22 NEV. L.J. 145

RE-IMAGINING RISK: THE ROLE OF RESILIENCE AND PREVENTION

Timothy Malloy*

TABLE OF CONTENTS

* Frank G. Wells Endowed Chair in Environmental Law, UCLA School of Law. I am grateful to the participants of the 2019 Colloquium on Environmental Scholarship for insightful comments on a prior draft and to Igor Linkov and Benjamin Trump for numerous conversations on this topic.

INTRODUCTION

Bad things happen. Chemicals meant to lead to better living sometimes cause cancer, reproductive problems, Parkinson's disease, or other problems.[1] Industrial plants and nuclear power plants designed to operate efficiently and safely occasionally explode.[2] Despite attempting to anticipate contingencies, offshore drilling operations catastrophically fail in the face of the unexpected.[3] Despite our best efforts, infrastructure designed to protect communities collapses, inundating homes and businesses with floodwaters.[4] Over the past forty years, businesses and governments have largely relied on the process of risk analysis (consisting of risk assessment and risk mitigation) to minimize the frequency and magnitude of such events.[5] In essence, risk analysis seeks to identify the likely undesirable consequences associated with a given activity (risk assessment) and develop measures to reduce those consequences to acceptable levels (risk mitigation).[6] In practice, those risk mitigation measures attempt to control the source of the risk by capturing emissions and pollutants, curbing flood waters, and containing biological agents. However, as technological failures and natural disasters mount, doubts have arisen about the value of this conventional approach to risk analysis.[7] Similar doubts also abound regarding the capacity of conventional risk analysis to handle threats presented by conventional chemicals and newly emerging materials.[8]

Why the loss of confidence in conventional risk analysis? Part of it stems from the nature of risk assessment itself, at least as it is typically practiced. Risk

---

[1] *See* WILLIAM L. BIRD, JR., "BETTER LIVING": ADVERTISING, MEDIA, AND THE NEW VOCABULARY OF BUSINESS LEADERSHIP, 1935–1955, at 22–23 (1999) (tracing the history of Dupont's 1935 iconic slogan "Better Things for Better Living . . . through Chemistry"). The slogan is perhaps better known today in its bastardized version: "Better living through chemistry."

[2] *See* Timothy F. Malloy, *Of Natmats, Terrorists, and Toxics: Regulatory Adaptation in a Changing World*, 26 J. ENV'T L. 93, 99–101, 109 (2008) [hereinafter Malloy, *Natmats*].

[3] *See* Robin Kundis Craig, *Legal Remedies for Deep Marine Oil Spills and Long-Term Ecological Resilience: A Match Made in Hell*, 2011 BYU L. REV. 1863, 1896 (2011).

[4] *See* Susan L. Cutter et al., *Disaster Resilience: A National Imperative*, 55 ENV'T: SCI & POL'Y FOR SUSTAINABLE DEV. 25, 25–29 (2013).

[5] *See, e.g.*, J. Park et al., *Integrating Risk and Resilience Approaches to Catastrophe Management in Engineering Systems*, 33 RISK ANALYSIS 356, 358–59 (2013); William Boyd, *Genealogies of Risk: Searching for Safety, 1930s–1970s*, 39 ECOLOGY L.Q. 895, 903 (2012). *See generally* PETER L. BERNSTEIN, AGAINST THE GODS: THE REMARKABLE STORY OF RISK (1998); Terje Aven, *Risk Assessment and Risk Management: Review of Recent Advances on Their Foundation*, 253 EUR. J. OPERATIONAL RSCH. (2016).

[6] *See* Gary E. Marchant & Yvonne A. Stevens, *Resilience: A New Tool in the Risk Governance Toolbox for Emerging Technologies*, 51 U.C. DAVIS L. REV. 233, 238 (2017) (describing risk analysis as including risk assessment to estimate risks and risk management to reduce risks to an acceptable level); Stan Kaplan, *The Words of Risk Analysis*, 17 RISK ANALYSIS 407, 415 (1997) (providing an overview of the general steps involved in risk analysis).

[7] *See, e.g.*, Lincoln L. Davies & Alexis Jones, *Fukushima's Shadow*, 48 VAND. J. TRANSNAT'L L. 1083, 1100 (2015); Craig, *supra* note 3, at 1869; Daniel A. Farber, *Uncertainty*, 99 GEO. L.J. 901, 906 (2011).

[8] Davies & Jones, *supra* note 7, at 1100.

assessment works well enough when the threat in question and the consequences that flow from that threat are pretty well understood, including the probability that the threat will become reality. When those conditions are absent—for example, where there is ambiguity or even ignorance regarding the nature of the threat or scope of the potential consequences—conventional risk assessment becomes problematic. Ambiguity and ignorance often arise when the threatened subject is part of a complex system, such as an ecosystem facing the introduction of a new species created through synthetic biology[9] or a coastal community staring down an increasingly unpredictable hurricane season.[10] Likewise, conventional risk analysis works poorly when data is unavailable due to cost or methodological challenges or when the human behavior being managed is indeterminate.

I will argue that conventional risk analysis—meaning risk analysis fixated on control—should expand to systematically integrate two related principles. The first is *prevention*. Conventional risk analysis mitigates the consequences of risky behavior; prevention-based thinking seeks to avoid the risk altogether. Its modern roots lie in public health and industrial hygiene.[11] The prevention principle is widely embraced but rarely implemented in a systematic fashion.[12] Even as a smattering of prevention-based regulatory programs are implemented in the United States and elsewhere,[13] debate continues over the place of prevention in conventional risk analysis.[14] The legal literature rarely addresses prevention's relationship to risk analysis.[15]

The second principle is *resilience*, which can be loosely defined as the capacity to respond to whatever does come to pass.[16] A resilient system absorbs a disturbance while maintaining its most critical functions and more quickly returns to optimal operation (or adapts well to the new normal).[17] While the concept of resilience has been around for centuries, in the twentieth century it took on particular significance in engineering, ecology and the natural sciences,

---

9 *See generally* Joel P. Hewett et al., *Human Health and Environmental Risks Posed by Synthetic Biology R&D for Energy Applications: A Literature Analysis*, 21 J. ABSA INT'L 177 (2016).
10 *See* W. Neil Adger et al., *Social-Ecological Resilience to Coastal Disasters*, 309 SCIENCE 1036, 1036 (2005).
11 *See* discussion *infra* Section II.A.
12 Timothy F. Malloy, *Principled Prevention*, 46 ARIZ. ST. L.J. 105, 109 (2014) [hereinafter Malloy, *Principled Prevention*].
13 *See* CAL CODE REGS. tit. 8, § 5189.1 (2017) (California regulations regarding refinery process safety); CAL CODE REGS. tit. 22, § 69501 (2013) (California Safer Consumer Products regulations); Commission Regulation 1907/2006, 2006 O.J. (L 396) 1 (chemicals directive for the European Union).
14 In 2014, the *Journal of Risk Research* published a special issue on the substitution principle. Ragnar Lofstedt, *The Substitution Principle in Chemical Regulation: A Constructive Critique*, 17 J. RISK RSCH. 543 (2014) and accompanying commentaries.
15 *But see* Malloy, *Principled Prevention*, *supra* note 12, at 111–17 (providing an overview of prevention in law).
16 *See* discussion *infra* Section II.B.
17 *See infra* Table 5.

medicine, and other disciplines.[18] Resilience has also made substantial inroads into the legal literature. Little of that work focuses explicitly on risk analysis, however.[19] At the risk of oversimplifying, the bulk of legal literature can be generally sorted into three broad categories:[20] resilience as a design principle for legal systems,[21] resilience as applied to natural resource management,[22] and

---

[18] *See* Jack Ahern, *From Fail-Safe to Safe-to-Fail: Sustainability and Resilience in the New Urban World*, 100 LANDSCAPE & URB. PLAN. 341, 341 (2011).

[19] Examples of legal scholarship on the topic include Marchant & Stevens, *supra* note 6, at 244. *See also* Craig, *supra* note 3, at 1863.

[20] The categories serve only as a rough organizational framework for a diverse set of articles. There is of course leakage between them, and a fair number of other articles scattered across other distinguishable topics. *See, e.g.*, Shalanda H. Baker, *Anti-Resilience: A Roadmap for Transformational Justice within the Energy System*, 54 HARV. CIV. RTS.-CIV. LIBERTIES L. REV. 1 (2019) (energy); Leigh Barton, Note, *Let It Burn: An Argument for an Adaptive Resilience Approach to Federal Wildfire Management in the Western United States*, 30 GEO. ENV'T L. REV. 695 (2018) (wildfire); Pierre de Vries, *The Resilience Principles: A Framework for New ICT Governance*, 9 J. ON TELECOMM. & HIGH TECH. L. 137 (2011) (information and communication technologies). Others engage with complexity theory and other resilience-related themes without explicitly invoking the concept of resilience. *See* Sara Gosman, *Planning for Failure: Pipelines, Risk, and the Energy Revolution*, 81 OHIO ST. L.J. 349 (2020); J.B. Ruhl, *Regulation by Adaptive Management—Is It Possible?*, 7 MINN. J.L. SCI. & TECH. 21 (2005); Donald T. Hornstein, *Complexity Theory, Adaptation, and Administrative Law*, 54 DUKE L.J. 913 (2005). For a detailed overview of legal scholarship on resilience up to 2014, see Tracy-Lynn Humby, *Law and Resilience: Mapping the Literature*, 4 SEATTLE J. ENV'T L. 85 (2014).

[21] *See, e.g.*, Robert L. Fischman, *Letting Go of Stability: Resilience and Environmental Law*, 94 IND. L.J. 689 (2019) (making the case for resilience as a guiding principle for environmental law); Brian C. Chaffin et al., *Transformative Environmental Governance*, 41 ANN. REV. ENV'T & RES. 399 (2016) (calling for new approach to environmental governance); Robin Kundis Craig, *Learning to Think About Complex Environmental Systems in Environmental and Natural Resource Law and Legal Scholarship: A Twenty-Year Retrospective*, 24 FORDHAM ENV'T L. REV. 87, 87–88, 102 (2013) (arguing that complexity theory and resilience theory provide strong theoretical foundations for environmental law and natural resources law); J.B. Ruhl, *Panarchy and the Law*, 17 ECOLOGY & SOC'Y 31 (2012) (applying panarchy theory to the design of legal systems); J.B. Ruhl, *General Design Principles for Resilience and Adaptive Capacity in Legal Systems—With Applications to Climate Change Adaptation*, 89 N.C. L. REV. 1373 (2011) [hereinafter Ruhl, *General Design*] (designing legal instruments and institutions to be resilient and adaptive); Donald T. Hornstein, *Resiliency, Adaptation, and the Upsides of Ex Post Lawmaking*, 89 N.C. L. REV. 1549 (2011) (resiliency of legal systems). Scholars from outside the legal academy have likewise addressed the linkage between law and resilience, most notably the ecologist C.S. Holling. *See* C.S. Holling & Lance H. Gunderson, *Resilience and Adaptive Cycles*, *in* PANARCHY: UNDERSTANDING TRANSFORMATIONS IN HUMAN AND NATURAL SYSTEMS 25 (Lance H. Gunderson & C.S. Holling eds., 2002).

[22] *See, e.g.*, Robin Kundis Craig, *Trickster Law: Promoting Resilience and Adaptive Governance by Allowing Other Perspectives on Natural Resource Management*, 9 ARIZ. J. ENV'T L. & POL'Y 140, 142–43 (2019) (application of resilience thinking to natural resources management); Ahjond S. Garmestani et al., *Can Law Foster Social-Ecological Resilience?*, 18 ECOLOGY & SOC'Y 37 (2013) (natural resource law and environmental policy); Robert W. Adler, *Resilience, Restoration, and Sustainability: Revisiting the Fundamental Principles of the Clean Water Act*, 32 WASH. U. J.L. & POL'Y 139 (2010) (water quality and restoration); Mary Jane Angelo, *Stumbling Toward Success: A Story of Adaptive Law and Ecological Resilience*, 87 NEB. L. REV. 950 (2009) (ecosystem protection and restoration); Sandra Zellmer & Lance Gunderson, *Why Resilience May Not Always Be a Good Thing: Lessons in Ecosystem*

resilience as applied to climate change mitigation and adaptation.[23] Over the last two decades, the peer-reviewed literature on risk analysis has begun to address resilience,[24] but the relationship of resilience to conventional risk analysis remains contested. Some commentators cast resilience as a supplement to conventional risk analysis or, in some cases, a replacement for it.[25] Many, but not all, reserve resilience for the type of complex situations discussed above, relegating other situations to conventional risk analysis.[26]

This Article will advance the legal and peer-reviewed literature in three ways. First, it will provide an integrated framework for risk analysis by weaving together principles of conventional risk analysis, prevention, and resilience. Today, the respective roles of the three are both confused and controversial. Confused in the sense that commentators often struggle to define the precise nature and scope of prevention and resilience and their respective relationships to risk analysis. Conventional risk analysis is clearly dominant, yet prevention and resilience already appear (albeit haphazardly) in various domains. Controversial in that the respective debates about the relative usefulness of prevention and resilience rage on. This Article will view the three as integrated concepts that should be used in concert to optimize the governance of threats. I will present a generalized framework for understanding the relationship among them and specifying how prevention and resilience can address the limits of conventional risk analysis.

Restoration from Glen Canyon and the Everglades, 87 NEB. L. REV. 893 (2009); Bradley C. Karkkainen, *Panarchy and Adaptive Change: Around the Loop and Back Again*, 7 MINN. J.L. SCI. & TECH. 59, 59, 61, 70–71 (2005) (natural resources management).

[23] *See, e.g.*, Peter Howard & Michael A. Livermore, *Sociopolitical Feedbacks and Climate Change*, 43 HARV. ENV'T L. REV. 119, 126, 165–66, 169, 174 (2019); Kelley Pettus, Note, *The First American Climate Refugees and the Need for Proactive Relocation*, 87 GEO. WASH. L. REV. 172, 190 (2019); Victor B. Flatt & Jeremy M. Tarr, *Adaptation, Legal Resiliency, and the U.S. Army Corps of Engineers: Managing Water Supply in a Climate-Altered World*, 89 N.C. L. REV. 1499, 1499 (2011); J.B. Ruhl, *Climate Change Adaptation and the Structural Transformation of Environmental Law*, 40 ENV'T L. 363 (2010).

[24] *See generally* Mary Warner et al., *From Probabilistic Risk Analysis to Resilience with Network Science: Lessons from the Literature and Best Practice*, *in* HANDBOOK ON RESILIENCE OF SOCIO-TECHNICAL SYSTEMS 99 (Matthias Ruth & Stefan Goessling-Reisemann eds., 2019); IGOR LINKOV & BENJAMIN D. TRUMP, THE SCIENCE AND PRACTICE OF RESILIENCE (2019); Ortwin Renn & Andreas Klinke, *Risk Governance and Resilience: New Approaches to Cope with Uncertainty and Ambiguity*, *in* RISK GOVERNANCE: THE ARTICULATION OF HAZARD, POLITICS AND ECOLOGY 19–20 (Urbano Fra.Paleo ed., 2015); Riana Steen & Terje Aven, *A Risk Perspective Suitable for Resilience Engineering*, 49 SAFETY SCI. 292 (2011). For early discussions of resilience in the field of risk analysis, see ORTWIN RENN, RISK GOVERNANCE: TOWARDS AN INTEGRATIVE APPROACH 46 (2005); T. Aven & V. Kristensen, *Perspectives on Risk: Review and Discussion of the Basis for Establishing a Unified and Holistic Approach*, 90 RELIABILITY ENG'G & SYS. SAFETY 1, 6 (2005); Denis Smith & Moira Fischbacher, *The Changing Nature of Risk and Risk Management: The Challenge of Borders, Uncertainty and Resilience*, 11 RISK MGMT. 1, 7–9 (2009).

[25] *See generally* Terje Aven, *The Call for a Shift from Risk to Resilience: What Does it Mean?*, 39 RISK ANALYSIS 1196 (2019); Renn & Klinke, *supra* note 24, at 3, 21; Park et al., *supra* note 5, at 357 (distinguishing between risk assessment and resilience).

[26] Renn & Klinke, *supra* note 24, at 2, 16.

Second, this Article will move from the conceptual to the practical by answering the question of "how." It will examine how the architecture of risk analysis—its structure, elements, and methodologies—must be changed so as to embrace prevention and resilience. Prevention and resilience inform aspects of risk assessment and risk mitigation that conventional risk analysis tends to ignore or assume away. To be sure, traces of prevention and resilience thinking exist in risk analysis efforts. For instance, prevention in the form of bans of products or processes sporadically occurs. Resilience in the shape of remediation or reclamation obligations occasionally surfaces. But there is much value to be gained by bringing prevention and resilience to the forefront.

Third, this Article will take on the question of "when"—when should risk managers rely upon the respective strategies of control, prevention, and/or resilience? In principle, one should select the optimal mix of strategies given the particular circumstances. Easier said than done. Comprehensive evaluation of diverse potential mitigation strategies can be costly (in terms of time and expense) and highly uncertain. This Article will offer general principles for selecting the optimal mix.

Following an overview of general risk analysis concepts, Part I will use three case studies to illustrate how risk analysis functions "on the ground." Building off those scenarios, it examines several common situations in which conventional risk analysis can fall short, namely when critical data regarding risk is missing, the natural or manmade system involved is complex, or there is significant indeterminacy regarding human behavior. Part II will turn to prevention and resilience, offering brief histories of their origins and summaries of their underlying precepts. Part III then will map prevention and resilience onto the conventional risk analysis framework, highlighting how integration of the three can resolve the problems of incomplete data, complexity, and indeterminacy. That Part will also survey how prevention and resilience fit into the four major elements of risk analysis: problem formulation, risk assessment, evaluation of mitigation options, and implementation.

I. RISK ANALYSIS: THEORY, PRACTICE AND LIMITATIONS

Risk analysis is a sophisticated and diverse discipline; its contours and details are beyond the reach of a single article. Thankfully, a granular view of risk analysis is not needed to understand its limitations or its relationship to prevention and resilience. What follows is a distillation of the essential features of risk analysis and an illustration of risk analysis as practiced in three brief case studies. This Part concludes by assessing several critical limitations of conventional risk analysis.

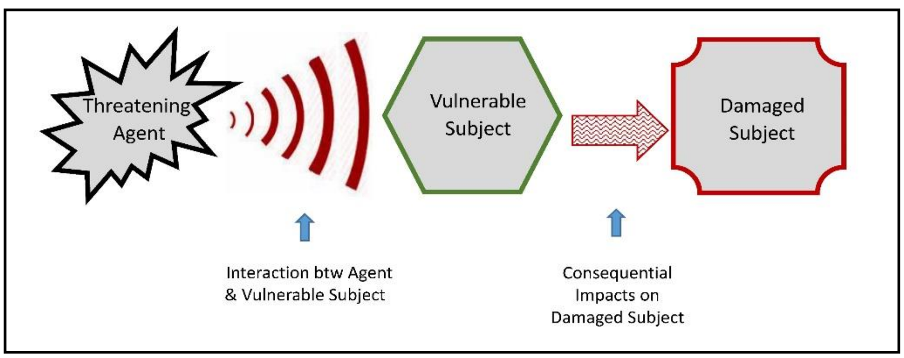
A. Risk Analysis Overview

Risk analysis is used in a variety of settings to assist in decision-making. In some cases, as in the evaluation of new chemicals or the design and operation of industrial facilities, it is used to identify and minimize unintended consequences of human activity. In others, it guides selection of measures to protect human communities from natural disasters; think here about flood control efforts. Unsurprisingly, risk analysis takes different forms depending upon the setting; risk analysis for nuclear power plant siting is decidedly different than that for new pesticide registration, which itself differs markedly from risk analysis of potential flood events.

Despite differences across domains, risk analysis in each setting has several common features. First, by definition, the focus is on risk. Risk is not simply a number, curve, or probability function. Rather, risk is the integrated response to three related questions: what can go wrong (*threat*)?, how likely is it to go wrong (*vulnerability*)?, and what are the results if it goes wrong (*consequences*)?[27] Although risk analysts frame this triplet of questions in diverse ways, all of these varied formulations aim to answer those three questions.

First, the risk triplet informs the basic organizing frame depicted in Figure 1, used throughout this Article to examine the relationship between control, prevention, and resilience. As illustrated in Figure 1, the typical scenario requiring risk analysis has three components: the thing or activity presenting the threat; the vulnerable individual, entity, or system being threatened; and the damaged subject. The threatening agent interacts with the vulnerable subject, which leads to adverse impacts upon the damaged subject.

FIGURE 1: THE RISK ANALYSIS FRAME



This frame can be used across a range of domains; Table 1 demonstrates its application to pesticide use, industrial facilities, and synthetic biology. I explore each of these scenarios in more detail below.

[27] Kaplan, *supra* note 6, at 408; *see also* U.S. ENV'T PROT. AGENCY, EPA/100/R-14/004, RISK ASSESSMENT FORUM WHITE PAPER: PROBABILISTIC RISK ASSESSMENT METHODS AND CASE STUDIES 40 (2014); Yacov Y. Haimes, *On the Definition of Vulnerabilities in Measuring Risks to Infrastructures*, 26 RISK ANALYSIS 293, 296 (2006).

TABLE 1: RISK SCENARIOS

Threatening Agent	Interaction	Vulnerable Subject	Impacts	Damaged Subject
Pesticide	Inhalation	Farmworker	Reproductive Toxicity Developmental Toxicity	Farmworker Farmworker's Child
Terrorist	Truck Bomb	Refinery H2F Tank	Toxic Cloud Release	Refinery Workers Nearby Residents
Synthetic Algae	Resource Competition Gene Transfer	Indigenous Algae	Extinction Ecosystem Disruption	Indigenous Algae Associated Ecosystem

Second, while contemporary risk analysis approaches vary somewhat in their details and vocabulary, risk analysis typically involves four primary elements: problem formulation, assessment, evaluation/selection of risk mitigation measures, and implementation.[28] Each of these elements consists of specific functional components, as indicated in Table 2. For ease of presentation and analysis, the elements are typically displayed in a linear, stepwise fashion. As I discuss further in Part III, the process is actually much more iterative.[29]

TABLE 2: THE ARCHITECTURE OF RISK ANALYSIS

Elements	Functional Components
Problem Formulation	Problem definition Identification of potential mitigation options
Assessment	Risk assessment
Evaluation/Selection	Evaluation and selection of potential risk mitigation measures
Implementation	Implementation of risk mitigation measures

While it goes by many names, problem formulation essentially serves a screening and prioritization function, identifying the particular problem(s) or

[28] *See* NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 11–13 (2009) [hereinafter NAT'L RSCH. COUNCIL, SILVER BOOK]; THE PRESIDENTIAL/CONG. COMM'N ON RISK ASSESSMENT AND RISK MGMT., FRAMEWORK FOR ENVIRONMENTAL HEALTH RISK MANAGEMENT, at i (1997) [hereinafter PCCRARM]; *Communication from the Commission on Consumer Health and Food Safety*, at 19, COM (97) 183 final (Apr. 30, 1997). Some definitions of risk analysis also include other steps, such as risk communication. *See, e.g.*, *id.*

[29] NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 81; PCCRARM, *supra* note 28, at 48.

risk(s) of concern for assessment.[30] Consider the scenarios set out in Table 1 above. For any given scenario, there is a fair amount of flexibility in identifying the relevant agents, subjects, and interactions. For example, the pesticide scenario above focuses on inhalation as the form of interaction, leaving out ingestion of contaminated ground water or pesticide residues on foods as possible interactions. The focus on air exposure might be driven by the nature of the threatening agent; some pesticide uses simply may not impact groundwater or leave residues on crops. Alternatively, the agency responsible for the analysis may have a limited mandate; an air quality regulatory agency is unlikely to focus on groundwater implications.

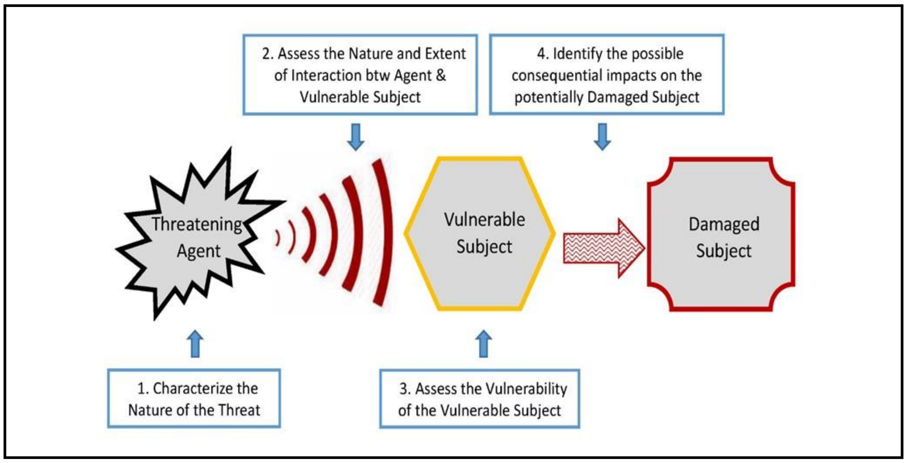
Problem formulation also involves identifying potential mitigation options for avoiding or minimizing the risk and associated adverse consequences.[31] Ultimately, risk analysis is a comparative exercise; in the assessment phase, the outcomes expected absent any intervention are typically compared to those occurring under a range of mitigation options. But which mitigation options are to be included in that comparison? That question is answered during problem formulation, setting initial boundaries for the scope of the subsequent steps of risk analysis.

Risk assessment picks up from there. Like problem formulation, risk assessment also means different things to different people, but generally speaking, it refers to an analytical process for characterizing the nature, extent, and consequences of risk. Risk assessment typically includes four basic steps, as illustrated in Figure 2: (1) identify the relevant threat, (2) assess the interaction between the threat and the vulnerable subject, (3) evaluate the extent of vulnerability, and (4) identify the potential consequences to the damaged subject.[32] As noted above, the risk assessment provides this information for the baseline scenario of no intervention and for the various mitigation option scenarios.

---

[30] NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 73–74 (discussing problem formulation and scoping).
[31] *Id.* at 11–12.
[32] *Id.* at 11.

FIGURE 2: RISK ASSESSMENT



A broad range of risk assessment methods exist, from qualitative to quantitative and from formal to informal. However, formal quantitative risk assessments generating numerical results tend to dominate in the literature and in prominent regulatory programs.[33] Performing a risk assessment typically requires specific training and expertise in a range of disciplines, although the particular disciplines will vary by context. For example, human-health risk assessment for chemical exposures may require, among other things, a toxicologist to assess hazard and characterize the risk and an environmental engineer or industrial hygienist to assess exposure.[34] Assessing the risks of explosion in a chemical plant calls for a team with somewhat different skills, such as process engineers, safety engineers, and operations personnel.[35]

The third step, evaluation of risk mitigation measures, faces an entirely different question than risk assessment: What should we do about the risk? As Figure 3 illustrates, in conventional risk analysis, risk mitigation focuses primarily upon control options, meaning those that block or reduce the interaction between the threatening agent and the vulnerable subject.[36]

---

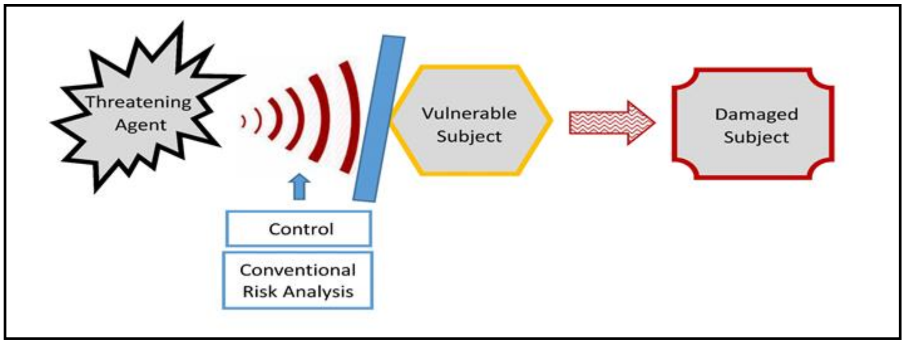
33 *See* Boyd, *supra* note 5; Terje Aven, *The Risk Concept—Historical and Recent Development Trends*, 99 RELIABILITY ENG'G & SYS. SAFETY 33, 42 (2012); NAT'L ACAD. OF SCIS., RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 18 (1983).

34 *See* Joel Tickner et al., *Alternatives Assessment: New Ideas, Frameworks and Policies*, 71 J. EPIDEMIOLOGY & CMTY. HEALTH 655, 655–56 (2017).

35 Paul Baybutt, *Analytical Methods in Process Safety Management and System Safety Engineering – Process Hazard Analysis*, *in* HANDBOOK OF LOSS PREVENTION ENGINEERING 501, 510–11 (Joel M. Haight ed., 2013); *see also* 29 C.F.R. § 1910.119(e)(4) (2013).

36 Malloy, *Principled Prevention*, *supra* note 12, at 112–13; Cora R. Roelofs et al., *Prevention Strategies in Industrial Hygiene: A Critical Literature Review*, 64 AIHA J. 62, 65–66 (2003).

FIGURE 3: CONVENTIONAL RISK MITIGATION



Looking at Figure 3, it appears that there are other potentially fruitful points for intervention. For example, why not intervene at the agent level, attempting to reduce the threat it presents? Or perhaps focus on the subject, reducing its vulnerability? In theory, a comprehensive risk analysis would consider these other points as well;[37] in practice, conventional risk analysis typically does not. Accordingly, this summary concentrates on control; more on other strategies later.

Crafting a control strategy typically involves two elements. The first is deciding how much interaction between the threatening agent and the vulnerable subject is acceptable. In many settings, this is done by specifying an acceptable level of residual risk—that is, the level of risk that society is willing to take on.[38] For example, when cleaning up a Superfund site, the Federal Environmental Protection Agency (EPA) protects people from increased cancer risk over their lifetimes.[39] Thus, a Superfund remediation is finished when exposure to the site presents an individual with a lifetime cancer risk of between one in ten thousand and one in one million.[40] In other settings, "safe enough" means applying an acceptable level of effort to reduce risk, rather than articulating a specific risk level.[41] Examples of level-of-effort approaches include identifying best available control technology to reduce air pollution[42] or reducing risk "as low as

[37] *See* RENN, *supra* note 24, at 41–44; PCCRARM, *supra* note 28, at 29–32.
[38] *See* Paul R. Hunter & Lorna Fewtrell, *Acceptable Risk*, *in* WATER QUALITY: GUIDELINES, STANDARDS AND HEALTH 207, 208–17 (Lorna Fewtrell & Jamie Bartram eds., 2001) (describing multiple approaches for defining "acceptable risk").
[39] Some readers may wonder why a Superfund cleanup would not be characterized as a repair, rather than a control, strategy. A reasonable point, but if one views the Superfund site itself (or the hazardous substances at it) as the threatening agent—as the underlying statute clearly does—then many cleanups are fairly viewed as involving control.
[40] 40 C.F.R. § 300.430(e)(2)(i)(A)(1,2) (2011). The federal Superfund program was established in 1980 to remediate sites at which hazardous substances have been released. *See* 42 U.S.C. § 9601. In any given case, the agency selects a specific acceptable risk within that range. The agency uses other methods to set acceptable risk levels for noncarcinogens. 40 C.F.R. § 300.430(e)(2)(i).
[41] As I illustrate in the pesticide case study below, in some cases, setting "safe enough" involves considering both risk and effort. *Infra*, Section I.B.1.
[42] 42 U.S.C. §§ 7412(b)(1), (d)(6), (g)(6)(A,B).

reasonably practicable."[43] In most cases, the acceptable level of risk or effort is then translated into an enforceable safety standard—the concentration of the hazardous substance left in the ground at the Superfund site or an air emission standard achievable using the best available technology, for example.

The second element of risk mitigation is choosing the means of attaining the safety standard. The means fall into two general categories: engineering controls and procedural controls.[44] Engineering controls use physical means to meet the safety standard, reducing or even completely barring interaction between the threatening agent and the vulnerable subject. Think here of things like add-on pollution control devices, such as baghouses, that capture particulate emissions; treatment units that purify industrial wastewater before discharge to a stream; or local area ventilation systems that suck toxic solvent vapors out of a workspace. Procedural controls, also called administrative controls, block or minimize interaction by influencing the behavior of the vulnerable subject. Examples include written standard operation procedures, checklists, and tagout protocols.[45]

B. The Case Studies

With this basic background in mind, I turn to three brief case studies to illustrate the varied forms that conventional risk analysis takes. The first case involves the registration of a new agricultural pesticide under California law, an approval process that is quite similar to the federal EPA's program. The second case concerns industrial facility safety and the federal process safety management program. The third examines risk analysis of synthetic biology used to create microbes for biofuel production.

1. Pesticide Registration

We all face pests—insects, worms, weeds, and rodents—from time to time. In agricultural operations, pesticides are a major tool for dealing with pests. A pesticide is a substance or mixture "of substances intended for preventing,

---

43 *Policy and Guidance on Reducing Risks as Low as Reasonably Practicable in Design*, U.K. HEALTH AND SAFETY EXEC., http://www.hse.gov.uk/managing/theory/alarp3.htm [perma.cc/6ED2-W3S8] (June 17, 2003); *see also* Edwards v. Nat'l Coal Bd. [1949] 1 All ER 743 (CA).

44 *See* Bruce K. Lyon & Georgi Popov, *Risk Treatment Strategies: Harmonizing the Hierarchy of Controls and Inherently Safer Design Concepts*, 64 PRO. SAFETY 34, 40 (2019). In the facility safety setting, engineering controls are broken into two categories: passive and active. Passive controls act on demand without the need for activation. Examples include pressure relief valves on a process unit that automatically release excess pressure to avoid an explosion. Active controls, such as an explosion suppression system that injects inert materials into a process to halt a reaction when a dangerous pressure increase is discovered, require detection and activation. Paul Amyotte et al., *Chemical Safety Board Investigation Reports and the Hierarchy of Controls: Round 2*, 37 PROCESS SAFETY PROGRESS 459, 463–64 (2018).

45 Lyon & Popov, *supra* note 44, at 38, 41.

destroying, repelling or mitigating any pest."[46] California has one of the most stringent pesticide regulation programs in the United States. Before a pesticide can be sold in California, its manufacturer must obtain approval—called "registration"—from California's Department of Pesticide Regulation (DPR).[47] The precise contours of the registration process are explicitly prescribed by several statutes.[48] Upon receiving a registration application, DPR staff scientists evaluate the scientific data concerning the efficacy of the product and the potential human health and environmental effects of its use. Drawing upon related federal rules,[49] DPR regulations require manufacturers to submit toxicity testing data for a specified set of adverse effects, such as acute toxicity, mutagenicity, and reproductive toxicity.[50] If DPR concludes that the product may present significant adverse health or environmental impacts, the agency must perform a risk assessment.[51]

On the basis of the risk assessment, DPR management considers potential mitigation approaches that could be used to keep exposure to acceptable levels. Typical mitigation requirements include buffer zones, limitations on the time or volume of pesticide use, and use of personal protective equipment, such as gloves, Tyvek clothing, or respirators. The mitigation measures are intended to protect the health of agricultural workers and of other individuals who live, work, or engage in activities nearby (sometimes called "bystanders"). If DPR management concludes that—taking into account the mitigation requirements—the pesticide meets the standards set out in the statute, it issues a proposed registration decision for public comment. After considering public comment, DPR management makes a final registration decision. The final mitigation requirements are issued as part of the approved label for the pesticide or in a separate regulation.[52]

2. *Industrial Facility Safety*

Shifts in the nature and course of environmental and safety regulations are often traced to catastrophic events or shocking discoveries.[53] Chemical safety at

---

[46] CAL. DEP'T PESTICIDE REGUL., A GUIDE TO PESTICIDE REGULATION IN CALIFORNIA 22 (2017) [hereinafter DPR, GUIDE], www.cdpr.ca.gov/docs/pressrls/dprguide/dprguide.pdf [perma.cc/4A8Z-AAN5].

[47] CAL. FOOD & AGRIC. CODE § 12811 (West 1996).

[48] Birth Defect Prevention Act of 1984, CAL. FOOD & AGRIC. CODE §§ 13121–13135 (1984) (addressing testing and registration); CAL. PUB. RES. CODE §§ 21000–21189.57 (West 2021) (requiring analysis of potential alternatives and evaluation of cumulative impacts).

[49] *See* 40 C.F.R. § 158.500 (2007) (setting out toxicology data requirements for federal registration).

[50] FOOD & AGRIC. § 12824 (general requirement to evaluate safety); CAL. CODE REGS. tit. 3, § 6159 (2021) (incorporating federal toxicology data requirements for meeting Section 12824 evaluation requirement); FOOD & AGRIC. § 13123 (mandatory health effects testing).

[51] FOOD & AGRIC. § 13134.

[52] DPR GUIDE, *supra* note 46, at 54–55. DPR classifies pesticides of particular concern as "restricted materials," which are subject to heightened requirements. *Id.* at 28.

[53] *See generally* David H. Sump, *The Oil Pollution Act of 1990: A Glance in the Rearview Mirror*, 85 TUL. L. REV. 1101 (2011) (recounting the impact of the Exxon Valdez spill on the

industrial plants had its own paradigm-shifting moment with the Bhopal tragedy in 1984, in which thousands died after an accident at the Union Carbide plant sent a toxic cloud of methyl isocyanate over the sleeping city.[54] Bhopal and other notorious industrial accidents contributed to the passage of a range of industrial-safety regulatory programs, including the Occupational Health and Safety Administration's (OSHA) process safety management (PSM) rule.[55] OSHA's PSM program requires certain industrial facilities to evaluate hazards associated with chemicals used in their processes and implement measures designed to minimize the risks and mitigate the effects of chemical releases.[56]

Unlike our first case study involving pesticide registration, in implementing its PSM rule, OSHA does not itself engage in risk analysis. Instead, the PSM rule is a form of meta-regulation, or "management-based regulation," which places that obligation on the regulated entity.[57] It requires certain facilities using or storing highly hazardous chemicals to establish comprehensive management programs aimed at preventing or minimizing the consequences of catastrophic releases.[58] Process safety management includes a wide range of elements; the process hazard analysis element—"a careful review of what could go wrong and what safeguards must be implemented to prevent releases of hazardous chemicals"—is most relevant here.[59]

The OSHA PSM regulations provide very general minimum requirements for process hazard analysis (PHA).[60] OSHA guidance documents set out some additional specifics, but essentially leave the details to facilities to work out in

---

passage of the Oil Pollution Act of 1990); David Stradling & Richard Stradling, *Perceptions of the Burning River: Deindustrialization and Cleveland's Cuyahoga Rive*r, 13 ENV'T HIST. 515, 518–19 (2008) (describing and questioning the narrative linking the 1969 Cuyahoga River fire to passage of the Clean Water Act); Timur Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 692–96 (1999) (discussing the role of Love Canal in enactment of Superfund).

54 RICHARD J. LAZARUS, THE MAKING OF ENVIRONMENTAL LAW 111 (2004); CHARLES PERROW, NORMAL ACCIDENTS: LIVING WITH HIGH-RISK TECHNOLOGIES 354–56 (1999).

55 NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., THE USE AND STORAGE OF METHYL ISOCYANATE (MIC) AT BAYER CROPSCIENCE 34–35 (2012) [hereinafter NAT'L RSCH. COUNCIL, BAYER]; Lisa A. Long, *History of Process Safety at OSHA*, 28 PROCESS SAFETY PROGRESS 128, 129 (2009).

56 29 C.F.R. § 1910.119 (2013).

57 *See* Charles Sabel et al., *Regulation Under Uncertainty: The Coevolution of Industry and Regulation*, 12 REGUL. & GOVERNANCE 371, 377 (2018) (defining meta-regulation); Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC'Y REV. 691, 691 (2003) (defining management-based regulation).

58 29 C.F.R. § 1910.119.

59 OCCUPATIONAL SAFETY AND HEALTH ADMIN., OSHA 3132, PROCESS SAFETY MANAGEMENT 5 (2000) [hereinafter OSHA 3132]. OSHA's PSM requirements include fourteen elements, including training, operating procedures, management of change, incident investigation, and emergency planning and response. 29 C.F.R § 1910.119(c)–(p). Other regulatory agencies and private organizations have developed similar PSM frameworks. *See* Paul R. Amyotte & Cathleen S. Lupien, *Elements of Process Safety Management*, *in* 1 METHODS IN CHEMICAL PROCESS SAFETY 87, 106–10, 115 (Faisal Khan ed., 2017).

60 29 C.F.R. § 1910.119(e) (describing the required focus of the PHA in general terms).

accordance with generally accepted industry practices.[61] Consistent with industry practice, many facilities structure their PHA in five phases, as described in Table 3.[62]

While the major focus of PHA is the assessment of risk, most approaches also expect the PHA team to make recommendations for safety improvements. Where the process risks are deemed unacceptable, recommendations provide strategies to reduce that risk. In developing recommendations, facilities follow a hierarchy of hazard control consisting of passive engineering controls, active engineering controls, and administrative controls in decreasing order of preference.

Administrative controls rely upon human action to direct or check engineered systems or human performance, such as inspections, operator responses to process deviations, and emergency response procedures. Engineering controls are equipment or systems designed to "maintain a process within safe operating limits, to safely shut it down in the event of a process upset, or to reduce human exposure to the effects of an upset."[63] Passive engineering controls provide protection without the need for automatic or manual activation; think here of dikes and berms or pressure relief valves. Active engineering controls require activation. Examples include a sprinkler system triggered by a heat or smoke sensor or a dust suppression system activated by a pressure sensor.

3. *Algae*

Synthetic biology is an emerging technology enabling the intentional, direct engineering of organisms to create novel or altered traits. It relies upon the synthesis or modification of DNA and associated genetic material using standardized and automated processes.[64] As the National Academy of Science observed, "engineering principles are applied to reduce genetics into DNA 'parts' so that those parts can be understood in isolation and reassembled into new biological parts, devices, and whole systems to build desired functions in living cells."[65] As with many new key enabling technologies, forecasts of the societal benefits of synthetic biology tend to be ebullient,[66] and acknowledgement of the potential

---

61 *See* OSHA 3132, *supra* note 59, at 9–11; OCCUPATIONAL SAFETY AND HEALTH ADMIN., OSHA 3133, PROCESS SAFETY MANAGEMENT GUIDELINES FOR COMPLIANCE 5–14 (1994) [hereinafter OSHA 3133].

62 Baybutt, *supra* note 35, at 502; NAT'L RSCH. COUNCIL, BAYER, *supra* note 55, at 132; CTR. FOR CHEM. PROCESS SAFETY, GUIDELINES FOR HAZARD EVALUATION PROCEDURES 17–18 (3d ed. 2008) [hereinafter CCPS, GUIDELINES].

63 CCPS, GUIDELINES, *supra* note 62, at xxiii.

64 Kent H. Redford et al., *Synthetic Biology and Conservation of Nature: Wicked Problems and Wicked Solutions*, 11 PLOS BIOLOGY 1 (2013).

65 NAT'L ACADS. OF SCIS., ENG'G, & MED., PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY 30 (2017) [hereinafter NAT'L ACADS., PREPARING].

66 *See* OFF. OF SCI. AND TECH. POL'Y, NATIONAL BIOECONOMY BLUEPRINT 15 (2012) [hereinafter OSTP] (noting that synthetic biology "holds vast potential for the bioeconomy, as engineered organisms could dramatically transform modern practices in high-impact fields such as agriculture, manufacturing, energy generation, and medicine"); James Collins, *Bits and*

health and environmental impacts is customary.[67] This case study uses the example of microalgae biofuel production to examine risk analysis in the context of synthetic biology.

Using engineered microalgae to produce "fourth generation" biofuel is one particularly promising near-term application of synthetic biology.[68] The three prior generations of biofuel production—processes using food crops, low-cost crops and agricultural residues, and seaweed and algae biomass as feedstock, respectively—suffer from issues regarding product performance, economic viability, and environmental sustainability. Fourth generation biofuel production aims to avoid or minimize those problems by tailoring the microalgae to the specific needs of the process.[69] Synthetic biology techniques would be used to alter or enhance a range of the organisms' traits, including photosynthetic efficiency, growth rate, resistance to pathogens, and increased lipid (oil) accumulation.[70]

Large-scale commercial production of biofuels from engineered microalgae requires the cultivation of large quantities of algae biomass. Cultivation typically occurs in open, outdoor circular ponds in which the algal broth is continuously circulated with a paddle wheel. The alternative method of closed photo-bioreactors (which circulate the broth through a system of transparent tubes) provides greater control over cultivation, but its use is more limited due to cost and energy demand.[71]

Pieces Come to Life: Scientists Are Combining Biology and Engineering to Change the World, 483 NATURE S8, S10 (2012) ("Many of the major global problems, such as famine, disease and energy shortages, have potential solutions in the world of engineered cells.").

67 *See* OSTP, *supra* note 66, at 4 (noting the importance of regulation but observing that when regulations "are not carefully crafted or become outdated, however, they can become barriers to innovation and market expansion and discourage investment"); NAT'L ACADS., PREPARING, *supra* note 65, at 10 ("The bioeconomy is growing rapidly and the U.S. regulatory system needs to provide a balanced approach for consideration of the many competing interests in the face of this expansion.").

68 Sheeja Jagadevan et al., *Recent Developments in Synthetic Biology and Metabolic Engineering in Microalgae Towards Biofuel Production*, 11 BIOTECHNOLOGY FOR BIOFUELS 1, 2 (2018); Deborah Scott et al., *Potential Positive and Negative Impacts of Components, Organisms and Products Resulting from Synthetic Biology Techniques on The Conservation and Sustainable Use of Biodiversity, and Associated Social, Economic and Cultural Considerations*, *in* SYNTHETIC BIOLOGY 5, 26 (Secretariat of the Convention on Biological Diversity, Technical Ser. No. 82, 2015).

69 *See* Jagadevan et al., *supra* note 68, at 2–6; Shashi Kumar, *GM Algae for Biofuel Production: Biosafety and Risk Assessment*, 9 COLLECTION BIOSAFETY REVS. 52, 55–56 (2015).

70 Ashmita Ghosh et al., *Progress Toward Isolation of Strains and Genetically Engineered Strains of Microalgae for Production of Biofuel and Other Value Added Chemicals: A Review*, 113 ENERGY CONVERSION & MGMT. 104, 108, 111, 114 (2016); Kumar, supra note 69, at 57–58; D. Ryan Georgianna & Stephen P. Mayfield, *Exploiting Diversity and Synthetic Biology for the Production of Algal Biofuels*, 488 NATURE 329, 329 (2012).

71 Christina E. Canter et al., *Large-Scale Cultivation of Microalgae for Fuel*, *in* PROCESS DESIGN STRATEGIES FOR BIOMASS CONVERSION SYSTEMS 135, 140–41 (Denny K. S. Ng. et al. eds., 2015); Kumar, *supra* note 69, at 56, 61; Raphael Slade & Ausilio Bauen, *Micro-algae Cultivation for Biofuels: Cost, Energy Balance, Environmental Impacts and Future Prospects*, 53 BIOMASS & BIOENERGY 29, 30 (2013).

Operation of an algal biorefinery using genetically engineered microalgae as input raises significant environmental and ecological concerns,[72] many of which begin with the unplanned releases. That release might occur when microalgae are carried away from an open pond by wind, birds, or other vehicles. Or, the pond or bioreactor may be compromised by an earthquake, flood, or other disaster.[73] Whatever the cause, two resulting scenarios in particular stand out. First, the microalgae's engineered DNA could find its way into the native algae species' genome or even other wild organisms, a phenomenon known as horizontal gene transfer.[74] For example, engineered microalgae often contain "marker" genes, such as genes coding for antibiotic resistance, added to facilitate the engineering and cultivation processes.[75] Transfer of that gene beyond the engineered microalgae could exacerbate the existing public health challenges presented by antibiotic resistance caused by other factors. Second, the value-added traits of the engineered microalgae may give it a competitive advantage over the native species, fundamentally altering the structure of the ecosystem through a loss of genetic diversity or unintended spread of undesirable phenotypic traits.[76]

The EPA regulates the development and use of engineered microalgae for biofuel production as part of its new chemicals review program under the Toxic Substances Control Act.[77] That statute provides for pre-market review of new chemicals by the EPA; anyone proposing to manufacture, import, or process microorganisms for commercial purposes must submit a Microbial Commercial Activity Notice (MCAN) to the EPA.[78] Commercial activity may not begin until a ninety-day period for EPA review has expired. During that review period, the agency must determine whether the microorganism presents an "unreasonable risk."[79] Table 4 describes the EPA's risk assessment process for 90-day reviews of MCANs. If the agency concludes that the organism is unlikely to present an unreasonable risk under the intended or reasonably foreseeable conditions of use, production can begin. If instead the EPA determines that the microorganism may present an unreasonable risk or that knowledge gaps prevent a reasoned

---

[72] Scott et al., *supra* note 68, at 31–33; David J. Glass, *Government Regulation of the Uses of Genetically Modified Algae and Other Microorganisms in Biofuel and Bio-Based Chemical Production*, *in* ALGAL BIOREFINERIES 23, 26–30 (Ales Prokop et al. eds., 2015).
[73] *See* Kumar, *supra* note 69, at 60; Allison A. Snow & Val H. Smith, *Genetically Engineered Algae for Biofuels: A Key Role for Ecologists*, 62 BIOSCIENCE 765, 765–66 (2012).
[74] Kumar, *supra* note 69, at 61; Glass, *supra* note 72, at 28.
[75] Monika Hlavova et al., *Improving Microalgae for Biotechnology—From Genetics to Synthetic Biology*, 33 BIOTECHNOLOGY ADVANCES 1194, 1196, 1199 (2015).
[76] Scott et al., *supra* note 68, at 10; Snow & Smith, *supra* note 73, at 766–67.
[77] *See generally* Toxic Substances Control Act, 15 U.S.C. §§ 2601–09; ENV'T PROT. AGENCY, DRAFT ALGAE GUIDANCE FOR THE PREPARATION OF TSCA BIOTECHNOLOGY SUBMISSIONS 1 (2016) [hereinafter EPA, ALGAE GUIDANCE].
[78] 40 C.F.R. § 725.100 (1997).
[79] 15 U.S.C. § 2604 (a)(3)(A).

evaluation of the risks, the EPA must issue a regulation or administrative order protecting against potential risks.[80]

TABLE 3: RISK ASSESSMENT PROCESSES

Phase	Pesticides: DPR	Facility Safety: OSHA	Synthetic Biology: EPA
Characterization of the Threat	**Hazard Identification:** Identifies the range of adverse effects by evaluating human data and animal testing. Human information tends to be sparse; most emphasis is placed upon in vitro animal testing.	**Hazard Identification:** Involves detecting hazards associated with the process in question, including scenarios such as fires, explosions, releases of toxic chemicals, and spills. The PHA team will choose from a range of methods depending upon the complexity of the process, the experience and training of the team members, and other factors.[81]	**Hazard Identification:** Begins with genetically engineered material (GEM) characterization,[82] followed by (1) a "Construct Hazard Analysis" to identify hazards associated with the engineered modifications, including horizontal gene transfer, (2) a Human Health Hazard Assessment, and (3) an Ecological Hazard Assessment. The EPA evaluates human health and ecological hazard qualitatively and, when data is available, quantitatively.[83]
Assessment of Interaction	**Exposure Assessment:** Uses data about the physical and chemical characteristics of the pesticide, along with field studies and computer modeling, to predict levels of the pesticide that individuals will	**Consequence Likelihood Assessment:** Estimates the likelihood that the relevant scenarios will occur. Typically, the estimate will be based on the team members' experience and, where available, failure rates at the plant and in the	**Engineering and Exposure Assessments:** The engineering assessment identifies *how*, under the reasonably foreseen conditions of use, the GEM could reach workers or the environment during manufacturing and in field

[80] 15 U.S.C. § 2604(e) (regarding a finding of insufficient information); § 2604(f) (regarding a finding of unreasonable risk). EPA action on insufficient information is limited to issuance of administrative orders pending submission of the information. In the event of a finding that the microorganism presents an unreasonable risk, the agency may issue an order or regulation.

[81] All the methods aim to identify the sequence of events by which an "initiating event" (or what we might call a "cause") could result in an actual incident. Initiating events are generally equipment or software failures, human errors, and external events. CCPS, GUIDELINES, *supra* note 62, at 20. Some methods are inductive, identifying initiating events through brainstorming, "what-if" analyses, standard checklists, or other means and tracking them forward as they progress to adverse impacts. Others, such as Fault Tree Analysis, are deductive in that they begin with a consequence of concern and trace back through the chain of events to the initiating event. *Id.* at 212–13; Baybutt, *supra* note 35, at 545–46, 548–49. For useful summaries of the various common methods, see OSHA 3133, *supra* note 61, at 30–32. *See generally* CHARLES YOE, PRINCIPLES OF RISK ANALYSIS: DECISION MAKING UNDER UNCERTAINTY 273 (2019).

[82] EPA, ALGAE GUIDANCE, *supra* note 77, at 1–2, 4 (including verification of the taxonomy of the GEM and analysis of its genetic construction).

[83] ENV'T PROT. AGENCY, POINTS TO CONSIDER WHEN PREPARING TSCA NEW CHEMICAL NOTIFICATIONS 12–13 (2018) [hereinafter EPA, POINTS TO CONSIDER]. Hazard is scored on a qualitative three-point scale ranging from "low" to "high." *Id.* Chemicals having a low hazard score and a production volume below 100,000 kg per year are typically dropped from further review.

Phase	Pesticides: DPR	Facility Safety: OSHA	Synthetic Biology: EPA
	inhale, ingest, or absorb through their skin.[84]	industry generally.[85] Likelihood is commonly expressed using an order-of-magnitude scale (e.g., once per century, decade, year, and so on).[86]	applications. Based on the engineering assessment, an exposure assessment focuses on environmental and human exposure.[87]
Assessment of Vulnerability	**Dose-Response Assessment:** Identifies the quantitative relationship between the dose (i.e., the amount of chemical a person is exposed to) and the expected toxic effect.[88]	**Consequence Severity Assessment:** Consequences are defined as "the direct impact of the hazard scenario in terms of its effects on *receptors* such as people, the environment, property, or equipment, the process, the company, and so on."[89] Methods for establishing the severity of consequences vary widely, ranging from qualitative approaches relying upon the collective experience and judgment of the PHA team members to sophisticated, complex quantitative methods.[90]	
Identification of Consequential Impacts	**Risk Characterization:** Essentially, integrates the analysis and conclusions of the prior phases. Generally speaking, the agency determines whether expected level of exposure (as estimated in the exposure assessment) will exceed the acceptable level	**Risk Characterization:** Integrates the prior assessments of the severity and likelihood of the potential consequences.[91] Again, approaches to risk characterization vary along the qualitative/quantitative range, but most PHAs use a qualitative or semi-quantitative approach.[92]	**Risk Characterization:** Integrates the hazard and exposure assessments, categorizing the GEM as either (1) not presenting an unreasonable risk and thus dropped from further review; (2) presenting an unreasonable risk but for which risk management decisions can be made

[84] DPR, GUIDE, *supra* note 46, at 47–50. The agency considers fate and transport of the pesticide, meaning how the material may travel through the air, water, and other media to reach individuals. *Id.* at 49–50. It also predicts how much of the material will enter the individual's body, taking into account the physical and behavioral characteristics of that person. *Id.* at 49. For example, the agency will typically generate specific exposure levels for workers and children and adult bystanders. *Id.*

[85] Baybutt, *supra* note 35, at 529–30; CCPS, GUIDELINES, *supra* note 62, at 217–18.

[86] CCPS, GUIDELINES, *supra* note 62, at 217–18. Some facilities may use quantitative methods for certain processes, particularly those that could give rise to catastrophic consequences. Baybutt, *supra* note 35, at 530; YOE, *supra* note 81, at 114.

[87] EPA, ALGAE GUIDANCE, *supra* note 77, at 5.

[88] DPR, GUIDE, *supra* note 46, at 47.

[89] Baybutt, *supra* note 35, at 502.

[90] CCPS, GUIDELINES, *supra* note 62, at 215; YOE, *supra* note 81, at 112. Many methods make use of an impact severity scale or other metric to categorize consequences and their impacts. Baybutt, *supra* note 35, at 503–04; CCPS, GUIDELINES, *supra* note 62, at 215.

[91] YOE, *supra* note 81, at 119; CCPS, GUIDELINES, *supra* note 62, at 220.

[92] CCPS, GUIDELINES, *supra* note 62, at 220–21. Quantitative methods include Layer of Protection Analysis (a simplified form of quantitative risk characterization) and more comprehensive Chemical Process Quantitative Risk Analysis. *See id.* at 223–30 (LOPA); CNTR. FOR CHEM. PROCESS SAFETY, GUIDELINES FOR CHEMICAL PROCESS QUANTITATIVE RISK ANALYSIS 395–451 (2000) (quantitative methods).

Phase	Pesticides: DPR	Facility Safety: OSHA	Synthetic Biology: EPA
	(based upon the dose response assessment.) The risk characterization also describes uncertainties present and explains the assumptions made or adjustments adopted to address those uncertainties.		without additional review; or (3) presenting an unreasonable risk that requires additional risk characterization.[93]

C. Limitations of Conventional Risk Analysis

This Section identifies limitations of conventional risk analysis as practiced in the case studies, limitations that have given rise to dissatisfaction and calls for reform.[94] By *conventional* risk analysis, I refer to risk analysis as it is actually practiced "on the ground." As previously noted, the notion of risk analysis takes many forms, and indeed, many of the major theoretical articulations of it and related concepts address the limitations discussed below.[95] But it is no answer to the continuing deficiencies in the practice of risk analysis to say that theories of risk analysis are on the job.

1. Data Availability

Risk analysis typically requires a significant amount of data. Data about hazards, about the likelihood and scope of the interactions, about the ultimate consequences, and more. This data is needed for all aspects of risk analysis. Consider the pesticide case study. Problem formulation calls for data to determine which of the dozens of potential toxicological endpoints the risk assessment should consider, and which of the multiple potential vulnerable subjects to focus upon.[96] The risk assessment itself relies heavily upon experimental and empirical data regarding toxicity and exposure drawn from in vitro analyses, animal testing, and epidemiological studies, as well as fate and transport analyses and modeling.[97]

---

[93] ENV'T PROT. AGENCY, CHEMISTRY ASSISTANCE MANUAL FOR PREMANUFACTURE NOTIFICATION SUBMITTERS 35 (1997); EPA, POINTS TO CONSIDER, *supra* note 83, at 34 (stating the third category is sent on to "Standard Review," during which the EPA performs a more in-depth evaluation, usually including newly available information provided by the manufacturer).

[94] Malloy, *Principled Prevention*, *supra* note 12, at 131–35.

[95] *See* ORTWIN RENN, INT'L RISK GOVERNANCE COUNCIL, RISK GOVERNANCE: TOWARDS AN INTEGRATIVE APPROACH 36–37, 39–41 (2006) (setting out an extensive methodology for identifying, assessing, and responding to risk, broadly defined); PCCRARM, *supra* note 28, at 3 (describing an integrated set of steps for comprehensive risk assessment and management).

[96] DPR, GUIDE, *supra* note 46, at 46–49; NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 77–79.

[97] *See* RISK ASSESSMENT OF CHEMICALS: AN INTRODUCTION 235–37 (C.J. van Leeuwen & T.G. Vermeire eds., 2d ed. 2007) (stating not all risk assessment leads to quantification of risk. Depending upon the needs of the decisionmaker and the availability of data, a qualitative

To varying degrees and for sundry reasons, that data may be unavailable at the time the decision is being made.

One major impediment to data availability is cost in terms of dollars and resources. Toxicity testing in the pesticide registration setting is illustrative. Depending upon the endpoint in question, testing can run from several thousand to more than a million dollars and sacrifice hundreds to thousands of animals, as seen in Table 4, below. California's program calls for testing for almost thirty human and ecological endpoints.[98] Pesticide manufacturers (and in some cases, regulators as well) seek to minimize costly or time-consuming testing requirements. They may rely on existing testing results in the academic literature or produced for other purposes, even where the test methods or data quality fail to meet the formal regulatory standards. Or, they may take advantage—rightly or wrongly—of exemptions from testing in the agency's regulations or informal practices.[99]

TABLE 4: SELECTED TOXICITY TESTING COSTS[100]

Endpoint	Animal (Number used)	Cost
Acute Toxicity	Rat (40)	$ 18,000
Fish Early Life Stage Toxicity	Rainbow Trout (480)	$ 73,000
Reproductive Toxicity (across 2 generations)	Rat (2600)	$ 420,000
Carcinogenicity	Mouse (400)	$1,675,000

In other instances, data gaps may result from a lack of technical or scientific capacity rather than economics. It may be that existing testing methods or analytic approaches cannot produce the desired data. Take the case of emerging technologies such as engineered nanomaterials, defined as materials with one or more dimensions at a size range of approximately one to one hundred nanometers.[101] Nanomaterials, such as carbon nanotubes, quantum dots, and fullerenes, exhibit unique chemical and physical properties, enabling often-astounding socially beneficial advances in materials engineering, electronics, medicine, and

assessment of the risk may be sufficient.); *see also* David M. Zalk & Deborah Imel Nelson, *History and Evolution of Control Banding: A Review*, 5 J. OCCUPATIONAL & ENV'T HYGIENE 330, 332–33 (2008) (describing qualitative methods of risk assessment used in industrial hygiene settings).

98 Kristie Sullivan et al., *A Discussion of the Impact of US Chemical Regulation Legislation on the Field of Toxicity Testing*, 25 TOXICOLOGY IN VITRO 1231, 1233 (2011).

99 *See* JOHN FROINES ET AL., RISK AND DECISION: EVALUATING PESTICIDE APPROVAL IN CALIFORNIA 10–11 (2013) (discussing efforts to avoid testing requirement for neurodevelopmental toxicity in the registration of methyl iodide).

100 STEPHANIE SUAZO, ENV'T PROT. AGENCY, ECONOMIC ANALYSIS OF EXPEDITED NEW USE RULE FOR FIFTEEN CHEMICAL SUBSTANCES, at D-3 (2013); Sullivan et al., *supra* note 98, at 1233.

101 ENV'T PROT. AGENCY, WORKING GUIDANCE ON EPA'S SECTION 8(A) INFORMATION GATHERING RULE ON NANOMATERIALS IN COMMERCE 1 (2017).

other areas.[102] Yet these same qualities made it difficult to use standard testing methods on those materials. Nanomaterials do not disperse in solution or move through biological systems as expected; they confounded well-established assays. For years, toxicologists and exposure scientists faced significant challenges in assessing the toxicity and fate and transport of numerous nanomaterials.[103] Over time, science caught up, and toxicity testing methods, environmental monitoring, and dispersion modeling adapted to the new nano-reality.[104] But in the meantime, risk analysts faced decisions with a paucity of data.

2. *Ignorance and Complexity*

Conventional risk analysis depends upon risk assessment to predict consequences of actions or events with some level of certainty (or uncertainty).[105] Will a process unit rupture during normal operations? Would a farmworker wearing a respirator suffer ill effects from a fumigant pesticide? Will an escaped strain of genetically engineered green algae flourish in a lake? Risk assessment is designed to answer these sorts of questions, but the answers typically will be subject to some uncertainty. For our purposes, uncertainty means the degree to which a calculated value or expected outcome may differ from the actual value or outcome.[106] Uncertainty can result from a range of factors, such as limited information requiring use of estimation or default assumptions, measurement difficulties and human error, or incomplete or mistaken understanding of how a system (e.g., an ecosystem or market) operates.[107]

---

[102] Andrew D. Maynard, *Nanotechnology: The Next Big Thing, or Much Ado About Nothing?*, 51 ANN. OCCUPATIONAL HYGIENE 1, 2–3 (2007).

[103] Georgia Miller & Fern Wickson, *Risk Analysis of Nanomaterials: Exposing Nanotechnology's Naked Emperor*, 32 REV. POL'Y RSCH. 485, 497–98 (2015); Elijah J. Petersen et al., *Adapting OECD Aquatic Toxicity Tests for Use with Manufactured Nanomaterials: Key Issues and Consensus Recommendations*, 49 ENV'T SCI. & TECH. 9532, 9533, 9535 (2015); Rina Guadagnini et al., *Toxicity Screenings of Nanomaterials: Challenges Due to Interference with Assay Processes and Components of Classic In Vitro Tests*, 9 NANOTOXICOLOGY 13, 14 (2013).

[104] Petersen et al., *supra* note 103, at 9536–37. *But see* Miller & Wickson, *supra* note 103, at 487 (arguing that even in 2015, risk assessment for nanomaterials is ineffective "both because of the overarching deficiencies of risk analysis but also because of the specific barriers to performing reliable risk analysis for nanomaterials").

[105] RISK ASSESSMENT OF CHEMICALS, *supra* note 97, at 21–23; *see also* Adam M. Finkel & George Gray, *Taking the Reins: How Regulatory Decision-Makers Can Stop Being Hijacked by Uncertainty*, 38 ENV'T SYS. & DECISIONS 230, 231–32 (2018) (describing advanced methods for quantitative uncertainty analysis in risk assessment).

[106] NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 97; SOC'Y FOR RISK ANALYSIS, SOCIETY FOR RISK ANALYSIS GLOSSARY 4 (2018).

[107] *See* RISK ASSESSMENT OF CHEMICALS, *supra* note 97, at 22; *see also* GLEN W. SUTER II, ECOLOGICAL RISK ASSESSMENT 70 (2d ed. 2007).

Sometimes, uncertainty can be reduced or eliminated by collecting more information.[108] Resolving uncertainty in this way can be impractical due to time, cost, and methodological constraints, so risk analysts often use other methods to address uncertainties or even simply describe them to decision-makers. At the most basic level, default values or assumptions can be used to fill in gaps in knowledge. In human-health risk assessment, toxicity testing on rats is used to draw conclusions regarding certain potential effects in humans, but the variation between the two species is uncertain. Toxicologists commonly apply a default assessment factor of ten to account for the expected greater sensitivity of humans to toxins.[109] Other, more sophisticated techniques, including sensitivity analysis and quantitative uncertainty analysis, may be used to describe the level of uncertainty, permitting risk managers to take uncertainty explicitly into account in crafting and evaluating mitigation options.[110]

Yet all of these approaches for dealing with uncertainty—default assumptions, qualitative methods, and quantitative uncertainty analysis—presume that the risk analyst has a fairly complete understanding of the set of potential threats, interactions, and impacts involved. Where that understanding is absent, uncertainty is eclipsed by ignorance,[111] and conventional risk analysis is hobbled.[112]

---

[108] YOE, *supra* note 81, at 34 (describing epistemic or knowledge uncertainty and distinguishing it from variability (or aleatory uncertainty), which reflects "the inherent variability in the physical world"); RISK ASSESSMENT OF CHEMICALS, *supra* note 97, at 21.

[109] *See* RISK ASSESSMENT OF CHEMICALS, *supra* note 97, at 266–67; YOE, *supra* note 81, at 14–15.

[110] Finkel & Gray, *supra* note 105, at 230–32; Julie Shortridge et al., *Risk Assessment Under Deep Uncertainty: A Methodological Comparison*, 159 RELIABILITY ENG'G & SYS. SAFETY 12, 12, 14–16 (2017) (evaluating qualitative uncertainty factors, probability bounds, and robust decision-making); NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 99–104 (describing techniques for uncertainty analysis); RISK ASSESSMENT OF CHEMICALS, *supra* note 97, at 23.

[111] Andy Stirling & David Gee, *Science, Precaution, and Practice*, 117 PUB. HEALTH REPS. 521, 524–25 (2002) (using the broad term "incertitude," which included risk, uncertainty, ambiguity, and ignorance); Robin M. Hogarth & Howard Kunreuther, *Decision Making Under Ignorance: Arguing with Yourself*, 10 J. RISK & UNCERTAINTY 15, 16 (1995). Other formulations that capture the same concepts but use slightly different definitions exist. *See, e.g.*, Andreas Klinke & Ortwin Renn, *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies*, 22 RISK ANALYSIS 1071, 1079–80 (2002) (describing uncertainty as including variability, systematic and random measurement errors, indeterminacy, and lack of knowledge (ignorance of relevant variables or information)); William D. Rowe, *Understanding Uncertainty*, 14 RISK ANALYSIS 743, 745–48 (1994) (discussing metrical, structural, temporal, and translational uncertainty).

[112] Timothy Malloy et al., *Risk-Based and Prevention-Based Governance for Emerging Materials*, 50 ENV'T SCI. & TECH. 6822, 6822 (2016); Stirling & Gee, *supra* note 111, at 525–26. *But see* T. Aven & R. Steen, *The Concept of Ignorance in Risk Assessment and Risk Management Context*, 95 RELIABILITY ENG'G & SYS. SAFETY 1117, 1117, 1121 (2010) (arguing that risk assessment could still be used for describing uncertainties and would be useful in "defining appropriate management policies and strategies"). The story of the regulatory response to endocrine disrupting chemicals (EDCs) likewise provides a stark example of the frustrating effects of ignorance on conventional risk analysis. Nina Honkela et al., *Coming to Grips with*

Ignorance is present where the analyst lacks knowledge about the nature of the threat, the form of the interactions, and the potential associated impacts.[113] Risk analysts regularly face ignorance when dealing with complex adaptive systems.[114] A complex adaptive system consists of a set of interconnected units or entities organized into a collective whole that uses information, generates (sometimes unpredictable) patterns and behaviors, and learns or evolves.[115] We are surrounded by and immersed in ecological, social, and technical complex systems, including the communities in which we live, the legal systems we work within and write about, the intermodal transportation systems we use to move about, and more.[116]

Complex adaptive systems have certain attributes that distinguish them from merely complicated systems.[117] Three are of particular relevance here: network connectivity, nonlinearity, and emergence. The various parts of a complex system are networked together with feedback loops through which resources and information flow, allowing the system to continuously respond to changes in

---

Scientific Ignorance in the Governance of Endocrine Disrupting Chemicals and Nanoparticles, 38 ENV'T SCI. & POL'Y 154, 158 (2014). The significant ignorance of the mechanisms by which EDCs operate within the body and the breadth of the physiological and behavioral consequences has undermined the usefulness of conventional risk assessment methods. Vivian Futran Fuhrman et al., *Why Endocrine Disrupting Chemicals (EDCs) Challenge Traditional Risk Assessment and How to Respond*, 286 J. HAZARDOUS MATERIALS 589, 591 (2015) (concluding that "detailed, systematic, standardized risk assessment paradigm for EDCs has not been established").

113 Stirling & Gee, *supra* note 111, at 525–26; Renn & Klinke, *supra* note 24, at 2, 5. Sterling and Gee group ignorance together with risk, uncertainty, and ambiguity as forms of "incertitude." For them, ambiguity exists where there is sufficient knowledge to assess some types of impacts, but other potential impacts are poorly defined. For other definitions of ignorance, see Aven & Steen, *supra* note 112, at 1118–19.

114 *See generally* DONELLA H. MEADOWS, THINKING IN SYSTEMS: A PRIMER 35–72 (Diana Wright ed., 2008) (providing an overview of different types of complex systems).

115 MELANIE MITCHELL, COMPLEXITY: A GUIDED TOUR 4 (2009).

> A system is a set of things—people, cells, molecules, or whatever—interconnected in such a way that they produce their own pattern of behavior over time. The system may be buffeted, constricted, triggered, or driven by outside forces. But the system's response to these forces is characteristic of itself, and that response is seldom simple in the real world.

MEADOWS, *supra* note 114, at 2. Definitions of complexity and complex systems are legion. Quantum physicist Seth Lloyd counted at least forty-two definitions of complexity in his informal survey of the literature; the actual number is likely much higher. SETH LLOYD, PROGRAMMING THE UNIVERSE: A QUANTUM COMPUTER SCIENTIST TAKES ON THE COSMOS 186–89 (2006). For our purposes, Melanie Mitchell's definition will do.

116 *See generally* MEADOWS, supra note 114, at 35–72 (describing a variety of technical, economic, and social systems); J.B. Ruhl, *Thinking of Environmental Law as a Complex Adaptive System: How to Clean Up the Environment by Making a Mess of Environmental Law*, 34 HOUSTON L. REV. 933, 935, 942–43 (1997) (analyzing environmental law as a complex adaptive system).

117 More specifically, the distinguishing features belong variously to the complex system and the agents that comprise it, respectively. *See* J.B. Ruhl, *Law's Complexity: A Primer*, 24 GA. ST. U. L. REV. 885, 892–901 (2008) (discussing the agent and system properties that characterize complex adaptive systems).

relevant variables.[118] Nonlinearity relates to the cause-and-effect relationships in a complex system; the system does not respond to stimuli or disruption in a linear or proportionate fashion. A small change in one variable can result in an unexpectedly large shift in the behavior of the system or its parts.[119] Lastly, system behavior emerges from the nonlinear, dynamic interactions of actors and variables within the system, behavior that cannot be predicted by analyzing the behavior of individual system parts.[120]

Predicting impacts of genetically engineered microorganisms escaping to the environment means grappling with the behavior of a classic complex adaptive system: an ecosystem. Synthetic biology thus provides a stark example of the frustrating effects of ignorance on conventional risk analysis. Consider two of the most chilling concerns regarding engineered microalgae: horizontal gene transfer (HGT) and invasiveness. HGT (also known as lateral gene transfer) refers to the transfer of genetic material from one organism to another, other than through the typical vertical transmission of genes from parent to offspring.[121] HGT occurs naturally in ecosystems and is typically benign and even beneficial.[122] Yet it raises the potential for unintended consequences in various ways: for example, the transfer of antibiotic resistance or traits relating to fitness and growth to wild strain bacteria.[123] Different transgenes originating from unrelated fugitive engineered microalgae could even end up "stacked" in a single wild strain with unpredictable results.[124] Conventional ecological risk assessment methods do not have the capacity to evaluate these issues.[125] Likewise, although laboratory experiments and modeling have shown that microalgae optimized for biofuel production compete poorly against native algae, there is a strong, consistent literature demonstrating that such reductionist approaches are unable to predict real-world impacts.[126]

Complexity concerns regarding conventional risk analysis are not limited to human interactions with natural systems. Similar concerns arise with respect to the interaction of humans with the technical and institutional systems to which

---

[118] *Id.* at 898.
[119] *See id.*; *see also* INT'L INST. FOR APPLIED SYS. ANALYSIS, ADAPTIVE ENVIRONMENTAL ASSESSMENT AND MANAGEMENT 32–33 (C.S. Holling ed., 1978) [hereinafter Holling (ed.), ADAPTIVE MANAGEMENT].
[120] Ruhl, *supra* note 117, at 899.
[121] Patrick J. Keeling & Jeffrey D. Palmer, *Horizontal Gene Transfer in Eukaryotic Evolution*, 9 NATURE REVS. GENETICS 605, 605 (2008).
[122] Joel P. Hewett et al., *Human Health and Environmental Risks Posed by Synthetic Biology R&D for Energy Applications: A Literature Analysis*, 21 APPLIED BIOSAFETY 177, 181 (2016); Natalie Jing Ma & Farren J. Isaacs, *Genomic Recoding Broadly Obstructs the Propagation of Horizontally Transferred Genetic Elements*, 3 CELL SYS. 199, 199 (2016); Christopher M. Thomas & Kaare M. Nielsen, *Mechanisms of, and Barriers to, Horizontal Gene Transfer between Bacteria*, 3 NATURE REVS.: MICROBIOLOGY 711, 711–12 (2005).
[123] Hewett, *supra* note 122, at 181; Snow & Smith, *supra* note 73, at 766–67.
[124] Hewett, *supra* note 122, at 181.
[125] Snow & Smith, *supra* note 73, at 766–67.
[126] Jonathan Gressel et al., *Cultivated Microalgae Spills: Hard to Predict/Easier to Mitigate Risks*, 32 TRENDS IN BIOTECHNOLOGY 65, 65–66 (2014).

they belong.[127] Consider the types of sophisticated industrial plants that perform process hazard analyses under OSHA's process safety management rule. Despite these and other extensive regulatory requirements, industrial accidents continue to occur. "Normal accident" theory, developed by sociologist Charles Perrow, posits that serious process incidents are to be expected due to the facilities' complex, tightly coupled nature.[128] Many industrial processes or plants are "interactively complex" in that they consist of numerous subsystems continuously interacting through feedback loops.[129] Moreover, the processes at such facilities are often tightly coupled, meaning that a change in the status of one system or subsystem can affect associated units quickly. The relatively short time between the initiating event and the ultimate consequences can prevent the plant operators from detecting and properly evaluating the developing problem.[130] Thus, in a normal accident, interactive complexity generates a cascading set of unexpected deviations, and tight coupling impairs the capacity of system operators to evaluate, understand, and respond.[131]

Normal accident theory is unimpressed by regimented process safety management programs and their engineering and administrative controls. For Perrow and others, these technical and organizational measures themselves may contribute to the likelihood of a normal accident. Alarms, interlocks, and engineering controls can increase system complexity and lead to unexpected interactions. New safety and operating procedures can limit flexibility and situational awareness of operators, exacerbating the taut linkages among subsystems.[132] As Perrow notes, "redundancies and safety systems are the biggest single source of catastrophic failure in complex, tightly coupled systems."[133]

3. *Indeterminacy*

Conventional risk analysis is also problematic in contexts involving significant indeterminacy.[134] At its core, risk analysis aims to understand and predict

---

[127] *See* Johan Bergstrom et al., *On the Rationale of Resilience in the Domain of Safety: A Literature Review*, 141 RELIABILITY ENG'G & SYS. SAFETY 131, 134 (2015) (providing an overview of literature on complexity as a barrier to conventional risk assessment in the facility safety field).
[128] PERROW, *supra* note 54, at 5, 101, 122.
[129] *Id.* at 77–78; Frederick G. Wolf, *Operationalizing and Testing Normal Accident Theory in Petrochemical Plants and Refineries*, 10 PRODUCTION & OPERATIONS MGMT. 292, 296–97 (2001) (generating a "complexity index" for measuring complexity in thirty-six petroleum refineries as part of an empirical test of normal accident theory).
[130] *See* PERROW, *supra* note 54, at 108–10, 115–17.
[131] Karen Marais et al., Beyond Normal Accidents and High Reliability Organizations: The Need for an Alternative Approach to Safety in Complex Systems 2 (Mar. 24, 2004) (presented at the Engineering Systems Division Symposium, MIT).
[132] Charles Perrow, *Organizing to Reduce the Vulnerabilities of Complexity*, 7 J. CONTINGENCIES & CRISIS MGMT. 150, 151–52 (1999); SCOTT D. SAGAN, THE LIMITS OF SAFETY: ORGANIZATIONS, ACCIDENTS, AND NUCLEAR WEAPONS 36–43 (1993).
[133] Perrow, *supra* note 132, at 152.
[134] Miller & Wickson, *supra* note 103, at 492.

the causal chains that run between a threat and its ultimate consequences. Indeterminacy refers to the open nature of such causal chains, particularly with respect to the remarkable unpredictability of human behavior, individually and in the aggregate.[135] Humans and social organizations in the real world often act in ways that deviate, sometimes substantially, from the assumptions made about human behavior by risk assessors and risk managers. Yet those assumptions are sticky.[136] Several examples from our case studies illustrate this point.

Let's begin with risk assessment in the EPA's new chemical review program. In assessing the hazards and exposures associated with a chemical or GEM, the EPA considers only the proposed use, known uses, and reasonably foreseen uses of the material.[137] The line-drawing between foreseen and unforeseen uses is critical; those uses deemed unforeseen by the agency are not evaluated in the risk assessment. It appears that the EPA does not consider accidental spills or releases caused by natural causes or nefarious acts, all of which regrettably occur more frequently than we would like.[138] A recent determination by the EPA regarding an MCAN submitted for a genetically engineered microorganism indicates that the EPA applies similar reasoning in this context. On the way to concluding that the microorganism is not likely to present an unreasonable risk, the agency found only one condition of use(production of biofuel) and no reasonably foreseen condition of use.[139] It is difficult to square the agency's

---

135 Ibo van de Poel & Zoe Rabaey, *Safe-by-Design: From Safety to Responsibility*, 11 NANOETHICS 297, 299 (2017); Brian Wynne, *Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm*, 2 GLOB. ENV'T CHANGE 111, 117–19 (1992). While this definition appears to be generally accepted, some aspects of the term indeterminacy are subject to debate. For example, there are contrasting views as to whether indeterminacy is simply a form of uncertainty or ambiguity or instead stands alone as different in kind. *See* Stirling & Gee, *supra* note 111, at 525 (characterizing it as a form of ambiguity); Wynne, *supra*, at 116, 118 (defining indeterminacy as distinct from uncertainty). For our purposes the distinction is unimportant as we are focused on the functional impact of indeterminacy on risk analysis.

136

> The extra concept of indeterminacy, therefore, introduces the idea that *contingent social behaviour* also has to be explicitly included in the analytical and prescriptive framework. (Of course, behavioural regulation is already implied in technical standards, but the full extent of contingency and indeterminacy, and the implications of this, are not recognized.

Wynne, *supra* note 135, at 119.

137 EPA, POINTS TO CONSIDER, *supra* note 83, at 2, 2 n.2; 40 C.F.R. § 702.33(5) (2021) ("Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.").

138 ENV'T DEF. FUND, ENVIRONMENTAL DEFENSE FUND COMMENTS ON TEN PROBLEM FORMULATIONS UNDER THE TOXIC SUBSTANCES CONTROL ACT 57 (2018) (commenting upon EPA's scoping document for ten chemicals undergoing risk evaluation under the existing chemicals program).

139 Env't Prot. Agency, TSCA Section 5(a)(3) Determination for Microbial Commercial Activity Notice (MCAN) J-18-0004 to 0009 (Sept. 6, 2018).

conclusion with the consistently voiced concern in the scientific literature about accidental, intentional, or disaster-related releases.[140]

Indeterminacy is also present with respect to risk mitigation, as reflected in California's pesticide regulation program. DPR regularly relies upon personal protective equipment, such as respirators, as a mitigation measure to keep exposures at or below acceptable levels.[141] But industrial hygiene and worker safety research has shown that workers consistently resist using respirators; when they do don respirators, many workers use them improperly.[142] The administrative measures favored by the industry in process safety management for mitigation of hazards suffer from the same vulnerability. Standard operating procedures, inspections, and emergency response depend heavily on conscientious and consistent implementation by people. And people fail in unexpected ways due to fatigue, inattention, cognitive biases, and other factors.[143] Over time, repeated inadvertent or intentional deviations from mandatory procedures or policy can become normalized among workers within an organization.[144]

Some view indeterminacy as just another manifestation of complexity, in this case taking into account the role of humans as participants in a complex, unpredictable system.[145] Fair enough. There certainly is an overlap with complexity in that social systems can exhibit emergent behavior. And normal accident theory—which itself is grounded in notions of complexity—recognizes human behavior as an important aspect of interactive complexity. But indeterminacy has relevance beyond complex systems. It can be a substantial factor the causal chains present in complicated or even simple systems as well.

II. BEYOND CONVENTIONAL RISK ANALYSIS: PREVENTION AND RESILIENCE

This Part first provides a look at the respective origins and basic tenets of prevention and resilience. It concludes by examining the ways in which prevention and resilience could complement conventional risk analysis, mapping the two onto the risk analysis frame discussed in Part I.

---

140 Scott et al., *supra* note 68, at 34; Gressel et al., *supra* note 126, at 65–66; Slade & Bauen, *supra* note 71, at 33–35.

141 DPR, GUIDE, *supra* note 46, at 55; FROINES ET AL., *supra* note 99, at 15 (discussing DPR's evaluation of respirators for mitigation of exposure to methyl iodide).

142 *See* FROINES ET AL., *supra* note 99, at 15–16; *see also* American Thoracic Society, *Respiratory Protection Guidelines*, 154 AM. J. RESPIRATORY & CRITICAL CARE MED. 1153, 1161–62 (1996).

143 H. Landis "Lanny" Floyd II & Anna H.L. Floyd, *Residual Risk and the Psychology of Lower Order Controls*, 53 IEEE TRANSACTIONS ON INDUS. APPLICATIONS 6009, 6012–13 (2017).

144 *See* Shakeel H. Kadri & David W. Jones, *Nurturing a Strong Process Safety Culture*, 25 PROCESS SAFETY PROGRESS 16, 18 (2006).

145 *See* C. Butler et al., *Public Values for Energy Futures: Framing, Indeterminacy and Policy Making*, 87 ENERGY POL'Y 665, 666–67 (2015) (casting indeterminacy as arising in the context of complexity).

A. Prevention

When Benjamin Franklin observed in 1735 that "an [o]unce of [p]revention is worth a [p]ound of [c]ure,"[146] he was discussing fire safety, but that perspective on prevention has a long history in medicine and public health.[147] John Snow, often hailed as the father of epidemiology, attained mythic status as far as prevention goes by persuading local authorities in 1854 to remove the handle from the Broad Street water pump, which he believed to be the source of a cholera outbreak.[148] Residents were thus forced to obtain water elsewhere, and the outbreak stemmed. [149] By the mid-twentieth century, the concept of prevention was formalized in the fields of medicine and public health. Prevention interventions were classified as primary (avoiding the onset of disease), secondary (reducing the occurrence of the disease's impacts), or tertiary (treating the impacts that do occur).[150] Debate over the particular types and meanings of the classifications continues.[151] This history of prevention provides some help in puzzling through the term's meaning in environmental law and occupational safety and health.

A major difficulty in articulating the prevention principle is the pervasive use of the word "prevent" in a variety of legal contexts. Domestic U.S. law and international law often speak of "preventing" risk or environmental degradation or call for "preventative measure[s]" in response to particular risks.[152] In almost

---

[146] *The Electric Ben Franklin: Philadelphia: In Case of Fire*, USHISTORY.ORG, http://www.ushistory.org/franklin/philadelphia/fire.htm [perma.cc/SR88-F846].

[147] For a history of prevention in medicine from ancient times through the 1700s, see George Rosen, *Historical Evolution of Primary Prevention*, 51 BULL. N.Y. ACAD. MED. 9, 9–14 (1975).

[148] George W. Albee & Kimberly D. Ryan-Finn, *An Overview of Primary Prevention*, 72 J. COUNSELING & DEV. 115, 117 (1993).

[149] *Id.* It is worth noting that cholera was already receding from the affected neighborhood by the time Snow persuaded officials to remove the pump handle. Nigel Paneth, *Assessing the Contributions of John Snow to Epidemiology: 150 Years After Removal of the Broad Street Pump Handle*, 15 EPIDEMIOLOGY 514, 514 (2004); George Davey Smith, *Commentary: Behind the Broad Street Pump: Aetiology, Epidemiology and Prevention of Cholera in Mid-19th Century Britain*, 31 INT'L J. EPIDEMIOLOGY 920, 922, 924–25 (2002).

[150] 1 COMM'N ON CHRONIC ILLNESS, CHRONIC ILLNESS IN THE UNITED STATES: PREVENTION OF CHRONIC ILLNESS 16 (1957).

[151] Martin Bloom & Thomas P. Gullotta, *Definitions of Primary Prevention*, *in* ENCYCLOPEDIA OF PRIMARY PREVENTION AND HEALTH PROMOTION 3, 6–10 (Thomas P. Gullotta & Martin Bloom eds., 2d ed. 2014); LAWRENCE O. GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 15–17 (3d ed. 2016). A loose version of that tripartite characterization of prevention made its way into environmental law and policy. For example, in the facility safety area, Ashford and his colleagues mapped substitution of hazardous materials, control of exposure, and response/remediation after release onto the primary, secondary, and tertiary classifications, respectively. NICHOLAS A. ASHFORD ET AL., THE ENCOURAGEMENT OF TECHNOLOGICAL CHANGE FOR PREVENTING CHEMICAL ACCIDENTS: MOVING FIRMS FROM SECONDARY PREVENTION AND MITIGATION TO PRIMARY PREVENTION, at VIII-2 (1993).

[152] *See* 15 U.S.C. § 2603(f) (requiring USEPA to take action to "prevent" risk associated with certain chemicals); 15 U.S.C. § 2643(d)(6) (defining "preventative measures" for dealing with

every case, however, those terms are left undefined. Prevention could mean at least two different things in those contexts. In its broadest sense, prevention could refer to any measure that reduces or ostensibly eliminates a harm or risk of harm. For example, in the case of air pollution, a pollution control device that captures and destroys benzene emissions from a refinery process unit could be said to prevent harms associated with those emissions. The narrower view of what it means to "prevent" harm focuses upon eliminating or avoiding the root cause of the harm. Prevention in this sense would involve changing the process unit operations, perhaps by using different feedstock or adjusting the operating parameters, to eliminate or meaningfully reduce the benzene emissions at the source.[153]

In the chemical policy setting, for example, the prevention principle provides that preventive actions that eliminate or reduce the use of the chemical or its inherent hazard are preferred over actions that control exposure to it.[154] Preventive actions are a set of strategies, often characterized as substitution, minimization, moderation, and simplification.[155] Substitution refers to the replacement of the hazardous chemical or process with a safer substitute.[156] Minimization means adjusting the product or process design to reduce the amount of the chemical required or performing a hazardous process (such as batch chemical production)

---

asbestos releases); 42 U.S.C. § 9601(24) (defining remedial action as action taken to "prevent or minimize the release of hazardous substances"); NICOLAS DE SADELEER, ENVIRONMENTAL PRINCIPLES: FROM POLITICAL SLOGANS TO LEGAL RULES 62–64, 66–72 (2002); PHILIPPE SANDS, PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW 246 (2d ed. 2003) (describing the preventive principle as "requiring the prevention of damage to the environment, and otherwise to reduce, limit or control activities which might cause or risk such damage"). This includes, as we shall see below, statutes and treaties incorporating the precautionary principle.

153 J. Hirschhorn et al., *Towards Prevention: The Emerging Environmental Management Paradigm*, *in* CLEAN PRODUCTION STRATEGIES: DEVELOPING PREVENTIVE ENVIRONMENTAL MANAGEMENT IN THE INDUSTRIAL ECONOMY 125, 130–31 (Tim Jackson ed., 1993).

154 *See* KEN GEISER, CHEMICALS WITHOUT HARM: POLICIES FOR A SUSTAINABLE WORLD 94–95 (2015); *see also* Malloy, *Natmats*, *supra* note 2, at 109–10. The conception of prevention lines up well with the substitution principle found in European chemicals policy. The substitution principle as such has its origins in Sweden, having been used in occupational health and safety legislation in 1949 and directly applied to chemical regulation as part of the 1973 Act on Products Hazardous to Health and to the Environment. Annika Nilsson, *The Precautionary Principle in Swedish Chemicals Law and Policy*, *in* IMPLEMENTING THE PRECAUTIONARY PRINCIPLE: APPROACHES FROM THE NORDIC COUNTRIES, EU AND USA 295, 305–07 (Nicolas de Sadeleer ed., 2007) [hereinafter NORDIC COUNTRIES]. *See* SVEN OVE HANSSON & CHRISTINA RUDÉN, SWEDISH CHEMS. AGENCY, REPORT NR 8/07, THE SUBSTITUTION PRINCIPLE 11 (2007) (describing the substitution principle of one instance of inherent safety, which encompasses substitution, moderation, minimization, and simplification). Other Nordic countries and the EU have incorporated the substitution principle into certain aspects of chemicals policy. Ellen Margrethe Basse, *Denmark*, *in* NORDIC COUNTRIES, *supra*, at 63, 65; Hans Christian Bugge, *Norway*, *in* NORDIC COUNTRIES, *supra*, at 102, 112; Lofstedt, *supra* note 14, at 543, 545 (European Union).

155 *See* Malloy, *Natmats*, *supra* note 2, at 114.

156 *Id.*; *see also* HANSSON & RUDÉN, *supra* note 154, at 14.

as infrequently as possible.[157] Alternatively, in a moderation strategy, the chemical itself (or the product or process in which it is used) is modified to reduce the hazards, such as by reducing the temperature at which a process operates to well below the flashpoint for a flammable chemical used in that process.[158] In simplification, processing equipment and procedures are designed in as simple a manner as possible so as to eliminate opportunities for errors.[159]

Prevention has a complicated relationship with regulation in the United States. Virtually every major federal U.S. environmental statute explicitly or implicitly acknowledges the importance of prevention as I use the term.[160] Some statutes even affirmatively embrace it.[161] Yet regulators in the United States have been generally reluctant to implement prevention as a mandatory element of their programs.[162] Risk analysis in the area of occupational health and safety is a good example of this. Safety standard development in private and governmental settings ostensibly follows the "hierarchy of controls" approach in which risk management strategies are to be considered in a ranked order.[163] As Figure 4 illustrates,[164] reduction measures, such as removing the threatening agent or replacing it with a more benign substitute, are preferred over control strategies designed to minimize interaction with the threat.

---

157 *See* Malloy, *Natmats*, *supra* note 2, at 114; *see also* HANSSON & RUDÉN, *supra* note 154, at 14.

158 Malloy, *Natmats*, *supra* note 2, at 114; HANSSON & RUDÉN, *supra* note 154, at 14.

159 Paul Amyotte & Fotis Rigas, *Applications of Process Safety Concepts to the Hydrogen Economy*, 31 CHEM. ENG'G TRANSACTIONS 31, 32 (2013); Malloy, *Natmats*, *supra* note 2, at 114; HANSSON & RUDÉN, *supra* note 154, at 14.

160 Malloy, *Principled Prevention*, *supra* note 12, at 114–30.

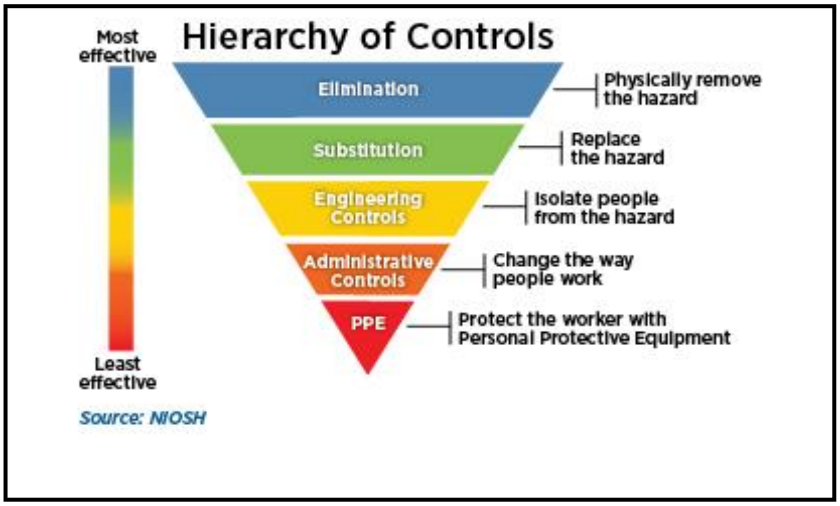
161 *See, e.g.*, 42 U.S.C. § 13101(b) ("The Congress hereby declares it to be the national policy of the United States that pollution should be prevented or reduced at the source whenever feasible.").

162 Richard J. Jackson & Timothy F. Malloy, *Environmental Public Health Law: Three Pillars*, 39 J.L. & MED. ETHICS 34, 35–36 (2011); Joel Tickner, *Commentary: Barriers and Opportunities to Changing the Research Agenda to Support Precaution and Primary Prevention*, 17 INT'L J. OCCUPATIONAL MED. & ENV'T HEALTH 163, 163–71 (2004).

163 Lyon & Popov, *supra* note 44, at 36; FRED A. MANUELE, ADVANCED SAFETY MANAGEMENT 268–76 (2014).

164 *Hierarchy of Controls*, CTRS. FOR DISEASE CONTROL AND PREVENTION: NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), https://www.cdc.gov/niosh/topics/hierarchy/default.html [perma.cc/YZ26-FJVW] (Jan. 13, 2015).

FIGURE 4



In practice, however, OSHA has been very reluctant to mandate elimination or substitution.[165] Rather, both in practice and in the legal literature regarding risk analysis, prevention is typically treated as a component of voluntary private action. For example, in the United States, the concept of pollution prevention for industrial waste discharges and emissions took hold in the latter part of the twentieth century largely as a voluntary regime rather than a regulatory mandate.[166]

B. Resilience

The term "resilience" has existed for centuries, gaining a foothold in material engineering in 1858.[167] In those early years, the concept was largely limited to describing the fairly mundane (but important) attributes of strength and ductility

---

[165] Malloy, *Principled Prevention*, *supra* note 12, at 125–27; Cora R. Roelofs et al., *Prevention Strategies in Industrial Hygiene: A Critical Literature Review*, 64 AIHA J. 62, 65 (2003). Even in Europe, where one might expect greater regulatory emphasis on prevention given its historical roots, implementation of the principle in practice has been spotty. ANDREAS AHRENS ET AL., HAZARDOUS CHEMICALS IN PRODUCTS AND PROCESSES: SUBSTITUTION AS AN INNOVATIVE PROCESS 22 (2006).

[166] For a comprehensive history of the development and implementation of federal and state pollution prevention programs though the early 1990s, see Robert F. Blomquist, *Government's Role Regarding Industrial Pollution Prevention in the United States*, 29 GA. L. REV. 349, 357–424 (1995).

[167] D. E. Alexander, *Resilience and Disaster Risk Reduction: An Etymological Journey*, 13 NAT. HAZARDS & EARTH SYS. SCIS., 2707, 2708–09 (2013); Małgorzata Pęciłło, *The Concept of Resilience in OSH Management: A Review of Approaches*, 22 INT'L J. OF OCCUPATIONAL SAFETY AND ERGONOMICS 291, 291 (2016).

of solid materials, such as timber or steel.[168] Over time, the concept has migrated into other disciplines—ecology, safety engineering, economics, disaster management, and organizational management—and its definitions and uses evolved.[169] One commentator identified over seventy definitions for the term.[170] (See Table 5 for examples of leading definitions.)

---

[168] Alexander, *supra* note 167, at 2708–10 (also noting that Sir Francis Bacon used the term to describe certain properties of echoes in 1625); Park et al., *supra* note 5, at 356 (citing JOHN C. TRAUTWINE, THE CIVIL ENGINEER'S POCKET-BOOK (1907)).

[169] *See* Thomas G. Koslowski & Patricia H. Longstaff, *Resilience Undefined: A Framework for Interdisciplinary Communication and Application to Real-World Problems*, *in* DISASTER MANAGEMENT: ENABLING RESILIENCE 3, 6–13 (Anthony Masys ed., 2015); Royce Francis & Behailu Bekera, *A Metric and Frameworks for Resilience Analysis of Engineered and Infrastructure Systems*, 121 RELIABILITY ENG'G & SYS. SAFETY 90, 100–102 (2014). Note that as early as 1857, the term resiliency in the sense of the capacity to rebound from a natural disaster was used to describe the restoration efforts of residents of the Japanese city of Shimoda in the aftermath of a major earthquake. ROBERT TOMES, THE AMERICANS IN JAPAN: AN ABRIDGMENT OF THE GOVERNMENT NARRATIVE OF THE U.S. EXPEDITION TO JAPAN UNDER COMMODORE PERRY 379 (1857).

[170] Len Fisher, *More Than 70 Ways to Show Resilience*, 518 NATURE 35 (2015). Fisher provides no support for his claim, although having been immersed in the literature I have no reason to doubt it. That said, Dahlberg via Tierney provides more support for his claim of over fifty definitions. *See* Rasmus Dahlberg, *Resilience and Complexity: Conjoining the Discourses of Two Contested Concepts*, 7 CULTURE UNBOUND 541, 543 (2015) (citing KATHLEEN TIERNEY, THE SOCIAL ROOTS OF RISK: PRODUCING DISASTERS PROMOTING RESILIENCE 162 (2014)); *see also* Fridolin Simon Brand & Kurt Jax, *Focusing the Meaning(s) of Resilience: Resilience as a Descriptive Concept and a Boundary Object*, 12 ECOLOGY AND SOC'Y 23 (2007) (providing a typology of ten distinct categories of resilience definitions).

TABLE 5: RESILIENCE DEFINED ACROSS DOMAINS

Author	Definition	Domain
Holling[171]	"A measure of the persistence of systems and of their ability to absorb change and disturbance and still maintain the same relationships between populations or state variables."	Ecology
National Research Council[172]	"The ability to prepare and plan for, absorb, recover from, and more successfully adapt to adverse events."	Disaster Management
Hollnagel, et al.[173]	"The intrinsic ability of a system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required operations under both expected and unexpected conditions."	Safety Science (Resilience Engineering)
Society for Risk Analysis[174]	"The ability of a system to reduce the initial adverse effects (absorptive capability) of a disruptive event (stressor) and the time/speed and costs at which it is able to return to an appropriate functionality/equilibrium (adaptive and restorative capability)"	Risk Analysis
United Nations[175]	"The ability of a system, community or society exposed to hazards to resist, absorb, accommodate to, and recover from the effects of a hazard in a timely and efficient manner, including through the preservation and restoration of its essential basic structures and functions"	Disaster Management
Department of Homeland Security[176]	The ability of systems, infrastructures, government, business, and citizenry to resist, absorb, recover from, or adapt to an adverse occurrence that may cause harm, destruction, or loss of national significance	Counterterrorism
Federal Energy Regulatory Commission[177]	"The ability to withstand and reduce the magnitude and/or duration of disruptive events, which include the capability to anticipate, absorb, adapt to, and/or rapidly recover from such an event."	Electrical Grid Regulation

171 C. S. Holling, *Resilience and Stability of Ecological Systems*, 4 ANN. REV. ECOLOGY & SYSTEMATICS 1, 14 (1973).

172 NAT'L RSCH. COUNCIL, DISASTER RESILIENCE: A NATIONAL IMPERATIVE 14 (2012).

173 RESILIENCE ENGINEERING IN PRACTICE: A GUIDEBOOK xxxvi (Erik Hollnagel et al. eds., 2011) [hereinafter Hollnagel (ed.), RESILIENCE ENGINEERING]; *see also* Erik Hollnagel, *Resilience: The Challenge of the Unstable*, *in* RESILIENCE ENGINEERING: CONCEPTS AND PRECEPTS 9, 16 (Erik Hollnagel et al. eds., 2006) (defining resilience as "the intrinsic ability of an organization (system) to maintain or regain a dynamically stable state, which allows it to continue operations after a major mishap and/or in the presence of a continuous stress").

Looking at these definitions and others, two essential themes emerge. First, broadly speaking, resilience relates to how something or someone (a physical structure or an institution, an ecosystem or an industrial facility, a person or population) responds to shocks or disturbances. A community faces a tsunami; an economy responds to economic sanctions; a grassland ecosystem struggles with a drought. Second, resilience includes protective, restorative, and even transformative responses. It aims to avoid or minimize adverse impacts by resisting or absorbing the shock while maintaining essential functions and structure. But should adverse impacts occur, it seeks to recover from them or to adapt to changed circumstances. However, these are general themes only. There are significant differences across and even within the various disciplines in terms of what resilience is and how it is operationalized. Two disciplines stand out in terms of their impact upon risk analysis and law: ecology and safety science. Readers are familiar with the discipline of ecology. Safety science develops "knowledge . . ., concepts, theories, principles and methods to understand, assess, communicate and manage (in a broad sense) safety."[178]

In his seminal article, *Resilience and Stability of Ecological Systems*, Holling introduced the property of resilience as a means of describing ecological systems.[179] He distinguished it from "stability," meaning an ecosystem's capacity to remain near a stable equilibrium point. Consider the classic predator/prey relationship; the dominant paradigm in ecology was largely fixated on the system's ability to maintain the respective populations in equipoise. While natural variations and exogenous disturbances could disrupt the equilibrium, a stable system would minimize the frequency and impacts of disturbance, swiftly returning the system to equilibrium.[180] Holling and others have rebranded stability over time, referring to it as "equilibrium resilience"[181] and later as "engineering resilience (as opposed to ecological resilience)."[182] For reasons that will become clear later, I will use the original term—stability.

Holling saw resilience as a different, important property of ecosystems: the capacity to persist—to maintain its essential structure and function—in the face of changes or disruptions.[183] The notion that a particular ecosystem could flip

---

174 SOC'Y FOR RISK ANALYSIS, *supra* note 106, at 6.
175 U.N. Off. for Disaster Risk Reduction, 2009 UNISDR Terminology on Disaster Risk Reduction 24 (2009).
176 U.S. DEP'T OF HOMELAND SEC., RISK STEERING COMM., DHS RISK LEXICON 26 (2010).
177 Order Terminating Rulemaking Proceeding, Initiating New Proceeding, and Establishing Additional Procedures, 162 FERC ¶ 61,012 para. 23 (2018).
178 Terje Aven, *What is Safety Science?*, 67 SAFETY SCIENCE 15, 18 (2014).
179 Holling, *supra* note 171, at 14–15.
180 *Id.* at 14.
181 C. S. Holling & Gary K. Meffet, *Command and Control and the Pathology of Natural Resource Management*, 10 CONSERVATION BIOLOGY 328, 330 (1996) (defining stability as "equilibrium resilience").
182 C. S. Holling & Lance H. Gunderson, *Resilience and Adaptive Cycles*, *in* PANARCHY, *supra* note 21, at 25, 27 (characterizing stability as "engineering resilience").
183 Holling, *supra* note 171, at 14.

from one fundamental state to another is central to resilience. A grassland consisting of various typical types of vegetation, insects, and animals can flip, sometimes relatively quickly, to a forest with a different set of animal, plant, and insect populations and ecological functions.[184] Such flips generally result from random, sometimes extreme, natural events, such as drought or fire or from human action, such as agricultural practices. A resilient system is one that can absorb natural or human-induced perturbations without altering its fundamental state or that can "bounce back" to the prior state after a flip.[185] Eutrophication of shallow freshwater lakes is illustrative. In an impaired lake with low resilience, the continued discharge of nutrients in agricultural runoff brings the lake to a tipping point, critically reducing aquatic vegetation, oxygen content, and fish populations. Small additional discharges can cause the collapse of the lake's existing system and a jump to a murky state dominated by algae.[186] Cessation of runoff and reduction of nutrient levels will not, without some other intervention, return the lake to its alternative clear, vegetated state. [187] To a great degree, then, resilience is about thresholds—at what point will changes or disruptions of the system or its drivers push the system over the edge into that alternative state?[188]

Intuitively and logically, stability and resilience appear complementary. Stability is about staying close to an equilibrium state, and resilience is about staying away from a flipping point. At first glance, it would seem that maintaining stability should necessarily enhance resilience. If a system is close to the equilibrium point, it must be distant from the flipping point. It turns out, however, that stability and resilience have a more complicated relationship, due in large part to the complex nature of ecosystems. Interventions to maintain the equilibrium can make the system brittle, decreasing its capacity to stay away from the flipping point in the event of a major disturbance:

> We call the result "the pathology of natural resource management" . . . . [A] system in which natural levels of variation have been reduced through command-

---

[184] *Id.* at 6–10.

[185] Not all ecosystems hover around a single equilibrium. Some are "oscillators," naturally shifting back and forth between two alternative equilibria. The classic example is the budworm-forest system, in which the system moves between low budworm populations and budworm outbreaks with associated changes in the populations of trees. Donald Ludwig et al., *Sustainability, Stability, and Resilience*, 1 CONSERVATION ECOLOGY 7, 16–17 (1997); *see also* Deepa S. Pureswaran et al., *Paradigms in Eastern Spruce Budworm (Lepidoptera: Tortricidae) Population Ecology: A Century of Debate*, 45 ENV'T ENTOMOLOGY 1 (2016) (discussing a range of theories regarding the drivers of the budworm-forest dynamic).

[186] BRIAN WALKER & DAVID SALT, RESILIENCE THINKING: SUSTAINING ECOSYSTEMS AND PEOPLE IN A CHANGING WORLD 55–58 (2006); Holling, *supra* note 182, at 7–8.

[187] Marten Scheffer et al., *Dynamic Interaction of Societies and Ecosystems—Linking Theories from Ecology, Economy and Sociology*, *in* PANARCHY, supra note 21, at 195, 198–99.

[188] Lance H. Gunderson et al., *Resilience of Large-Scale Resource Systems*, *in* RESILIENCE AND THE BEHAVIOR OF LARGE-SCALE SYSTEMS 9 (Lance H. Gunderson & Lowell Pritchard Jr. eds., 2002); WALKER & SALT, *supra* note 186, at 53–63; NAVIGATING SOCIAL-ECOLOGICAL SYSTEMS: BUILDING RESILIENCE FOR COMPLEXITY 5 (Fikret Berkes et al. eds., 2003) ("At a certain level of change in conditions (threshold), the system can change very rapidly and even catastrophically (called a flip).").

and-control activities will be less resilient than an unaltered system when subsequently faced with external perturbations, either of a natural (storms, fires, floods) or human-induced (social or institutional) origin. We believe this principle applies beyond ecosystems and is particularly relevant at the intersection of ecological, social, and economic systems.[189]

How, then, to avoid the pathology of command and control? One clear message from this thread of resilience literature is to practice humility when intervening in complex systems.[190] Expect the unexpected.[191] This principle is operationalized in two practices. First, rather than attempting to directly control system behavior and keep the system close to the desired stable state, choose interventions that seek to enhance the system's ecological resilience.[192] Such interventions focus on building capacity to absorb shocks without losing critical functions or to recover from losses that do occur.[193] There is a fair amount of variance among commentators regarding the specific nature of the interventions and the metrics used to measure their effectiveness.[194] That said, most formulations include interventions designed to maintain or increase monitoring/scanning for early signs of disturbances, redundancy, substitutability and diversity of system components and functions, and optimal interconnection and communication across system components.[195] Second, implement those interventions iteratively through adaptive management. Adaptive management is a dynamic process in which the selected management strategy is essentially implemented as an "experiment," testing explicit hypotheses regarding the expected response of the system. The results of the strategy are systematically monitored and evaluated, and the strategy is revised as necessary.[196]

Thus far, the discussion of resilience has focused largely on ecological resilience, namely, the resilience of complex ecosystems and coupled socio-ecological systems. Much of the theory and practice in that area is relevant to the resilience of socio-technical systems.[197] However, the parallel discipline of resilience engineering focuses squarely on the role of resilience in enhancing the safety of

---

189 Holling & Meffet, *supra* note 181, at 330.
190 WALKER & SALT, *supra* note 186, at 195; Holling & Meffet, *supra* note 181, at 334.
191 WALKER & SALT, *supra* note 186, at 198–199; Park et al., *supra* note 5, at 357.
192 *See* Holling & Meffet, *supra* note 181, at 334 (describing the "Golden Rule" of management: "management should facilitate existing processes and variabilities rather than changing or controlling them.").
193 WALKER & SALT, *supra* note 186, at 71–72; Jack Ahern, *From Fail-Safe to Safe-to-Fail: Sustainability and Resilience in the New Urban World*, 100 LANDSCAPE AND URB. PLAN. 341, 341–43 (2011).
194 *See* David A. Kerner & J. Scott Thomas, *Resilience Attributes of Social-Ecological Systems: Framing Metrics for Management*, 3 RESOURCES 672 (2014) (providing an overview of the wide-ranging literature).
195 *See id.*; WALKER & SALT, *supra* note 186, at 19; AMORY B. LOVINS & L. HUNTER LOVINS, BRITTLE POWER: ENERGY STRATEGY FOR NATIONAL SECURITY 192–98 (2001).
196 Holling (ed.), ADAPTIVE MANAGEMENT, *supra* note 119, at 20–21; WALKER & SALT, *supra*, note 186, at 128–29.
197 Adrian Smith & Andy Stirling, *The Politics of Social-Ecological Resilience and Sustainable Socio-Technical Transitions*, 15 ECOLOGY & SOC'Y 11 (2010).

technological and socio-technical systems.[198] Here, think of industrial plants, such as oil refineries or offshore drilling platforms, power plants, and infrastructure. The central thesis of resilience engineering is that:

> [F]ailure, as individual failure or performance failure at the system level, represents the temporary inability to cope effectively with complexity. Success belongs to organizations, groups and individuals who are resilient in the sense that they recognize, adapt to, and absorb variations, changes, disturbances, disruptions, and surprises—especially disruptions that fall outside the set of disturbances that the system is designed to handle.[199]

Like ecological resilience, engineering resilience recognizes the difficulty in managing complexity. And similar to its ecological counterpart, engineering resilience views inflexible command and control measures as counter-productive in the face of changing circumstances and unexpected disturbances. But there are important differences between the two schools of thought.

First, engineering resilience places more emphasis on maintaining stability (i.e., staying close to a stable equilibrium) than on assuring resilience as Holling uses the term (i.e., staying away from a flipping point to a new equilibrium). Holling's indictment of command and control efforts at maintaining stability has reverberated through much of the resilience literature, casting stability (sometimes called reliability or robustness) as a bit of a pariah.[200] This antagonism to the pursuit of stability is also evident in the legal literature on resilience.[201] The prominence of stability in resilience engineering is understandable; safe, reliable operation of industrial facilities and infrastructure is a central goal of safety science.[202] However, this emphasis on stability does not inevitably lead to use of

---

198 For a brief history of resilience engineering, see Jean-Christophe Le Coze, *New Models for New Times. An Anti-Dualist Move*, 59 SAFETY SCI. 200, 208–09 (2013). The term "resilience engineering" is distinct from Hollings's "engineering resilience," which refers to stability in ecological and socio-ecological systems.

199 David D. Woods & Erik Hollnagel, *Prologue: Resilience Engineering Concepts*, *in* RESILIENCE ENGINEERING: CONCEPTS AND PRECEPTS, *supra* note 173, at 1, 3.

200 For an example of the controversy over the respective roles of stability and ecological resistance, see Sean D. Connell & Giulia Ghedini, *Resisting Regime-Shifts: The Stabilising Effect of Compensatory Processes*, 30 TRENDS ECOLOGY & EVOLUTION 513, 515 (2015) (arguing that stabilizing processes such as trophic compensation are understudied); Shana M. Sundstrom et al., *Letter: Resisting Resilience Theory: A Response to Connell and Ghedini*, 31 TRENDS ECOLOGY & EVOLUTION 412 (2016) (countering that Connell and Ghedini fail to place their work in the context of resilience as that concept is generally understood); Sean D. Connell et al., *Letter: Ecological Resistance Why Mechanisms Matter: A Reply to Sundstrom et al.*, 31 TRENDS ECOLOGY & EVOLUTION 413 (2016) (emphasizing the need to consider both processes that "limit change (i.e., resistance) and processes that adjust and recover from disturbance (i.e., resilience)").

201 *See* Tracey-Lynn Humby, *Law and Resilience: Mapping the Literature*, 4 SEATTLE J. ENV'T L. 85, 108 (2014) (noting that law is locked into an engineering resilience paradigm); Ruhl, *General Design*, *supra* note 21, at 1387 ("As a general matter, however, the lesson from resilience theory is that conditions of high variability and low predictability point in the direction of ecological resilience strategies as the default design rule.").

202 JAMES A. KLEIN & BRUCE K. VAUGHEN, PROCESS SAFETY: PRACTICAL APPLICATIONS FOR SAFE AND RELIABLE OPERATIONS (2016).

rigid command and control management of the sort condemned in ecological resilience circles. Rather, resilience engineering relies upon other means to absorb and respond to expected and unexpected disruptions and changes to minimize and bounce back from departures from normal operations. This leads us to the second difference in emphasis.

Resilience engineering deals with disruption and change *proactively* by leveraging organizational structure, process, and culture, taking into account human cognition and behavior.[203] In other words, it aims to create the capacity (at all levels of the organization) to identify and adjust to changing conditions in real time, so as to reasonably maintain facility operations. While ecological resilience theory and practice certainly considers the role of institutional capacity, the focus on the organization and its component individuals lies at the very center of resilience engineering.[204] As Table 6 illustrates, this focus is evident in the four essential capacities for resilient organizations, also known as the cornerstones of resilience engineering: anticipation, monitoring, responding, and learning.[205]

TABLE 6: CORNERSTONES OF RESILIENCE ENGINEERING[206]

Cornerstone	Description
Anticipation	The capacity to anticipate expected and imagine unexpected threats and disturbances and the willingness to devote resources to actively support anticipatory efforts.

[203] *See* Kenneth A. Pettersen & Paul R. Schulman, *Drift, Adaptation, Resilience and Reliability: Toward an Empirical Clarification*, 117 SAFETY SCIENCE 460, 460–61 (2019) (describing the roots of resilience engineering in organizational research); Marcelo Fabiano Costella et al., *A Method for Assessing Health and Safety Management Systems from the Resilience Engineering Perspective*, 47 SAFETY SCIENCE 1056, 1056 (2009) (tracing the origins of resilience engineering to cognitive systems engineering); David D. Woods, *Essential Characteristics of Resilience*, *in* RESILIENCE ENGINEERING: CONCEPTS AND PRECEPTS, *supra* note 173, at 21, 22–23 (describing resilience as affected by organizational context and capacities and by actions of individuals within the organization). Indeed, engineering resilience as typically associated with the work of Hollnagel, Woods, and Leveson has been critiqued on this very point. *See* Stefan Hiermaier et al., *Resilience Engineering: Chances and Challenges for a Comprehensive Concept*, *in* HANDBOOK ON RESILIENCE OF SOCIO-TECHNICAL SYSTEMS 155, 158 (Matthias Ruth & Stefan Goessling-Reisemann eds., 2019) (arguing that classic engineering resilience "is too generic and it focuses too much on human factors" and offering an alternative conception centered more on technology and engineering).

[204] Pęciłło, *supra* note 167, at 294–96; Costella et al., *supra* note 203, at 1057.

[205] Pęciłło, *supra* note 167, at 294; Park et al., *supra* note 5, at 361; Hollnagel (ed.), RESILIENCE ENGINEERING, s*upra* note 173, at 33. Given the recent emergence of the field, the scope and guiding principles of resilience engineering continue to be debated, although most commentators follow the lead of Hollnagel and his colleagues. *See* David Yu et al., *Toward General Principles for Resilience Engineering*, 40 RISK ANALYSIS 1509, 1511–14 (2020).

[206] Erik Hollnagel, *The Four Cornerstones of Resilience Engineering*, *in* 2 RESILIENCE ENGINEERING PERSPECTIVES: PREPARATION AND RESTORATION 117, 121–29 (Christopher Nemeth et al. eds., 2009).

Monitoring	The capacity to monitor internal and external states relying upon leading indicators and shift into a state of readiness when conditions indicate that a disturbance may be brewing.
Responding	The capacity to respond to regular and irregular disturbances in accordance with plans and procedures that incorporate a range of discretion to account for unexpected circumstances. Response includes adjustments to normal operations and activities proactively and reactively so as to deal with emerging or occurring disturbances.[207]
Learning	The capacity to adjust and normalize monitoring, anticipation, and response in light of experience, including safety successes, near misses, and failures.[208]

These cornerstones are relevant at every level of organization, from the individual worker on the floor to management at the particular facility, and the organization as a whole. For example, at the organizational level, resilience engineering emphasizes development of a strong "safety culture," meaning prevailing beliefs, attitudes, and behaviors establish a strong imperative for safety in operations.[209] Such a culture provides managers and workers the permission and encouragement to implement the four cornerstones in meaningful ways. The cornerstones strike a difficult balance between flexibility and consistency. At the individual level, managers and workers maintain awareness of shifting conditions, assessing whether adjustments to normal activities are necessary. In abnormal circumstances, those individuals would have the flexibility to depart from default rules and procedures designed to respond to normal variations in operations.

III. PUTTING THE PIECES TOGETHER

What then to make of all this in the context of risk analysis? This Part explores the meaningful integration of prevention and resilience into risk analysis. In a sense, it begins at the end by considering how risk mitigation strategies

---

207 Park et al., *supra* note 5, at 361.
208 Pęciłło, *supra* note 167, at 296.
209 Yu et al., *supra* note 205, at 1512; Costella et al., *supra* note 203, at 1058; *see also* W.L. Frank, *Process Safety Culture in the CCPS Risk Based Process Safety Model*, 26 PROCESS SAFETY PROGRESS 203, 204 (2007) (defining safety culture).

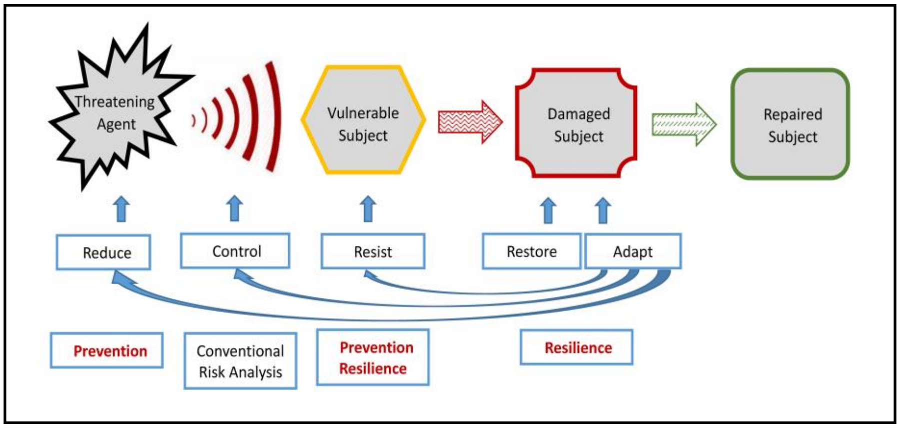
would change if policymakers were to wholeheartedly embrace prevention and resilience. I then turn to how integration would change the architecture of risk analysis: problem formulation, assessment, evaluation, and implementation. Throughout this thought experiment, I use risk analysis as currently practiced as the baseline.

A. Risk Mitigation Strategies

Part I observed that conventional risk analysis focuses on control: blocking or reducing the interaction between the threatening agent and the vulnerable subject. As Figure 5 illustrates, integrating prevention and resilience into risk analysis drives the inclusion of several other mitigation strategies: reduction, resistance, restoration, and adaptation. This Section examines each strategy more closely.

Before digging into these strategies in detail, a few words about scope are useful. First, what follows primarily addresses mitigation options at the operational level—decisions made by regulators and private risk managers regarding specific activities, processes, and products. These are the sort of undertakings described in the three case studies. This excludes consideration of broader measures meant to transform the fundamental structure or function of socio-technical or socio-ecological systems. Second, each of the mitigation strategies identified in Figure 5 are sometimes used in current risk analysis practice. The point here is not that these strategies are necessarily new, but rather that they should be considered in a systematic, integrated manner. Section III.B on the architecture of risk analysis takes this issue on directly.

FIGURE 5: INTEGRATED RISK ANALYSIS



1. *Prevention: Bringing Reduction and Resistance to Bear*

Prevention includes *reduction* and *resistance* as mitigation strategies. Reduction focuses on the inherent nature of the threatening agent itself, asking whether the agent can be removed entirely from the scenario or modified in some way to reduce its inherent hazard. There is a tendency to equate prevention with bans: the complete prohibition of a material, process, or activity. As Section II.A showed, however, prevention includes much more than bans. It also considers retaining the agent but reducing its hazard through minimization, moderation, and simplification. So, in the pesticide case study, prevention would include not only adoption of a safer alternative pesticide, but also use of application methods of the pesticide that minimize amounts used. Prevention also could play a role in the engineered microalgae case study. Rather than relying only upon containment in the cultivation pond to control interaction between the microalgae and the natural environment, the attributes of the algae itself would be modified to reduce its threatening nature. Existing proposals include "kill switches" in the microalgae genome that would trigger cell death in the presence of an environmental trigger, such as temperature, or the presence of certain naturally occurring chemicals.[210]

Prevention also seeks to avoid adverse consequences by building resistance. Unlike threat reduction, which focuses upon the threating agent, resistance directs attention to the vulnerable subject. The classic example of resistance in

---

[210] Helena Čelešnik, *Biosafety of Biotechnologically Important Microalgae: Intrinsic Suicide Switch Implementation in Cyanobacterium Synechocystis sp. PCC 6803*, 5 BIOLOGY OPEN 519, 519 (2016). Some commentators characterize kill switches as a form of resilience-focused mitigation. *See* Gary E. Marchant & Yvonne A. Stevens, *Resilience: A New Tool in the Risk Governance Toolbox for Emerging Technologies*, 51 U.C. DAVIS L. REV. 233, 244 (2017). Resilience-focused strategies are directed at building or triggering the threatened system's resilient capacity rather than the inherent nature of the threatening agent.

public health is vaccination.[211] By enhancing the immunological capacity of the individual, the vaccine diminishes the individual's vulnerability to disease. Resistance is relevant beyond the traditional public health setting. For example, in the pesticide case study, outreach and education programs regarding diet can help workers and nearby residents increase their resistance to pesticide exposures.[212]

Facility safety can also be enhanced by building the "resistance" of the facility processes. In 2012, a major fire occurred at Chevron's Richmond, California, oil refinery after flammable, high temperature gas oil escaped through a ruptured pipe and created a large vapor cloud.[213] Administrative measures meant to detect and respond to the increasing corrosion of the carbon steel pipe had failed.[214] Corrosion was caused by "sulfidation" of the carbon steel resulting from the high sulfur content of the gas oil.[215] The federal Chemical Safety and Hazard Investigation Board (CSB) concluded that installation of higher chromium steel piping would have minimized the vulnerability of the refinery process to corrosion and avoided the incident.[216]

Prevention adds value to risk analysis by mitigating the three limitations of conventional risk analysis discussed in Section I.C: data availability, ignorance, and indeterminacy. Regarding data availability, while prevention does not provide missing data, in certain cases it may obviate the need to obtain that data. In the face of high data costs or intractable methodological barriers to data generation, the use of an ostensibly safer alternative that performs effectively can be the optimal solution.[217] Here again, the pesticide case is illustrative. Suppose that a particular pesticide is suspected of causing neurological damage when inhaled by farmworkers and bystanders but that toxicity testing for this effect would be prohibitively costly. The pesticide formulation could be revised to include an inert ingredient—an adjuvant—such as a surfactant, oil, or other material that prevents or minimizes air dispersion during application or volatilization afterward.[218] Assuming one is confident that the adjuvant is sufficiently effective and the inhalation route foreclosed, the toxicity data is no longer needed.

---

[211] NAT'L ACAD. OF SCIS., REDUCING RISKS FOR MENTAL DISORDERS: FRONTIERS FOR PREVENTIVE INTERVENTION RESEARCH 19 (1994).

[212] *See* Todd P. Whitehood et al., *Childhood Leukemia and Primary Prevention*, 46 CURRENT PROBS. PEDIATRIC ADOLESCENT HEALTH CARE 317, 344–45 (2016) (describing use of folate supplements to reduce vulnerability to pesticide-exposure-related childhood leukemia).

[213] U.S. CHEM. SAFETY AND HAZARD INVESTIGATION BD., REPORT NO. 2012-03-I-CA, FINAL INVESTIGATION REPORT: CHEVRON RICHMOND REFINERY PIPE RUPTURE AND FIRE 1 (2015) [hereinafter CSB].

[214] *Id.* at 7–8.

[215] *Id.* at 5.

[216] *Id.* at 7, 47.

[217] Rune Hjorth et al., *The Applicability of Chemical Alternatives Assessment for Engineered Nanomaterials*, 13 INTEGRATED ENV'T ASSESSMENT & MGMT. 177, 180 (2017).

[218] *See* HANS DE RUITER ET AL., WAGENINGEN UNIV. & RSCH., INFLUENCE OF ADJUVANTS AND FORMULATIONS ON THE EMISSION OF PESTICIDES TO THE ATMOSPHERE 29–30 (2003) (analyzing the use of adjuvants to minimize dispersion and volatilization of pesticides upon application).

Likewise, prevention can dodge ignorance and indeterminacy by removing or substantially reducing the threat. As a pioneer in the field of inherently safer design of industrial facilities put it, "What you don't have, can't leak."[219] By altering the threating agent or enhancing the resistance of the vulnerable subject—rather than attempting to control human behavior—prevention can minimize the impacts of indeterminacy.[220] In the Richmond refinery case, Chevron depended upon conventional inspection and maintenance procedures to manage risk, essentially assuming away the possibility that personnel may deviate from those procedures. The effects of indeterminacy could have been avoided by relying instead upon less vulnerable process design. Of course, assessing and implementing alternatives raises its own challenges of data availability and complexity, which is dealt with below in the discussion of necessary methodological tools.

2. *Resilience: Leveraging Resistance, Restoration, and Adaptation*

Resilience relies upon *resistance*, *restoration*, and *adaptation* as mitigation strategies.[221] In the context of resilience thinking, resistance refers to the capacity of vulnerable subjects to absorb the impacts of a risk that is becoming or has become a reality.[222] Resistance in this context could be a tricky concept for two reasons. First, some perspectives on resilience would exclude resistance from the resilience bucket because of the linkage between resistance and stability.[223] However, this aversion to stability appears to be limited to strong versions of ecological resilience; most other formulations of resilience accept the role of resistance in the broader concept of resilience.[224] Second, resistance measures can sometimes also be characterized as control measures. Take the case of constructing homes on stilts to cope with flooding risks associated with climate change.[225] The stilts prevent the interaction of flood waters with the home. Does that make stilts a control measure? On the other hand, integration of stilts into the house design renders the structure less vulnerable to the effects of floods. Perhaps it is better viewed as enhancing resistance. As in much of life, we can live with a bit of gray at the margins of these concepts. The main point is that organizing potential measures into these categories of reduction, control, resistance, restoration, and adaptation helps ensure that analysts and decision-makers identify and evaluate a full range of measures.

---

219 Trevor Kletz, *What You Don't Have, Can't Leak*, 6 CHEM. IND., 287 (1978).

220 *See* ASHFORD ET AL., *supra* note 151, at IV-4–IV-5 (1993) (discussing role of primary prevention in minimizing accidents ostensibly due to "human error").

221 *See* SOC'Y FOR RISK ANALYSIS, *supra* note 106, at 6–7 (the capacity of a system to "reduce the initial adverse effects (absorptive capability) of a disruptive event (stressor)").

222 *Id.*

223 *See supra* note 198–199 and related text.

224 *See supra* Table 5.

225 Roger Few, *Flooding, Vulnerability and Coping Strategies: Local Responses to a Global Threat*, 3 PROGRESS DEV. STUD. 43, 47 (2003).

Resilience engineering is particularly relevant to resistance-based mitigation. In that context, resistance measures optimize the capacity and flexibility of the vulnerable subject to sense and respond to subtle shifts from normal operations to disruptions as they occur. Consider the case of the Chevron refinery again. The use of corrosion-resistant piping discussed above is an example of technological resistance. Organizational resilience of the sort envisioned in resilience engineering provides another complementary form of resistance. In the Chevron example, a prior Sulfidation Failure Prevention Initiative report for the facility had identified the threat of corrosion-related pipe failure. It recommended more detailed inspections and/or pipe replacement throughout the facility during the next turnaround at the plant.[226] The recommendations were rejected.[227] Managers concluded that deterioration of the piping did not meet rigid criteria in the facility's procedures for prioritizing turnaround work, despite recent work on nearby similar piping that revealed substantial corrosion.[228] This is just the sort of inflexible command and control strategy assailed by Holling and others. Resilience engineering measures would embrace a stronger safety culture, including policies and resources supporting more effective monitoring and anticipation of emerging problems. For example, such policies would encourage more flexible application of the turnaround prioritization criteria given new evidence of potential disruption from adjacent piping.[229] Resistance of this sort calls for monitoring and anticipation on the part of management and staff, using leading indicators of performance to detect emerging variations and disturbances. Alerted to the developing problem, facility personnel also must be free to respond as needed, adjusting or even suspending operations.

Recognizing that some causal chains and potential consequences will not be sensed or cannot be effectively absorbed, resilience also includes measures that prepare for restoration and adaptation in the aftermath of substantial disturbance. Restoration, or more specifically, reclamation, is a familiar concept in mining and other extractive industries.[230] Regulatory programs commonly mandate that operators restore the disturbed land or waters to their prior condition or to some

---

[226] CSB, *supra* note 213, at 8–11. A "turnaround" is an expensive, time-consuming "planned stoppage of production for conducting a comprehensive maintenance of plants and equipment with the purpose of restoring the processes to their original state." Umar Al-Turki et al., *Trends in Turnaround Maintenance Planning: Literature Review*, 25 J. QUALITY MAINT. ENG'G 253, 253 (2019).

[227] CSB, *supra* note 213, at 8.

[228] *Id.*

[229] The CSB also determined that managers had failed to consider other indicators of corrosion problem and that once the initial leak that led to the rupture was identified, workers and first line workers were reluctant to shut down the unit. CSB, *supra* note 213, at 11.

[230] Amy Yeldell & Victor R. Squires, *Restoration, Reclamation, Remediation and Rehabilitation of Mining Sites: Which Path Do We Take Through the Regulatory Maze?*, *in* ECOLOGICAL RESTORATION: GLOBAL CHALLENGES, SOCIAL ASPECTS AND ENVIRONMENTAL BENEFITS 37, 51 (Victor R. Squires ed., 2016); Anna T. Lima et al., *The Legacy of Surface Mining: Remediation, Restoration, Reclamation and Rehabilitation*, 66 ENV'T SCIENCE & POL'Y 227, 228–29 (2016).

other beneficial use upon completion of activities.[231] That obligation is often secured through financial assurance mechanisms, such as bonds or insurance.[232] Such programs do not involve risk analysis as this Article uses the term though; the damage addressed through that sort of restoration is expected.

The concept of restoration is likewise well developed in the ecological resilience literature dealing with natural resources management.[233] Ecological restoration—defined as "the process of assisting the recovery of an ecosystem that has been degraded, damaged or destroyed"[234]—has grown rapidly over the last twenty-five years.[235] It has found its way into the legal literature regarding various aspects of natural resources management, including habitat management, forest management, and water quality.[236] Such programs tend to be reactive and *ad hoc* rather than proactive; that is, they respond to problems after the fact. In a risk analysis context, restoration would be one of several mitigation measures systematically considered at the front end of the decision process.

Restoration for these purposes aims to repair the harms that do occur—to deal with the adverse consequences that ultimately could not be avoided through threat reduction, control, or resistance. The concept is broad, including immediate emergency response measures as well as longer term remedial efforts.[237] Restoration in the form of emergency response is prevalent in the realm of facility safety.[238] There, various regulatory programs require extensive emergency planning for disturbances and disasters, both in terms of design and operation of facilities.[239] Restoration efforts beyond immediate response are generally left out of risk analysis, left to other programs and institutions that may be largely

[231] Yeldell & Squires, *supra* note 230, at 51.
[232] Marchant & Stevens, *supra* note 210, at 263.
[233] Liana Wortley et al., *Evaluating Ecological Restoration Success: A Review of the Literature*, 21 RESTORATION ECOLOGY 537 (2013); José M. Rey Benayas et al., *Enhancement of Biodiversity and Ecosystem Services by Ecological Restoration: A Meta-Analysis*, 325 SCIENCE 1121, 1121 (2009).
[234] SOC'Y FOR ECOLOGICAL RESTORATION, INTERNATIONAL PRINCIPLES AND STANDARDS FOR THE PRACTICE OF ECOLOGICAL RESTORATION 78 (2d ed. 2019).
[235] Wortley et al., *supra* note 233, at 539.
[236] Arika Virapongse et al., *A Social-Ecological Systems Approach for Environmental Management*, 178 J. ENV'T MGMT. 83, 86 (2016) (natural resources); Melinda Harm Benson & Ahjond S. Garmestani, *Can We Manage for Resilience? The Integration of Resilience Thinking into Natural Resource Management in the United States*, 48 ENV'T MGMT. 392 (2011) (forest management); Robert W. Adler, *Resilience, Restoration, and Sustainability: Revisiting the Fundamental Principles of the Clean Water Act*, 32 WASH. U. J.L. & POL'Y 139, 142 (2010) (water quality).
[237] *See* Gosman, *supra* note 20, at 391–92 (discussing emergency response planning); Marchant & Stevens, *supra* note 210, at 262–66 (financial assurance mechanisms and regulatory programs to support remediation and closure of hazardous sites).
[238] Claire Olive et al., *Relationship of Safety Culture and Process Safety*, 130 J. HAZARDOUS MATERIALS 133, 137 (2006).
[239] *See* Gosman, *supra* note 20, at 392.

disconnected from the risk analysis process.[240] Think back to the case of synthetic algae production, which potentially could result in damage to natural ecosystems in the event of a release. MCANs submitted to the EPA seeking approval for such activities must describe how the algae production and use will be monitored and must set out emergency termination and containment procedures.[241] However, applicants are not required to include restoration planning and implementation procedures in the MCAN.

The final mitigation strategy—adaptation—is a core element of resilience. Like restoration, it acknowledges that risks sometimes become realities.[242] Adaptation leverages the capacity of a system to change in light of events and experience.[243] Notice in Figure 5 that adaptation can operate at two levels. First, at the system level, the impacted agent—the facility, ecosystem, or human population—may change aspects of its essential structure or functioning in the face of the disturbance. This sort of fundamental shift is difficult to plan for; perhaps the most that can be done *ex ante* is to establish the capacity and resources for the subject to identify and implement fundamental change, whatever that may look like, in the future. The second form of adaption is more relevant to risk analysis as we have discussed it above. This type of adaptation focuses on adjusting the originally deployed mitigation measures in light of experience. Risk analysis approaches grounded in ecological resilience would call this adaptive management.[244] As noted above, the existing legal literature explores the nature, value, and limitations of adaptive management extensively.[245] For our purposes, it is sufficient to note that adaptation involves reconsideration of the full set of mitigation measures based on monitoring of their implementation—it is not limited to modifying a resilience-based mitigation measure. So, for example, if monitoring and experience indicate that a selected prevention, control, or resistance measure is failing, adaptation may adjust that measure or replace it altogether with new measures, depending upon the circumstances.

In the realm of engineering resilience in particular, adaptation operates at the individual level in the moment and at the organizational level. By way of example, recall that resistance occurs when workers observe variances in operations and respond by departing from established default procedures or by developing new strategies for unforeseen threats on the fly.[246] Adaptation occurs when individuals incorporate those responses into their normal repertoire, when they learn

---

240 *But see* Subpart F - Releases from Solid Waste Management Units, 40 C.F.R. § 264.100 (2016) (establishing corrective action program prospectively requiring cleanup of future releases of contaminants at hazardous waste treatment, storage, and disposal facilities).
241 EPA, ALGAE GUIDANCE, *supra* note 77, at 16–24.
242 Woods & Hollnagel, *supra* note 199, at 3 (emphasizing the importance of responding when the unanticipated has occurred).
243 Park et al., *supra* note 5, at 361.
244 WALKER & SALT, *supra* note 186, at 33.
245 *See supra* text accompanying notes 242–44.
246 Erik Hollnagel & Yushi Fujita, *The Fukushima Disaster – Systemic Failures as the Lack of Resilience*, 45 NUCLEAR ENG'G & TECH. 13, 13–14 (2013).

from the experience.[247] Similarly, at the organization level, adaptation occurs when the facility revises standard procedures and standards based on what it has learned from accidents, near misses, or success stories, including adopting (and thus normalizing) adaptive responses by individual workers.[248]

Thus, through resistance, restoration, and adaptation, resilience both accepts and responds to complexity, ignorance, and indeterminacy. Accepting that some interactions and consequences cannot be predicted or controlled well in advance, resilience instead develops greater capacity to identify disturbances as they approach and respond closer in time. It provides resistance strategies that reduce vulnerability and emphasize nimble, timely adjustments to dynamic, largely unpredictable conditions. Through restoration strategies, resilience builds capacity to rebuild the damaged subject. And at the meta-level, resilience relies upon adaptive strategies, using experience to adjust or replace previously selected mitigation measures.[249] Ultimately, resilience counters the surprises flowing from complexity, ignorance, and indeterminacy by moving from rigid fail-safe approaches characteristic of a control-oriented strategy to a "safe-to-fail" approach.[250]

B. *Changing the Architecture of Risk Analysis in Practice*

This Section turns to the "what if" question—how would risk analysis look if it fully embraced prevention and resilience thinking? To answer that question, we turn to the four elements of risk analysis set out in Table 2: problem formulation, assessment, evaluation/selection, and implementation. Earlier, I warned that risk analysis is not nearly as linear a process as Table 2 suggests. Rather, each element of risk analysis builds toward the ultimate decision regarding how to manage risk, if at all. Consider problem formulation. It is not simply focused on the nature of the baseline threat or the likelihood and severity of impacts if left unmitigated. Problem formulation is contextual; it defines the issue to include how risk would be altered under potential risk mitigation scenarios.[251] The menu of potential risk mitigation strategies to be considered also drives the nature and scope of the assessment element. But we have to start somewhere. In this Section, I walk through each element in sequence, drawing cross-connections as we go. Table 7 provides a roadmap, identifying in italics the major changes needed to integrate prevention and resilience.

---

[247] *Id.*
[248] Andrew Hale et al., *Auditing Resilience in Risk Control and Safety Management Systems*, *in* RESILIENCE ENGINEERING: CONCEPTS AND PRECEPTS, *supra* note 173, at 289, 308–10.
[249] *Id.*
[250] *See* Jeryang Park et al., *Lessons in Risk- Versus Resilience-Based Design and Management*, 7 INTEGRATED ENV'T ASSESSMENT & MGMT. 396, 398 (2011) ("[R]esilience thinking demands a *safe-fail* approach that minimizes damage when new risks are revealed."); Ahern, *supra* note 193, at 341 ("'[S]afe-to-fail' anticipates failures and designs systems strategically so that failure is contained and minimized.").
[251] NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 11–12.

TABLE 7: THE INTEGRATED ARCHITECTURE OF RISK ANALYSIS

Elements	Functional Components
Problem Formulation	Problem definition *Include identification of "irregular threats" and "unexamined events"* Identification of potential mitigation options *Include prevention, resistance, restoration, and adaptation measures*
Assessment	Risk assessment *Expand vulnerability assessment* *Include alternatives assessment*
Evaluation/Selection	Evaluation and selection of potential risk mitigation measures *Include prevention, resistance, restoration, and adaptation measures* *Engage in systematic trade-off analysis of measures*
Implementation	Implementation of risk mitigation measures *Monitor/Evaluate implementation* *Revise risk mitigation measures*

1. *Problem Formulation*

Problem formulation is critical because it sets the boundaries of the risk analysis along two dimensions: the threats or problems to be assessed and the mitigation measures to be evaluated.[252] Integration of prevention and resilience requires changes relevant to each of these dimensions.

First, consider the range of threats captured by conventional problem formulation. At the end of the day, risk analysis is meant to support rigorous, timely decision-making. Therefore, it must balance the goal of being comprehensive against the need to be efficient and expeditious. In striking that balance, problem formulation in conventional risk analysis tends to drop certain categories of threats from further consideration. Problem formulation is very good at identifying standard risks and issues, what Westrum calls "regular" threats.[253] It is less attentive to Westrum's "irregular threats" and "unexampled events." Irregular threats are low-probability events that carry high consequences if they do occur.[254] We know that they can happen, but drop them from further consideration because their likelihood is deemed negligible based on historical data or expert subjective belief.[255] For example, in performing a process hazard analysis, the

---

252 PCCRARM, *supra* note 28, at 7.

253 Ron Westrum, *A Typology of Resilience Situations*, *in* RESILIENCE ENGINEERING: CONCEPTS AND PRECEPTS, *supra* note 173, at 55, 55–56.

254 *Id.* at 57.

255 These are the so-called black swans. Terje Aven, *Implications of Black Swans to the Foundations and Practice of Risk Assessment and Management*, 134 RELIABILITY ENG'G AND SYS.

review team excludes a total power loss from the scenarios it assesses because, in the team's experience, such an event is not credible.[256] Or, in evaluating use of synthetic algae for biofuel production, the EPA restricts the risks it considers to those associated with "reasonably foreseen" conditions of use.[257] Unexampled threats are the unknown unknowns that are exceedingly difficult to imagine.[258] Such threats are obscured by the sort of ignorance discussed in Section I.C.2. And not surprisingly, unexampled events are not typically included in the definition of the problem in conventional risk analysis.[259]

Prevention and resilience strategies can help to avoid or minimize irregular and unexampled events, but only if such events are included in the scope of the identified problem.[260] Including an irregular event in the problem definition is straightforward enough—just do not drop it from further evaluation. Of course, retaining irregular threats is not costless; resource and time constraints undoubtedly constrain our capacity to address every eventuality comprehensively.[261] That said, we must recognize that prevention-based and resilience-based mitigation options may offer cost-effective opportunities to blunt some irregular threats. The trick will be finding the right balance in what to retain and what to jettison during problem formulation.

Unexampled events are more troublesome; how does an analyst include an unknown threat in the problem scope? Two approaches can enhance problem formulation here. The first is to focus on consequences in addition to causes. Much of existing problem formulation relies upon our knowledge about whether

---

SAFETY 83, 84–85 (2015); Elisabeth Pate-Cornell, *On "Black Swans" and "Perfect Storms": Risk Analysis and Management When Statistics Are Not Enough*, 32 RISK ANALYSIS 1823, 1824–25 (2012); John F. Murphy & Jim Conner, *Beware of the Black Swan: The Limitations of Risk Analysis for Predicting the Extreme Impact of Rare Process Safety Incidents*, 31 PROCESS SAFETY PROGRESS 330, 331 (2012).

256 Murphy & Conner, *supra* note 255, at 331.

257 15 U.S.C. § 2602(4) and § 2604(a)(2)(D). The EPA defines reasonably foreseen conditions of use as "future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the MCAN microorganism to be manufactured, processed, distributed, used, or disposed of." Env't Prot. Agency, *supra* note 139, at 1 n.1.

258 Westrum, *supra* note 253, at 57–58. Such unexampled events fall within the ambit of "deep uncertainty." *See* INST. OF MED. OF THE NAT'L ACADS., ENVIRONMENTAL DECISIONS IN THE FACE OF UNCERTAINTY 38 (2013) [hereinafter INST. OF MED., ENVIRONMENTAL DECISIONS] (defining deep uncertainty as "uncertainty about the fundamental processes or assumptions underlying a risk assessment").

259 Pate-Cornell, *supra* note 255, at 1824–25. Of course, in any given case, the categorization of an event as irregular versus unexampled is open to dispute. Take the case of the Fukushima disaster in which an earthquake and subsequent forty-foot-high tsunami devastated the Tokyo Electrical Power Company's nuclear facility at Fukushima. Hollnagel and co-author concluded that the Fukushima disaster clearly was an unexampled event, while Pate-Cornell classified it as an irregular event. *Compare id. with* Hollnagel & Fujita, *supra* note 246, at 16.

260 *See* Murphy & Conner, *supra* note 255, at 331 (noting that risk analysis tools in facility safety "cannot estimate the risk of hazard scenarios that have not been identified").

261 *See* Hollnagel & Fujita, *supra* note 246, at 17 ("It is not very difficult to find a very large number of potential risks or threats, but there may be insufficient time and resources – or even motivation – to do so, and to evaluate them thoroughly. The anticipation is therefore constrained, often by referring to shared assumptions about what is likely and what is not.").

and how a given threatening agent could lead to problems. For example, in considering whether a particular chemical process could lead to an explosion or fire, conventional problem formulation may look to historical industry experience or engineering assessments based on standard assumptions and models.[262] Where complexity creates ignorance or indeterminacy undermines assumptions regarding human behavior, the limits of our knowledge can hamper adequate problem formulation. In such cases, problem formulation can be supplemented by focusing on potential consequences of concern—explosions, fish kills, horizontal gene transfer from synthetic organisms, and so on—without regard to the pathway. We can envision the event and its severe impact even when the path leading to it remains murky.[263] (Although skeptical readers may be concerned about the possible costs involved in protecting against such events, keep in mind that we are focused here on problem formulation; that is, what things should we consider in the next steps of risk analysis. In other words, we are simply keeping these consequences—and their associated "shadow" unexampled events—on the table, not concluding that mitigation measures should be taken.)

The second approach calls for bringing greater imagination and broader participation from stakeholders and experts to bear on problem formulation. Unexampled events seen as unimaginable before a tragedy are often characterized as predictable after the fact.[264] This is so because reviewing an event and its consequences in retrospect can reveal causal pathways and interdependencies that were difficult to see beforehand. Often, this occurs when multiple predictable events converge in unusual ways; think here of the so-called "perfect storm."[265] Various strategies can assist analysts in identifying unexampled events for further assessment.[266] Two in particular stand out. First, analysts can identify consequences of concern and then work backwards from there to brainstorm a range of situations from which such consequences could flow, even if those situations seem improbable.[267] This strategy differs from the approach described in the paragraph above, which focuses on consequences without regard to casual pathways, in that this strategy *does* ultimately seek to identify the initiating events and pathways. Second, analysts could engage more broadly in the generation of

---

262 Murphy & Conner, *supra* note 255, at 332.

263 *See* Terje Aven, *How Some Types of Risk Assessments Can Support Resilience Analysis and Management*, 167 RELIABILITY ENG'G & SYS. SAFETY 536, 538 (2017) (noting that while causal paths may be surprising, the resulting events may not be and suggesting that "focus can be placed on . . . these type of events").

264 Aven, *supra* note 255, at 84.

265 Pate-Cornell, *supra* note 255, at 1824–25; Murphy & Conner, *supra* note 255, at 331–32.

266 *See* Piret Tõnurist & Angela Hanson, *Anticipatory Innovation Governance: Shaping the Future Through Proactive Policy Making* 58–62 (Org. for Econ. Co-operation and Dev. (OECD), Working Paper No. 44, 2020) (describing a range of foresight methods and scenario planning instruments).

267 Murphy & Conner, *supra* note 255, at 332.

scenarios,[268] defined as a "set of events that could, within reason, take place."[269] In particular, exploratory scenario generation uses a mix of knowledge, experience, and imagination in the face of ignorance to envision elusive causal pathways and their outcomes.[270] There is a broad range of quantitative and qualitative scenario generation tools and methods; some rely more heavily on broad stakeholder participation, while others focus on expert input.[271] The goal in exploratory scenario development is not to predict what is likely to occur, but rather to pinpoint what is plausible.[272] Plausible unexampled events uncovered through scenario generation would be held over for subsequent assessment.[273]

Recall that in addition to framing the problems to be addressed, existing best practice in problem formulation also calls for identifying potential solutions.[274] Given that the focus on control is so central to conventional risk analysis, prevention-based and resilience-based are not typically identified as alternative options. Integration of prevention and resilience into risk analysis thus would require expanding problem formulation practice to include a broader range of mitigation options. This provides prevention and resilience with a place at the table as assessment and evaluation move forward. Take the case of pesticide registration. In addition to control options (such as limits on when and how to apply the pesticide or personal protective equipment mandates for workers), problem formulation might also cite less-toxic alternative pesticides or modified agricultural practices as potential mitigation options.[275]

---

[268] INST. OF MED., ENVIRONMENTAL DECISIONS, *supra* note 258, at 154–55; Alan Raybould, *The Bucket and the Searchlight: Formulating and Testing Risk Hypotheses About the Weediness and Invasiveness Potential of Transgenic Crops*, 9 ENV'T BIOSAFETY RES. 123, 125–26 (2010).

[269] INST. OF MED., ENVIRONMENTAL DECISIONS, *supra* note 258, at 240–41. *See* PHILLIP VAN NOTTEN, WRITING ON THE WALL: SCENARIO DEVELOPMENT IN TIMES OF DISCONTINUITY 7 (Zwaar Water ed., 2005) (defining scenarios as "coherent descriptions of alternative hypothetical futures that reflect different perspectives on past, present, and future developments, which can serve as a basis for action").

[270] Graeme A. Riddell et al., *Tomorrow's Disasters – Embedding Foresight Principles into Disaster Risk Assessment and Treatment*, 45 INT'L J. DISASTER RISK REDUCTION 1, 3 (2020).

[271] *Id.*; H.R. Maier et al., *An Uncertain Future, Deep Uncertainty, Scenarios, Robustness and Adaptation: How Do They Fit Together?*, 81 ENV'T MODELLING & SOFTWARE 154, 157 (2016).

[272] INST. OF MED., ENVIRONMENTAL DECISIONS, *supra* note 258, at 241; Raybould, *supra* note 268, at 125–26.

[273] Riddell et al., *supra* note 270, at 3–4; Raybould, *supra* note 268, at 125–26.

[274] NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 11–12.

[275] In 2017, a California appellate court held that the evaluation process for pesticides must include "consideration of feasible alternatives." Pesticide Action Network N. Am. v. Dep't of Pesticide Regul., 16 Cal. App. 5th 224, 245–47 (2017). The Department of Pesticide Regulation (DPR) issued a directive implementing this requirement in 2019. 2018-26 Cal. Regulatory Notice Reg. 1–3 (May 1, 2019), https://www.cdpr.ca.gov/docs/registration/canot/2018/ca2018-26.pdf [perma.cc/EW8B-FJLK].

2. Assessment

Discussions of the assessment element of risk analysis usually focus on risk assessment. As Section I.B explains, risk assessment consists of four basic steps: characterization of the threat, assessment of the interaction between the threat and the affected subject, assessment of the subject's vulnerability, and characterization of the consequences.[276] Integration of prevention and resilience entails two revisions to current practice: (1) expansion of vulnerability assessment to explicitly judge the baseline resilience of the affected subject[277] and (2) addition of alternatives assessment to systematically identify and measure the trade-offs presented by mitigation options, including prevention-based and resilience-based options.

To varying degrees, current approaches to vulnerability assessment implicitly take into account the resilience of the affected subject. For example, risk assessment for pesticide registration includes dose-response assessment, which identifies the level of exposure a person can handle without experiencing adverse health impacts. In other words, dose-response assessment measures the capacity of individuals to resist toxic effects of the pesticide; the capacity to resist a disruptive event is an attribute of resilience. Framing dose-response assessment more explicitly as an assessment of resilience centers attention more clearly on the affected individual, rather than on the threatening agent. This emphasizes the need to scrutinize how the individual's physiological functions and physical/social environment influence that individual's resilience.

The failure of California's pesticide program to scrutinize cumulative exposures illustrates this point. DPR evaluates pesticide active ingredients individually, so dose-response assessment assumes that workers and bystanders are exposed just to the active ingredient under review.[278] In the real world, individuals are exposed to mixtures of active ingredients. This affects the individual's capacity to resist the toxic insult for the pesticides. For example, substances such as glutathione, a naturally occurring antioxidant central to detoxifying certain toxins in mammals, can be depleted by one pesticide, making it harder for the body to resist the other pesticide.[279] An individual's or population's resilience in the face of pesticide exposure can of course be affected by other factors as well, including reduced resistance in sensitive sub-populations, such as children or the elderly,[280] and exposure to other chemical or non-chemical stressors, such as

---

[276] *See supra* Figure 2. Depending upon the regulatory context, these steps go by different names. *See supra* Table 3.
[277] Francis & Bekera, *supra* note 169, at 92.
[278] VIRGINIA ZAUNBRECHER ET AL., UCLA SUSTAINABLE TECH. & POL'Y PROGRAM, EXPOSURE AND INTERACTION: THE POTENTIAL HEALTH IMPACTS OF USING MULTIPLE PESTICIDES 4–5 (2016).
[279] *Id.* at 12–13.
[280] *See* NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., ASSESSING THE HUMAN HEALTH RISKS OF TRICHLOROETHYLENE: KEY SCIENTIFIC ISSUES 323 (2006) (noting that toxicologic and epidemiologic data "rarely provide" sufficient information regarding effects on "potentially susceptible subpopulations, such as children [and] the infirm").

physical stress and psychosocial stress (e.g., community violence, unemployment).[281] Thus, meaningful integration of the concept of resilience into vulnerability assessment requires substantially more attention to cumulative impacts broadly defined. Identification of specific methods for cumulative impact assessment is beyond the scope of this Article. It is perhaps enough to note that although this area is not nearly as developed as conventional assessment, a wide range of cumulative assessment frameworks, methods, and tools are available.[282]

Socio-technical systems (such as industrial facilities and the electrical grid) and natural ecosystems also face vulnerabilities. Understanding such vulnerabilities likewise requires integration of the relevant system's resilience. What is the baseline capacity of a natural gas power plant to resist and recover from a terrorist attack or, as in the case of Fukushima, the combination of an earthquake and tsunami? To what extent could a lake recover from invasion by a highly competitive synthetic algae strain? Risk assessment embracing a resilience perspective must be able to address such questions, but there are no well-established methods for actually measuring the resilience of socio-technical or natural systems.[283] There is progress along this front, however. As with cumulative assessment, a wide array of frameworks, methods, and tools for assessing the resilience capacity are available in various domains,[284] including, among others,

[281] Richard Todd Niemeier et al., *A Cumulative Risk Perspective for Occupational Health and Safety (OHS) Professionals*, 17 INT'L J. ENV'T RSCH. & PUB. HEALTH 6342, 6344, 6349 (2020) (noting the presence of "emerging scientific evidence that chronic psychosocial stress may make individuals more susceptible to health effects from physical and chemical exposures").

[282] *See* Simon John More et al., *Guidance on Harmonised Methodologies for Human Health, Animal Health and Ecological Risk Assessment of Combined Exposure to Multiple Chemicals*, 17 EFSA J. 1, 16–18 (providing an overview of existing regulatory approaches to cumulative impact assessment). *See generally* CHEMICAL MIXTURES AND COMBINED CHEMICAL AND NONCHEMICAL STRESSORS: EXPOSURE, TOXICITY, ANALYSIS, AND RISK (Cynthia V. Rider & Jane Ellen Simmons eds., 2018); Margaret M. MacDonell et al., *Cumulative Risk Assessment Toolbox: Methods and Approaches for the Practitioner*, 2013 J. TOXICOLOGY 1 (2013); Hans Løkke et al., *Tools and Perspectives for Assessing Chemical Mixtures and Multiple Stressors*, 313 TOXICOLOGY 73 (2013).

[283] *See* Stuart L. Pimm et al., *Measuring Resilience is Essential If We Are to Understand It*, 2 NAT. SUSTAIN. 895, 895–96 (2019) (noting the continued difficulty in "operationalizing resilience"); Igor Linkov et al., *Measurable Resilience for Actionable Policy*, 47 ENV'T SCI. & TECH. 10108, 10108 (2013) ("[T]he failure to understand resilience in the context of these complex systems has precluded the creation of an actionable metrics framework to inform resilience decisions.").

[284] *See* Aven, *supra* note 263, at 537 (surveying methods and metrics for assessing resilience).

infrastructure,[285] industrial facility safety,[286] and socio-ecological systems.[287] Developing and validating methods fit for use in the various regulatory programs will entail significant effort.

Expansion of vulnerability assessment builds off an existing aspect of risk assessment. Integrating prevention and resilience into risk analysis will also require the addition of a largely distinct form of assessment—alternatives assessment. First, a bit a background for context. In conventional risk analysis, the risk assessment would typically characterize the risk associated with the threat under review and the relative risk reductions flowing from candidate risk control options identified during problem formulation. For example, during registration of a methyl iodide (MI), a fumigant used to kill pests affecting strawberries, DPR's risk assessment characterized certain risks of MI use—carcinogenicity and neurotoxicity—and predicted the reduction in those risks expected from control measures such as buffer zones, personal protective equipment, and so on.[288] While such an assessment requires sophisticated methods and expertise, it is relatively straightforward because it essentially involves one comparison across one attribute—risk presented by the unmitigated and mitigated use of the pesticide.

Now assume that prevention-based and resilience-based measures were included in the slate of mitigation options considered, things like potentially less toxic chemical alternatives, steam treatment of strawberry fields, and solarization of the fields.[289] Meaningful assessment of the proposed pesticide and the alternatives now requires comparison across a range of sometimes incommensurable attributes. For example, does the non-carcinogenic chemical alternative nonetheless present risk of endocrine disruption or respiratory toxicity? Does steam treatment increase the risk of serious worker injury? How well does solarization work as compared to MI application in terms of eliminating pests? Some type of broad-based comparative assessment is needed to lay out the relative benefits and pitfalls presented by the baseline material, chemical, or activity and its alternatives.[290]

---

[285] *See* Warner et al., *supra* note 24, at 107–08 (use of network analysis to quantify the resilience of railway infrastructure); Francis & Bekera, *supra* note 169, at 95–97 (proposing "a resilience metric that incorporates the three resilience capabilities [absorptive, adaptive, and restorative] and the time to recovery").

[286] *See* Steen & Aven, *supra* note 24, at 294–97 (extended risk assessment); G.H.A. Shirali et al., *Assessing Resilience Engineering Based on Safety Culture and Managerial Factors*, 31 PROCESS SAFETY PROGRESS 17, 17 (2012).

[287] Peter Weißhuhn et al., *Ecosystem Vulnerability Review: Proposal of an Interdisciplinary Ecosystem Assessment Approach*, 61 ENV'T MGMT. 904, 904–05 (2018); Samuel S. Mamauag et al., *A Framework for Vulnerability Assessment of Coastal Fisheries Ecosystems to Climate Change—Tool for Understanding Resilience of Fisheries (VA—TURF)*, 147 FISHERIES RSCH. 381, 381–82 (2013).

[288] Notice of Final Decisions to Register Pesticide Products Containing Methyl Iodide and Written Evaluation, Vol. 2010-50, Cal. Dept. of Pesticide Regul. (Dec. 1, 2010).

[289] FROINES ET AL., *supra* note 99, at 12.

[290] *See* Malloy, *Principled Prevention*, *supra* note 12, at 140–44 (exploring the value of comparative assessment in prevention-based regulation); MARY O'BRIEN, MAKING BETTER

Risk assessment as currently practiced does not typically address such issues, primarily because "on the ground" risk analysis does not generally give meaningful attention to prevention-based and resilience-based options. That is not to say that risk managers engaging in conventional risk analysis would ignore considerations such as the relative cost and efficacy of control options in choosing among control-based mitigation measures. Rather, just that broader inclusion of prevention-based and resilience-based options renders the comparative assessment more complex.

Comparative assessment methods of this sort are available; they go by different names in different domains.[291] For example, alternatives assessment has developed extensively in the chemicals area,[292] with roots in the U.S. Environmental Protection Agency's Design for the Environment program.[293] Alternatives assessment (AA) is a method for systematically identifying and comparing potentially safer alternatives to materials, processes, or activities on the basis of their hazards, performance, and economic viability.[294] Likewise, forms of comparative assessment have been developed for application in the facility safety area to assist in consideration of prevention- and resilience-based measures.[295]

The particulars of the comparative assessment method will vary depending upon the decision context. As a general matter, though, any such method will

---

ENVIRONMENTAL DECISIONS: AN ALTERNATIVE TO RISK ASSESSMENT 191–202 (2000) (describing the essential features of alternatives assessment, broadly defined).

[291] O'BRIEN, *supra* note 290, at 147–69 (surveying forms of comparative assessment used in a variety of settings, including the National Environmental Policy Act, the Endangered Species Act, and the Montreal Protocol on Substances that Deplete the Ozone Layer).

[292] *See generally* NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., A FRAMEWORK TO GUIDE SELECTION OF CHEMICAL ALTERNATIVES (2014) (providing guidance on methods for chemicals alternatives assessment).

[293] Timothy Malloy et al., *Decisions, Science, and Values: Crafting Regulatory Alternatives Analysis*, 35 RISK ANALYSIS 2137, 2140 (2015) [hereinafter Malloy et al., Decisions, Science, and Values]; Emma T. Lavoie et al., *Chemical Alternatives Assessment: Enabling Substitution to Safer Chemicals*, 44 ENV'T SCI. & TECH. 9244, 9244–46 (2010). In a growing number of jurisdictions, including California and the European Union, manufacturers of certain chemicals of high concern are required to engage in AA. Christian Beaudrie et al., *Evaluating the Application of Decision Analysis Methods in Simulated Alternatives Assessment Case Studies: Potential Benefits and Challenges of Using MCDA*, 17 INTEGRATED ENV'T ASSESSMENT & MGMT. 27, 28 (2021).

[294] Molly M. Jacobs et al., *Alternatives Assessment Frameworks: Research Needs for the Informed Substitution of Hazardous Chemicals*, 124 ENV'T HEALTH PERSPS. 265, 265–67 (2016); O'BRIEN, *supra* note 290, at 191–202 (describing the essential features of alternatives assessment).

[295] *See, e.g.*, Faisal I. Khan & Paul R. Amyotte, *I2SI: A Comprehensive Quantitative Tool for Inherent Safety and Cost Evaluation*, 18 J. LOSS PREVENTION PROCESS INDUS. 310, 312–20 (2005) (describing a method for assessment of potentially inherently safer processes); Lars Koch & Nicholas A. Ashford, *Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH*, 14 J. CLEANER PROD. 31, 36–37 (2006) (discussing Technology Options Analysis).

include at least three key steps.[296] First, the assessor must identify the potential slate of mitigation measures. (Much of this would occur during problem formulation.)[297] Second, key criteria against which the alternatives are compared must be selected. For example, in the chemicals area the criteria typically cover five major areas: physical chemical hazards (i.e., explosivity and flammability), human health impacts, environmental and ecological impacts, technical feasibility, and economic feasibility.[298] Last, the assessor must collect and compile data regarding how well each alternative performs with respect to each criterion.[299] The results of the comparative assessment are often presented in a performance matrix, allowing for visual inspection of disaggregated data to easily identify trade-offs presented by the alternatives.[300]

3. Evaluation

The evaluation element, sometimes called "risk management" step,[301] involves appraisal of the trade-offs presented by the slate of candidate mitigation measures, culminating in selection of a preferred option. Regulators and regulated entities face choices among mitigation measures in a wide range of settings,[302] including approving uses of toxic substances and pesticides, choosing Superfund remedies,[303] and selecting worker protection measures.[304] Much has

---

[296] Jacobs et al., *supra* note 294, at 275–78. Some comparative assessment methods may also include a fourth step: evaluation of the relevant trade-offs among the alternatives, culminating in the selection of an alternative, if appropriate. *Id.* at 275. This sort of trade-off analysis is discussed in Section II.B.3 (Evaluation), below. Renn and Klinke consider all of these steps as part of evaluation. *See* Renn & Klinke, *supra* note 24, at 17, 19.

[297] In the chemicals and pesticides area, prevention alternatives may include drop-in chemical substitutes or product/process redesign, which eliminates the need for a chemical. Joel A. Tickner et al., *Advancing Safer Alternatives Through Functional Substitution*, 49 ENV'T SCI. & TECH. 742, 743–44 (2015).

[298] Jacobs et al., *supra* note 294, at 267.

[299] Malloy et al., *Decisions, Science, and Values*, *supra* note 293, at 2140. This step draws upon a variety of methods, tools, and disciplines. Depending on the focus of the criteria, resources, and availability, the data may be observational, experimentally derived, or predicted. Ziye Zheng et al., *Combining in Silico Tools with Multicriteria Analysis for Alternatives Assessment of Hazardous Chemicals: A Case Study of Decabromodiphenyl Ether Alternatives*, 53 ENV'T SCI. & TECH. 6341, 6342 (2019).

[300] Malloy et al., *Decisions, Science, and Values*, *supra* note 293, at 2141.

[301] *See* NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 241–43 ("Risk management involves choosing among the options after the appropriate assessments have been undertaken and evaluated.").

[302] Malloy et al., *Decisions, Science, and Values*, *supra* note 293, at 2147.

[303] *See* 40 C.F.R. § 300.430 (2020) (setting out remedy selection process for hazardous site cleanup under Superfund).

[304] *See* 29 C.F.R. pt. 1910, 1915, 1917, 1918, 1926 (2020) (describing the Occupational Safety and Health Administration's evaluation of a variety of engineering controls and work practices in light of technical feasibility, economic impact, and risk reduction to establish permissible exposure limits).

been written about how to structure the evaluation process.[305] In practice, there is typically little in terms of specific regulatory standards or guidance regarding how the agency makes the decision. Consider the new chemical review process for synthetic algae. The EPA provides much guidance regarding how to conduct the risk assessment but virtually no formal direction about how to choose mitigation measures.[306] Likewise, the OSHA Process Safety Management regulations offer no standards for how to select among viable mitigation measures.[307] The story for pesticide approval in California is somewhat better; DPR guidance articulates a general standard for selection among mitigation measures and explicitly acknowledges the subjective nature of such value-based judgements.[308] That said, DPR does not establish a systematic evaluative process to guide the decision-making or keep subjectivity within bounds.

The evaluation process can be difficult when considering a set of control-based options. For example, mandating that a volatile pesticide be mixed into the soil may reduce the risks of airborne drift to neighboring homes more cheaply than tarping the field but could increase the risk to groundwater.[309] The trade-offs can be thorny, and the decision-maker must be careful to not replace one risk with another potentially worse risk.[310] Incorporating prevention- and resilience-based options can exacerbate the complexity of the decision-making, particularly because such options may expand the set of criteria to be considered in comparing options. Most control options are "add-on" technologies that impact neither the basic technology used by the regulated entity nor the entity's organizational structure or norms.[311] Prevention-based options (such as substitution of materials and process changes) and resilience-based measures (including adoption of safety culture practices) can require reconsideration of core business operations. Consider the case of pesticide application. It is one thing to choose between personal protective equipment for workers versus use of tarps to control occupational exposure. It is quite another to evaluate whether the trade-offs in efficacy and cost presented by an alternative, safer pesticide is warranted, or whether substantial changes to a grower's established agricultural practices are preferrable to using the toxic pesticide.

---

305 NAT'L RSCH. COUNCIL, SILVER BOOK, *supra* note 28, at 249–51; PCCRARM, *supra* note 28, at 29–39.
306 *See supra* Section I.B.3.
307 *See supra* pp. 15–17.
308 DPR, GUIDE, *supra* note 46, at 52 (Regulators are to "select a risk-reduction strategy of integrated measures that are scientifically sound and cost-effective, and that reduce or prevent risks while taking into account social, cultural, ethical political and legal considerations.") and 54 ("The process is necessarily subjective in that it requires value judgments on safety margins and the reasonableness of control measures.").
309 *Id.* at 54.
310 *See* Jonathan Baert Wiener, *Managing the Iatrogenic Risk of Risk Management*, 9 RISK: HEALTH, SAFETY & ENV'T 39, 40 (1998) ("Interventions may reduce 'target risks' but may also increase 'countervailing risks.' ").
311 *See supra* pp. 13–14.

How then to select from the slate of mitigation measures? The literature does not offer much in the way of guidance. Few commentators explicitly confront the role of prevention-based and resilience-based measures as forms of risk mitigation. Those that do tend to leave the evaluation process somewhat open, acknowledging the value of context-specific evaluation without specifically elaborating on how it would be done.[312] There is a tendency to essentially allocate control, prevention, and resilience mitigation strategies to different default contexts. Recall that conventional risk analysis is hindered in three contexts: where important data is unavailable, where substantial complexity or ignorance is present, and where indeterminacy exists.[313] Marchant and Stevens reserve resilience-based measures primarily for dealing with complexity and ignorance.[314] Renn and Klinke suggest that prevention is best suited to situations of "intolerable risk"—meaning situations in which likely catastrophic impacts outweigh any potential benefits.[315] In the face of complexity, they recommend adoption of "adaptive" resilience-based measures, namely, monitoring and evaluation of outcomes.[316] For data unavailability, which they categorize as a form of uncertainty, Renn and Klinke call for "coping" resilience-based measures such as monitoring, emergency preparedness, and diversification of protective measures.[317]

No doubt that the "sorting hat" function of such categories highlights some particular strengths of the different types of mitigation measures. It can also help simplify the evaluation and selection process. But too much categorical thinking can generate unjustified silos, obscuring the broader benefits of prevention-based and resilience-based measures and discouraging integrated use of multiple measures. As I discuss in Sections III.A.1 and 2, prevention and resilience are not as limited in value as a categorical approach suggests; they can both be

---

312 *See* Marchant & Stevens, *supra* note 6, at 245 ("Each of the . . . governance approaches will have some relevance for any risk management decision, with the relative weight given to any particular tool in a given context dependent on the strengths and weaknesses of each of the other three approaches and the reinforcement of the four methods upon each other."); Renn & Klinke, *supra* note 24, at 14, 19–20 (observing that the evaluation process "can be described in terms of classical decision theory" and citing other works that lay out a systematic framework for selecting among risk management options).

313 *See supra* Section I.C.

314 Marchant & Stevens, *supra* note 6, at 247–48 ("[R]esilience is best suited for more complex systems that have the potential to create unanticipated or sudden surprises that were not foreseeable or preventable ex ante."). Marchant and Stevens do not discuss the role of prevention as defined in this Article, apparently conflating prevention-based options with conventional control-based approaches. *See id.* at 247 ("[R]esilience is different from, but complementary to, traditional ex ante risk assessment and risk management approaches for avoiding or preventing harm, which are well entrenched in regulatory law." (citations omitted)).

315 *See* Renn & Klinke, *supra* note 24, at 12, 14. Renn and Klinke also suggest without elaboration that "substitution" should be considered under conditions of data unavailability, which they define as a form of uncertainty. *Id.* at 15.

316 *Id.* at 15.

317 *Id.*

helpful in dealing with data unavailability, complexity, and indeterminacy.[318] And they can be used in combination to supplement one another.

To select the optimal set of mitigation measures, regulators ought to treat selection of mitigation measures like the classic multi-criteria decision that it is. Accordingly, they should draw upon well-established frameworks, methods, and tools from the field of decision analysis.[319] Multi-criteria decision-making involves selecting a course of action from a set of alternatives, based on how well the alternatives perform across a set of important criteria.[320] Anyone who has purchased a car or a smart TV has faced a multi-criteria decision problem. (For example, for the car, one may balance criteria such as purchase cost, reliability, gas mileage, safety, and other things.) Even such everyday decisions can present difficult trade-offs; for example, suppose one car excels on reliability but is quite expensive, while a very affordable alternative has "so-so" reliability. Selecting mitigation measures in a regulatory setting can be even more difficult with a larger number of criteria to weigh, greater uncertainty regarding performance, and higher stakes at the societal level.

Of course, the particular criteria relevant to evaluation of mitigation measures will vary depending upon the applicable law and the preferences of the regulator and stakeholders. But at a more general level, and assuming at least some level of rationality in their decision-making process, there ought to be some evaluative criteria against which the potential policy approaches are evaluated.[321] Drawing upon the evaluative criteria that appear in the literature, Table 8 sets out the types of criteria that are relevant to mitigation measure selection.[322]

---

318 *See supra* Section III.A.1, Section III.A.2.

319 A decision framework means the overall structure of the decision-making process—the particular steps in a certain order. Timothy F. Malloy et al., *Advancing Alternative Analysis: Integration of Decision Science*, 125 ENV'T HEALTH PERSPS. 066001-1, 066001-3 (2017) [hereinafter Malloy et al., *Advancing Alternative Analysis*]. Methods and tools are formal and informal aids, rules, and techniques that guide or facilitate those particular steps. *Id. See also* Malloy et al., *Decisions, Science, and Values*, *supra* note 293, at 2139 ("If one is cooking a meal, for example, the recipe is the framework, sauteing is a method, and pans and spatulas are tools.").

320 VALERIE BELTON & THEODOR J. STEWART, MULTIPLE CRITERIA DECISION ANALYSIS: AN INTEGRATED APPROACH 13–16 (2002).

321 Robert M. Friedman et al., *Environmental Policy Instrument Choice: The Challenge of Competing Goals*, 10 DUKE ENV'T L. & POL'Y F. 327, 328 (2000); ELINOR OSTROM ET AL., INSTITUTIONAL INCENTIVES AND SUSTAINABLE DEVELOPMENT: INFRASTRUCTURE POLICIES IN PERSPECTIVE 111 (1993).

322 *See* Malloy, *Principled Prevention*, *supra* note 12, at 166–68; Peter Bohm & Clifford S. Russell, *Comparative Analysis of Alternative Policy Instruments*, *in* 1 HANDBOOK OF NATURAL RESOURCE AND ENERGY ECONOMICS 395, 399–402 (Allen V. Kneese & James L. Sweeney eds., 1985); U.S. CONGRESS, OFF. OF TECH. ASSESSMENT, ENVIRONMENTAL POLICY TOOLS: A USER'S GUIDE 50–53 (1995).

TABLE 8: MITIGATION MEASURE EVALUATION CRITERIA

Effectiveness/ Protectiveness	The extent to which the measure is expected to achieve and maintain the regulatory goal/standard: for example, reduction of unreasonable risk or protection of human health and the environment.[323] This includes the reliability of the measure; that is, how prone it is to technology failure or operator error.[324]
Cost-Effectiveness	The cost of achieving a specified regulatory goal/standard, measured at the societal level and at the regulated entity level.[325]
Dynamic Efficiency	The capacity of the measure to encourage innovation and the diffusion of new technology.[326]
Social Efficiency	The extent to which the measure optimizes net social benefits.[327]
Social Equity	The extent to which the measure enhances equitable distribution of risks and benefits and advances meaningful participation in decision-making.[328]
Ease of Monitoring/ Enforcement	The difficulty in monitoring and measuring compliance and engaging in sufficient enforcement.[329]
Adaptability	The capacity of the measure to be revised to adjust to changed circumstance or new information.[330]
Individual Autonomy	The extent to which a regulatory approach restricts or enhances the choices available to the individual, including choices that may cause the individual injury.[331]
Economic Autonomy	The extent to which the measure constrains the regulated entity's capacity to order its operations and make economic decisions without interference.[332]
Institutional Capacity	The capacity of the regulated entity and/or the regulatory agency to effectively implement the measure, considering the entity or agency's skills, resources, and information sources.[333]

Multi-criteria decision analysis (MCDA) can help regulators sort through this messy decision environment. MCDA is not a single method or approach. Instead, it is a family of methods and tools designed to facilitate this type of

323 Friedman et al., *supra* note 321, at 345–47.
324 Malloy, *Principled Prevention*, *supra* note 12, at 168.
325 *Id.* at 170–71; Friedman et al., *supra* note 321, at 354–56.
326 Malloy, *Principled Prevention*, *supra* note 12, at 173; Friedman et al., *supra* note 321, at 365–67; Bohm & Russell, *supra* note 322, at 400–01.
327 Malloy, *Principled Prevention*, *supra* note 12, at 176–77; Bohm & Russell, *supra* note 322, at 399.
328 Friedman et al., *supra* note 321, at 351–53.
329 *Id.* at 346; Bohm & Russell, *supra* note 322, at 400.
330 Friedman et al., *supra* note 321, at 364–65; Bohm & Russell, *supra* note 322, at 400.
331 Malloy, *Principled Prevention*, *supra* note 12, at 179.
332 *Id.* at 183–84.
333 *Id.* at 186–87; Friedman et al., *supra* note 321, at 358–61.

decision-making in different contexts.[334] Some forms of MCDA are qualitative and simple to implement. Others are highly sophisticated, mathematically based methodologies. The various methods and tools have distinctive theoretical bases and address data uncertainty, the relative importance of decision criteria, an+d other issues differently.[335] That said, each MCDA approach essentially provides a systematic, observable process for evaluating alternatives in which an alternative's performance across the decision criteria is synthesized to generate a relative ranking.[336] At the conceptual level, most MCDA methods include three basic steps. In problem structuring, the decision-maker identifies the relevant alternatives, the criteria by which they are to be judged, and the metrics used to measure performance on each criterion. In model building, each alternative is assessed to determine how well it performs on each criterion, and the criteria are weighted to indicate their relative importance to the decision-maker. In model application, the alternatives' respective performance on the criteria and criteria weights are used to rank each alternative relative to the other alternatives.[337] Importantly, the MCDA output is not "the decision"; it simply assists the decision-maker and interested stakeholders in understanding the alternatives and trade-offs.[338]

The National Academy of Science has embraced the use of MCDA in regulatory decision making,[339] as have scholars.[340] Potential benefits of MCDA include greater transparency, facilitation of stakeholder engagement, more systematic consideration of disparate quantitative and qualitative criteria, and greater understanding of the trade-offs presented by the decision problem.[341] Yet MCDA

---

334 BELTON & STEWART, *supra* note 320, at 2.

335 *See* IGOR LINKOV & EMILY MOBERG, MULTI-CRITERIA DECISION ANALYSIS: ENVIRONMENTAL APPLICATIONS AND CASE STUDIES 4–7 (2012) (providing a brief overview of three types of MCDA—multi-attribute utility theory, analytical hierarchy process, and outranking); BELTON & STEWART, *supra* note 320, at 119–260 (describing several MCDA methods in detail).

336 Malloy et al., *Decisions, Science, and Values*, *supra* note 293, at 2142.

337 *See* LINKOV & MOBERG, *supra* note 335, at 4 (problem identification and structuring, model assessment and building, and model application); BELTON & STEWART, *supra* note 320, at 14 (discussing problem identification and structuring, model building, and model use).

338 Stefan Hajkowicz, *A Comparison of Multiple Criteria Analysis and Unaided Approaches to Environmental Decision Making*, 10 ENV'T SCI. & POL'Y 177, 177 (2007).

339 NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., DECISION MAKING FOR THE ENVIRONMENT: SOCIAL AND BEHAVIORAL RESEARCH PRIORITIES 23–40 (Garry D. Brewer & Paul C. Stern eds., 2005) (calling for the development and testing of formal tools for structuring decision processes).

340 Benjamin Trump et al., *A Decision Analytic Model to Guide Early-Stage Government Regulatory Action: Applications for Synthetic Biology*, 12 REGUL. & GOVERNANCE 88 (2018); Catherine D. Gamper & Catrinel Turcanu, *Multi-Criteria Analysis: A Tool for Going Beyond Monetization?*, *in* THE TOOLS OF POLICY FORMULATION: ACTORS, CAPACITIES, VENUES AND EFFECTS 121, 132–36 (Andrew J. Jordan & John R. Turnpenny eds., 2015); Malloy, *Principled Prevention*, *supra* note 12, at 146–48; NICHOLAS A. ASHFORD ET AL., EVALUATING CHEMICAL REGULATIONS: TRADE-OFF ANALYSIS AND IMPACT ASSESSMENT FOR ENVIRONMENTAL DECISION-MAKING (1980).

341 Beaudrie et al., *supra* note 293, at 28; Gamper & Turcanu, *supra* note 340, at 132–33; Gregory A. Kiker et al., *Application of Multicriteria Decision Analysis in Environmental Decision Making*, 1 INTEGRATED ENV'T ASSESSMENT MGMT. 95, 106 (2005).

approaches can be technically demanding and resource intensive, requiring skill sets not currently common within many regulatory agencies. And the breadth of MCDA methods available can make selection of the appropriate tool challenging.[342] From a more cynical perspective, some policymakers concerned about constraining their own professional or political discretion may be reluctant to employ MCDA.[343] For these and other reasons, while some regulatory agencies in the United States and Europe have begun to employ MCDA, regular use is spotty.[344] Meaningful incorporation of prevention and resilience into risk analysis will require adoption of some form of rigorous, structured decision making.

4. Implementation

Adoption of a resilience perspective calls for, among other things, the capacity to adapt to changing conditions. In light of this imperative, the implementation element of risk analysis must explicitly incorporate active monitoring and adaptation. The notion that risk analysis, broadly defined, should include post-implementation monitoring, evaluation, and revision is hardly new. Some twenty-five years ago, the Presidential/Congressional Commission on Risk Assessment and Risk Management observed that "[e]valuation is critical to accountability and to ensure wise use of scarce resources. Too often, past risk management actions have had little or no evaluation or follow-up after implementation . . . ."[345] It is easy enough to agree that we ought to evaluate how our mitigation measures are working and revise them as necessary. But what does that look like on the ground? The answer depends in large part on the particular context; there are many tools and methods for monitoring and evaluation available for varied settings. We return to the industrial safety and pesticide case studies to sample two "shovel-ready" approaches not currently in wide use.

Conventional risk assessment and mitigation in the industrial safety setting tends to be static. Facilities collect and analyze data regarding a process at a single moment in time, essentially assuming that the process operates unchanged until the next round of regular assessment.[346] But assumptions about the current status of the process or efficacy of mitigation options may be flawed. And the process and its associated risk mitigation systems degrade over time.[347] Dynamic

342 Malloy et al., *Advancing Alternative Analysis*, *supra* note 319, at 066001-8–066001-9; Gamper & Turcanu, *supra* note 340, at 132–33; Kiker et al., *supra* note 341.
343 Gamper & Turcanu, *supra* note 340, at 134–35.
344 *Id.* at 131–32; Kiker et al., *supra* note 341.
345 PCCRARM, *supra* note 28, at 45. *See also* RENN, *supra* note 24, at 43 (calling for monitoring of option performance—defined as "the systematic observation of the effects of the options once they are implemented"—as the last step of risk analysis).
346 Nicola Paltrinieri et al., *Towards Dynamic Risk Analysis: A Review of the Risk Assessment Approach and Its Limitations in the Chemical Process Industry*, 89 SAFETY SCI. 77, 84 (2016); Nicola Paltrinieri et al., *Dynamic Approach to Risk Management: Application to the Hoeganaes Metal Dust Accidents*, 92 PROCESS SAFETY AND ENV'T PROT. 669, 669–70 (2014).
347 Faisal Khan et al., *Dynamic Risk Management: A Contemporary Approach to Process Safety Management*, 14 CURRENT OPINION CHEMICAL ENG'G 9, 10 (2016).

risk assessment and management (DRA) is an emerging approach that monitors ongoing performance of the industrial process and the risk mitigation measures.[348] It "updates estimated risk of a deteriorating process according to the performance of the control system, safety barriers, inspection and maintenance activities, the human factor, and procedures."[349]

Identification of particular DRA-based approaches for ongoing monitoring and evaluation of risk mitigation is beyond the scope of this Article. It is worth noting, however, that numerous such approaches exist, differing in (among other things) the data used to monitor changing conditions[350] and the methods used to update risk estimates and mitigation options. Many DRA approaches focus upon accident precursor data and alarm databases to monitor and reassess risk.[351] Data regarding ongoing operations can then be used iteratively in conventional risk analysis methods, such as bow-tie analysis,[352] and other methods, such as Bayesian analysis, principal component analysis, or risk barometers.[353] In this way, risk estimates and mitigation measures update risk estimates and mitigation measures based upon actual operating conditions.[354]

Dynamic risk assessment illustrates monitoring and adaptation in a management-based regulatory scheme. The regulated entity itself is engaging in risk analysis—including monitoring and adaptation—at the operational level. Monitoring and adaptation are also important functional components of implementation by regulatory agencies. The pesticide registration case is illustrative. As described in Section I.B.1, California's Department of Pesticide Regulation runs a robust pre-market registration program for pesticides, identifying and enforcing mitigation standards for the use of hazardous pesticides.[355] Mitigation standards include use of personal protective equipment for workers applying the pesticides, buffer zones to protect residents of adjacent property, and required application

---

348 *Id.*
349 *Id.* at 10.
350 *Id.* at 11–13.
351 *Id.* An "accident precursor" is an abnormal event that could have—but did not—result in death or substantial property damage, often called a "near miss." Nima Khakzad et al., *On the Application of Near Accident Data to Risk Analysis of Major Accidents*, 126 RELIABILITY ENG'G AND SYS. SAFETY 116, 116 (2014). "Alarm data" is data regarding specified events that caused the process to vary from expected operating parameters. Warren D. Seider et al., *Introduction to Dynamic Risk Analyses*, *in* METHODS IN CHEMICAL PROCESS SAFETY, *supra* note 59, at 201, 202–03.
352 Nima Khakzad et al., *Dynamic Risk Analysis Using Bow-Tie Approach*, 104 RELIABILITY ENG'G AND SYS. SAFETY 36, 37 (2012).
353 Khan et al. *supra* note 347, at 12.
354 Requiring incorporation of resilience engineering concepts into facility safety processes would also enhance systematic monitoring and evaluation of risk assessment and management. Like dynamic risk assessment, resilience engineering acknowledges that an industrial facility is subject to constant, sometimes unexpected changes that affect safety. Dynamic risk assessment focuses on continuous evaluation of discrete processes. Resilience engineering instead focuses more broadly on the organization as a whole and on building the sensing and learning capacity of individuals.
355 *See supra*, Section I.B.1.

methods, among other things. Yet such mitigation standards are typically based on modeling and other predictive methods and tools. How do the agency and stakeholders know whether the assumptions and predictions made as part of the risk analysis process hold up on the ground over time?

DPR has several vehicles for monitoring and reevaluation of registered pesticides. The agency conducts exposure monitoring studies to assess pesticide exposure patterns and the effectiveness of existing controls.[356] However, the frequency and focus of such monitoring activities are *ad hoc*; such monitoring is not typically linked to or required as part of any specific registration. Two other features of the California pesticide program provide for somewhat more systematic monitoring and adaptation. First, registrants are under a continuing obligation to report to DPR any information the registrant receives or generates regarding adverse effects associated with the product.[357] Second, under certain conditions, DPR must reevaluate registered products: for example, where adverse effects reporting or air monitoring indicate that a registered pesticide may cause a significant adverse impact.[358] During reevaluation, DPR reviews existing data as well as new data required as part of the reevaluation process.[359] Depending upon the outcome of its analysis, DPR may impose additional mitigation measures or suspend or cancel the registration.[360] Overall, DPR's monitoring and adaptation approach is a bit reactive; the monitoring is not systematic and the standards triggering reevaluation are vague. But it does stand as a well-established effort to build resilience into the implementation element of risk analysis.

CONCLUSION

Risk analysis can trace its beginnings to the practices of the Asipu, a priest-like group living in the Tigris-Euphrates valley around 3200 B.C.[361] Members of the Asipu provided advice to individuals considering risky undertakings by analyzing alternatives using a simple ledger system, visualizing pros and cons, and

---

[356] DPR, GUIDE, *supra* note 46, at 71–72. DPR and county officials also investigate reports of pesticide exposures and pesticide-related illnesses submitted by local health officers, employee or public complaints, and news media, among other sources. *Id.* at 67–68. These activities and others reflect DPR's implementation of its "continuous evaluation" obligation under state law. *See* CAL. CODE. REGS. tit. 3, § 6226 (2021) (requiring DPR to "undertake continuous evaluation of all registered products").

[357] *Id.* § 6210 (requiring immediate disclosure of any "factual or scientific evidence of any adverse effect or risk of the pesticide to human health or the environment (including ambient air quality)").

[358] *Id.* § 6220.

[359] *Id.*

[360] DPR, GUIDE, *supra* note 46, at 39–40. DPR is required to report on the status of ongoing reevaluations semi-annually. *See* DEPT. OF PESTICIDE REGUL., SEMIANNUAL REPORT SUMMARIZING THE REEVALUATION STATUS OF PESTICIDE PRODUCTS DURING THE PERIOD OF JANUARY 1, 2020 THROUGH JUNE 30, 2020 (2020), https://www.cdpr.ca.gov/docs/registration/canot/2020/ca2020-11.pdf [perma.cc/ER78-JKKB].

[361] Vincent T. Covello & Jeryl Mumpower, *Risk Analysis and Risk Management: An Historical Perspective*, 5 RISK ANALYSIS 103, 103 (1985).

submitting reports on clay tablets.[362] The practice of risk analysis has evolved over the last 5000 years, taking advantage of theoretical and methodological advances in probability theory and other related fields.[363] In the last fifty years, conventional risk analysis has come to play a central role in decision making by regulators and private parties.[364] But it must continue to change with the times, responding to a broader range of risks and embracing advances in disciplines such as complexity theory and decision analysis. And it must confront its own limitations—incomplete data, complexity and ignorance, and indeterminacy.

The principles of prevention and resilience offer a means of surmounting those limitations. While isolated applications of the prevention and resilience principles exist, risk analysis practice has yet to systematically incorporate these principles. This Article makes the case for integration and lays out a path forward, recognizing that taking prevention and resilience seriously will require fundamental changes to the architecture of risk analysis. Some of the most pressing challenges are methodological, including developing and implementing more comprehensive vulnerability assessment and comparative assessment methods and crafting rigorous, but practical, multi-criteria decision analysis tools. Much promising work in these areas is already underway; drawing upon that work can expediate this next step in the evolution of risk analysis.

362 *Id.*
363 *See* Aven, *supra* note 5, at 1–3 (discussing advances in risk analysis).
364 *Id.* at 1.