment, it certainly reflects Congress’s awareness that issues of aggregate exposure are relevant to risk evaluations. When read in light of the “best available science” mandate, it creates a structure whereby the EPA will have to justify any decision to exclude such information.

For all of these reasons, the EPA should systematize its use of cumulative risk assessment under the Chemical Safety Act. The timing of such a move is good. The Act requires the EPA to develop risk evaluation regulations within a year of the Act’s effective date. While the ossification of rulemaking will likely extend this timeframe, these are the issues that ought to be on the EPA’s agenda as it sets those risk evaluation protocols for the future.

2. “Unreasonable Adverse Effects” and FIFRA

Similar to the Chemical Safety Act, the EPA is authorized under FIFRA to limit the distribution, sale or use of a pesticide “to prevent unreasonable adverse effects to the environment.”³⁴¹ And like the Chemical Safety Act, nothing in the language of FIFRA suggests that cumulative exposures fall outside the safety thresholds. FIFRA’s safety standard, in fact, is already borne out of a conception of the environment as a series of interconnected and interacting parts. In particular, FIFRA’s safety standard turns on the effects to the environment, where environment is broadly defined to mean “water, air, land and all plants and man and other animals living therein, and the interrelationships that exist among these.”³⁴²

To the extent that Congress intended to narrow the impact of FIFRA’s safety threshold, that narrowing was not in the consideration of biological effects. Rather, Congress narrowed the impact of FIFRA’s regulatory bite by requiring regulatory decisions to balance public health risks with economic and social benefits of pesticide use. To that end, FIFRA defines “unreasonable adverse effects on the environment” as “taking into account the economic, social, and environmental costs and bene-

340. *Id.* § 2605(b)(4)(F).

341. 7 U.S.C. § 136a(a) (2012).

342. *Id.* § 136(j).

fits of the use of any pesticide.”³⁴³ It is this balancing that ultimately will limit the usefulness of the cumulative risk analysis. To be clear, however, the statute does not prevent regulators from taking full account of the risks. And it stands to reason that the balancing of risk and benefits cannot properly take place without a full understanding of the risks in their social context.

Given the breadth of the safety standard under both regulatory frameworks, the unreasonableness of risks should necessarily turn on real-world exposures and public health impacts. Logic dictates that cumulative risks would be part of that assessment. In fact, given the advancements in risk science and the frank acknowledgement by regulators that questions of cumulative risk are highly relevant to public health burdens, the failure of the EPA to consider cumulative risks, even if on a qualitative level, could be grounds for legal challenge. In other words, *not* considering cumulative risks might reasonably give rise to a claim that the agency engaged in arbitrary and capricious decision-making for failure to consider all the relevant factors.³⁴⁴

In *Michigan v. EPA*, the Supreme Court held that the EPA failed to consider all relevant factors when it failed to consider cost in the first step of regulating mercury emissions from power plants.³⁴⁵ The Court observed that cost is so obviously a factor in the usual regulatory calculus that it must be considered when determining whether regulation is “necessary and appropriate” under the Clean Air Act.³⁴⁶ Like cost, assessing cumulative risk is clearly a key ingredient in the understanding of public health risks from chemicals and pesticide regulation. And, like the Clean Air Act’s regulatory threshold (“appropriate and necessary”), the safety thresholds of FIFRA and the Chemical Safety Act invite a broad consideration of risks. It stands to

343. *Id.* § 136(bb).

344. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

345. *Michigan v. EPA*, 135 S. Ct. 2699, 2706 (2015).

346. *Id.* (holding that the EPA’s decision to regulate mercury emissions from power plants without considering cost was arbitrary and capricious because “[n]ot only must an agency’s decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational. It follows that agency action is lawful only if it rests on a consideration of the relevant factors” (internal citations and quotation marks omitted)).

reason, that under the arbitrary and capricious rulemaking standard, the EPA must systematically consider cumulative risks when evaluating safety.

B. HURDLES TO REGULATING CUMULATIVE RISK

Risk science supports a more central role for cumulative risk. The statutes contain an obvious regulatory hook. Rational decision-making demands that all relevant factors be considered. So, why then, hasn't cumulative risk assumed a more central role in assessing chemicals and pesticide safety? What makes the policy lag behind the science? I suggest that there are two major types of hurdles that cause policy to lag behind science. The first is informational. The second centers on nettlesome questions of equity.

1. Informational Hurdles

Though approaching chemicals regulation through a cumulative risk lens would better serve public health, there is one significant reason why taking a cumulative risk focus may have been difficult under TSCA and FIFRA even if the EPA had wanted to: information gaps. In particular, making a risk finding requires data regarding chemical toxicity and exposure.

Data, however, is not so easy to come by.³⁴⁷ Fewer than 200 of the 61,000 "existing" chemicals grandfathered into the TSCA inventory have been reviewed by the EPA for human health risks.³⁴⁸ In 1998, the EPA released a study that revealed shockingly little information was known about High Production Volume (HPV) chemicals, which are those chemicals produced or imported into the United States in excess of 1,000,000 lbs. per year.³⁴⁹ In particular, of the 3000 HPV chemicals, there was no publicly available toxicity information for forty-three percent of the chemicals, and a full set of basic toxicity data for only seven percent.³⁵⁰ Since that time, the EPA has been engaged in the HPV Chemical Challenge and has partnered with the chemical industry to obtain greater information.³⁵¹ The results have been mixed.

347. Wagner, *supra* note 19.

348. Ekey, *supra* note 51, at 171–72.

349. U.S. ENVTL. PROT. AGENCY, CHEMICAL HAZARD DATA AVAILABILITY STUDY (1988).

350. *Id.* at 6.

351. See David W. Case, *The EPA's HPV Challenge Program: A Tort Liability Trap?*, 62 WASH. & LEE L. REV. 147, 160–61 (2005) (describing the pro-

For new chemicals, where manufacturers have been required to submit chemical information as part of the registration process, one might anticipate a different situation. In actuality, few manufacturers submitted complete information for new chemical review. The EPA estimates that only about fifteen percent of companies report any health or safety data.³⁵² Most fail to report test data of any sort.³⁵³ Information gaps for pesticides are similarly disheartening.³⁵⁴

One can imagine these information gaps have contributed to the agency's reluctance in considering cumulative risk at all. In fact, during the same year that the Fifth Circuit dealt a hardy blow to TSCA in the *Corrosion Pipe Fittings* case, the Citizens for Better Environment filed a TSCA case in the U.S. District Court for the Northern District of Illinois on an issue involving cumulative risks. The Center filed a petition requesting that the EPA use its TSCA authority to require coke plants on the South side of Chicago to test the cumulative and synergistic interactions of eleven different chemicals emitted from the facilities.³⁵⁵ While the Center argued that the cumulative impacts presented an unreasonable risk under TSCA, the EPA denied the petition on the grounds that "the commencement of cumulative and synergistic testing of the 11 identified substances, as well as of other chemical substances and mixtures—is *not* scientifically feasible."³⁵⁶ Notably, neither the EPA nor the testifying experts argued that cumulative risks were inappropriate under TSCA's safety standard; only that the testing protocols had not advanced to the point where such inquiries would be useful.

Given that the Fifth Circuit had rejected the EPA's efforts on the regulation of asbestos, which had been supported by extensive scientific evidence, one can sympathize with the EPA's reluctance to wade into the more scientifically difficult waters of cumulative risk assessment.³⁵⁷ With the adoption of the Chemical Safety Act, however, the EPA has a tremendous op-

gram).

352. U.S. GOV'T ACCOUNTABILITY OFFICE, OPTIONS FOR ENHANCING THE EFFECTIVENESS OF TSCA 7 (2009).

353. *Id.*

354. See Wagner & Blais, *supra* note 312.

355. *Citizens for a Better Env't v. Reilly*, No. 85-C-8000, 1991 WL 95040, at *3 (N.D. Ill. 1991).

356. *Id.*

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

portunity to make progress on understanding cumulative risk. Because the Chemical Safety Act takes the major step of shifting the burden of proving safety to manufacturers, it allows the EPA to set the terms of rational risk evaluation and ask manufacturers to fill in the information gaps accordingly. To the extent uncertainties continue to exist within the risk assessments, regulators can use safety factors to account for cumulative impacts.³⁵⁸ At least in this way the cumulative risk issues are part of a systematic analysis. By contrast, burying one's head in the sand simply shifts the perception of what the problem really is.

Once the EPA asserts its authority to consider cumulative risk as part of the safety thresholds under the Chemical Safety Act and FIFRA, it stands to reason that the information-generating authorities afforded by those Acts could be deployed as tools for filling in some information gaps on cumulative risks. In this way, the step of regulating cumulative risk through the safety threshold becomes the regulatory driver necessary for furthering the understanding of cumulative risk as well. The regulatory landscapes under which we exist might finally break free of the endless cycle of avoiding this critical issue for lack of information.

2. Policy Hurdles

Moving from risk identification to risk reduction, there are a cadre of nettlesome policy questions that regulators and scholars will have to wrestle with. In a nutshell, issues of cumulative risk raise a host of very difficult fairness concerns about which chemicals should be regulated and by how much. When all the other arguments and explanations have been laid on the table, these are the ones that cause commitments to cumulative risk to stray.

Consider, for instance, a scenario in which regulators undertake a cumulative risk assessment for endocrine disruptors and determine that the combined effects on public health are unreasonable. What then? Which chemicals, and on what basis, should the regulator seek to reduce that risk? Banning all endocrine disruptors would be untenable. But even if regulators sought to ban or restrict some of the endocrine disruptors, that

358. See Sargiannis & Hansen, *supra* note 262, at 5 (“One way to deal with the general lack of knowledge about interactions in a cumulative risk assessment context is to use an additional uncertainty factor accounting for potential synergy effects.”).

determination could be made on the basis of several factors: which chemical is most toxic, the volume of the chemical in commerce, the usefulness of the chemical to social life, or the chemical that was the first to enter the marketplace. Regulators might also give priority to the chemicals that are well studied, even if those studies uncover some risks.

Deciding which approach to take or how to appropriately weigh the various risk criteria is beyond the scope of this Article.³⁵⁹ For now, consider that similarly daunting problems of allocating responsibility for combined impacts are not new to environmental law. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)³⁶⁰ has been regulating toxic soup for decades. At times, that law has required the EPA and courts to allocate clean up liability for Superfund sites among hundreds of parties for adverse impacts generated by countless different chemicals. While the Act holds potentially responsible parties jointly and severally liable, courts must nonetheless allocate liability among solvent parties. In making that allocation determination, courts look to the “Gore factors,” which include equitable considerations like the amount of hazardous waste contributed to the site, the degree of toxicity of the waste, the degree of care exercised by the various parties, and the degree of cooperation in working with regulators to prevent harm.³⁶¹ Similarly, under the Clean Water Act’s TMDL program, regulators are tasked with working backward from an unacceptable ambient water quality, identifying the relevant point and nonpoint sources of water pollution, and developing an equitable distribution of discharge allowances so that the end goal—clean water—is ultimately met.³⁶² The same approach undergirds the Clean Air Act’s regulation of NAAQS and the EPA’s new Clean Power Plan.

The fact is that environmental problems are collective action issues at heart. Thus, regulating necessarily means sorting out issues of equitable distribution of cumulative impacts. The real difference between these other environmental regulatory

359. For a law and economics discussion of how pollution can be distributed among the population to reduce risk without reducing the total amount of pollution, see Arden Rowell, *Allocating Pollution*, 79 U. CHI. L. REV. 985, 1008 (2012).

360. 42 U.S.C. § 9601 (2012).

361. See John Copeland Nagle, *CERCLA, Causation, and Responsibility*, 78 MINN. L. REV. 1493, 1522–23 (1994) (explaining the Gore factors and allocation process).

362. See HOUCK, *supra* note 3 for a description of TMDLs.

programs and the ones that have historically been implemented for chemicals and pesticides is one of commitment, not difficulty. In that sense, the first step to effective chemicals and pesticide regulation may be shedding the notion that issues of cumulative risk in this context are unique or therefore excused from serious attention.

CONCLUSION

To argue that understanding cumulative risk is necessary is not to say that regulating cumulative risk is easy. In fact, programs in other environmental laws dealing with cumulative risk have proven difficult to implement. At the same time, these are the issues that drive to the heart of public health protection and cannot be ignored simply because they pose difficult issues. The EPA acknowledges as much in its Framework: “[L]imitations in methods or data should not be seen as a convenient reason for completely ignoring or not posing questions for which stakeholders may be seeking answers.”³⁶³

To that end, even in a world with complete information for any individual product, managing risk from chemicals exposure is beyond the control of the individual consumer for two fundamental reasons. First, individuals cannot reasonably be expected to self-assess the aggregate or cumulative risk profiles of some endless combination of products. Second, we have reached a point in our industrial economy where the ambient environment poses exposure risk. That is, the manufacture, distribution, use, and release of chemicals from everyday products and ubiquitously used pesticides have generated ambient risk in the greater environment. The individual consumer is not able to opt out of certain risks even with perfect information. Together these reasons make chemicals regulation a public health issue.

This may seem an intuitive enough point. And in fact there are entire fields of scientific study and institutions—e.g., the National Institute of Environmental Health and Safety—devoted to understanding the health implications of prolific chemicals and pesticide use. Unfortunately, federal legislation governing chemicals exposure through consumer products and pesticide use has failed to support that basic intuition. But it need not. This Article offers a critical starting point for regulating cumulative risk—it has laid the foundational arguments for

363. EPA, FRAMEWORK, *supra* note 10, at 33.

why we should. It has also begun to sketch the guiding framework for how we can. That leaves the question of whether we will.