PRINCIPLED PREVENTION

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I. INTRODUCTION

Is an ounce of prevention really worth a pound of cure when it comes to the regulation of chemicals? If you believe the aspirational statements of legislators, regulators, public health scientists and others, the answer is a definite "yes." Yet when you look at the structure of regulatory programs and actual practices on the ground, that ounce is hard to find. Chemical policy in the United States essentially relegates prevention of chemical exposures to voluntary programs and initiatives. Mainstream regulation focuses instead on managing exposures, largely relying on control technologies to capture or destroy emissions and discharges of hazardous chemicals. This article asks what a mainstream prevention-based regulatory system would look like. It presents a typology of prevention-based regulatory approaches and a set of principles for evaluating them. My ultimate aim is to offer policymakers and stakeholders a conceptual and normative map for getting to prevention.

Today there are more than 80,000 compounds in the EPA's inventory of chemicals.[1] We clean with chemicals in our homes, eat and drink them, treat our diseases with them, grow our food with them, slather them on to moisturize and protect our skin, and then wash them off with still other chemicals. We are a society deeply invested in the development and use of chemicals. Many of these chemicals are known to be hazardous, linked with a range of diseases and conditions including cancer, reproductive problems, birth defects, neurologic disorders, asthma, and other impairments.[2] Yet even more chemicals have never been systematically tested for their health or environmental effects. Indeed, fewer than 500 of the chemicals in commerce have been comprehensively studied regarding health effects. So

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1. Under Section 8(b) of the Toxic Substances Control Act, the EPA maintains an inventory of chemicals substances registered for distribution in commerce. Toxic Substances Control Act, Pub. L. No. 94-469, § 8(b), 90 Stat. 2003, 218–19 (2002), *available at* www.epw.senate.gov/tsca.pdf. The large number of chemicals on the inventory may be misleading, however, as 300 of those chemicals account for more than ninety-nine percent of the volume of chemicals currently sold in the United States each year. In fact, less than 5,500 chemicals are produced in amounts exceeding 10,000 pounds per year. David E. Adelman, *A Cautiously Pessimistic Appraisal of Trends in Toxics Regulation*, 32 WASH. U. J.L. & POL'Y 377, 385 (2010).

2. *See* Michael P. Wilson, Megan R. Schwarzman, Timothy F. Malloy, Elinor W. Fanning and Peter J. Sinsheimer, GREEN CHEMISTRY: CORNERSTONE TO A SUSTAINABLE CALIFORNIA 12–17 (University of California Centers for Environmental and Occupational Health 2007) (summarizing human health impacts associated with chemical exposures).

the societal benefits of chemistry have come with a price, albeit one which has yet to be clearly delineated.

The regulatory state has responded to these concerns. Initially that response came in the form of environmental and public health laws enacted in the early 1970s. Generally speaking, these laws and the regulatory programs they spawned tackled the pollutants and wastes resulting from the production and use of chemicals rather than the chemical products themselves. Congress finally turned to the regulation of chemicals as chemicals with the passage of the federal Toxic Substances Control Act (TSCA) in 1976.[3] More than thirty-five years later, the strong consensus among policymakers, academics, environmental groups, and even industry is that TSCA is a failure and reform is needed.[4] Clearly, as a policy matter (and a political matter) any reform of chemical regulation in the United States must address widely cited flaws in the TSCA.[5] Yet there is a more fundamental issue to be faced in crafting chemical policy reform, one that implicates the foundational structure of chemical regulation itself.

Existing chemical regulation is based upon what I call the "conventional risk management paradigm." This paradigm tends to accept the use of

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3. Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (codified as amended at 15 U.S.C. §§ 2601–2629 (2012)). President Nixon's Environmental Quality Council raised the alarm about toxic chemicals as early as 1971 with its *Toxic Substances* report. Linda-Jo Schierow, *The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements*, CONG. RESEARCH SERV. 2 (Apr. 1, 2013), *available at* https://www.fas.org/sgp/crs/misc/RL31905.pdf. Over the ensuing five years, during the Nixon and Ford administrations, the United States House of Representatives and the United States Senate wrangled over successive versions of a comprehensive chemical policy law until finally enacting the TSCA.

4. *See*, *e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-825, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS, 8–9 (2007), *available at* www.gao.gov/new.items/d07825.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM, 21–22 (2005), *available at* www.gao.gov/new.items/d05458.pdf; John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 318–30 (1991); Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 ENVTL. LAW. 99, 120–23 (1999); *see generally*, Richard Denison, *Ten Essential Elements in TSCA Reform*, 39 ENVTL. L. REP. (ENVTL. LAW INST.) 10020 (2009), *available at* http://www.edf.org/content/ten-essential-elements-tsca-reform.

5. In fact, the numerous bills seeking national reform over the last six years do just that. *See* Chemical Safety Improvement Act, S. 1009, 113th Cong. (2013); Safe Chemicals Act of 2011, S. 847, 112th Cong. (2011); Kid-Safe Chemicals Act of 2008, S. 3040, 110th Cong. (2008); Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. (2005); Child, Worker, and Consumer-Safe Chemicals Act of 2005, H.R. 4308, 109th Cong. (2005).

hazardous chemicals and production processes as a given, and mitigates their harmful impacts through engineering controls or work practices.[6] Concerned about the toxic effects of hexavalent chromium emissions on workers at an electroplating shop? Conventional risk management responds by identifying an acceptable exposure level based upon use of a ventilation system, and requires companies to meet that exposure level. Worried that hazardous pesticides sprayed in strawberry fields may drift to adjacent schools or homes? Conventional risk management establishes procedures for spraying and mandatory buffer zones to ensure that pesticide levels reaching the school and homes are "safe" as defined by the statute or regulatory agency. The efficacy of conventional risk management depends heavily upon two assumptions: (1) that regulators are able to identify acceptable or safe exposure levels; and (2) that engineering controls such as emission control devices can attain those levels consistently. Both assumptions have been under sustained attack in the chemical policy reform debates.

What I call the "prevention-based" approach to chemical regulation stands as an alternative to conventional risk management. At the conceptual level, a prevention-based approach seeks to avoid or minimize the use of hazardous materials or processes in the first place.[7] This eliminates (or at least substantially reduces) reliance on control measures and, in some forms of prevention-based regulation, even the need to identify safe exposure levels.[8] The notion of prevention has lurked in the periphery of regulatory programs and private environmental management for decades in various forms, including pollution prevention, cleaner production, inherently safer design, and most recently green chemistry. Yet rarely has it found a foothold in enforceable mainstream regulation. However, in the last few years, increasingly insistent calls for deployment of a "prevention-based" regulatory approach to environmental and occupational exposures to toxic chemicals have emerged from the chemical policy debates.[9]

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6. Timothy F. Malloy, *Of Natmats, Terrorists, and Toxics: Regulatory Adaptation in a Changing World*, 26 UCLA J. ENVTL. L. & POL'Y 93, 96–97, 109 (2008).

7. *Id.*

8. NICHOLAS A. ASHFORD & CHARLES C. CALDART, ENVIRONMENTAL LAW, POLICY AND ECONOMICS 41–42 (2008); Malloy, *supra* note 6, at 109.); Mark Rossi et al., *Alternatives Assessment Framework of the Lowell Center for Sustainable Production*, LOWELL CENTER FOR SUSTAINABLE PRODUCTION 3–4 (2006), *available at* www.chemicalspolicy.org/downloads/FinalAltsAssess06.pdf.

9. *See* National Conversation on Public Health and Chemical Exposures, *Addressing Public Health and Chemical Exposures: An Action Agenda* 19–29 (June 2011), *available at* http://www.nationalconversation.us/action-agenda/downloads; Richard J. Jackson & Timothy F.

In theory, prevention-based approaches have the potential to overcome the identified flaws in the risk management approach. However, because prevention-based approaches have not been widely adopted, there is little evidence regarding its actual performance in a mainstream regulatory setting. Moreover, much of the discussion of prevention-based approaches in the literature is conceptual; the approach has yet to be systematically operationalized in the context of mainstream regulation. The fractured history of prevention in environmental policy—swinging almost haphazardly over time through disjointed concepts of pollution prevention, clean production and the like—and its relegation to essentially voluntary contexts have undermined sustained, comprehensive attention to its normative and scientific foundations. As a result, two critical questions have been left largely unanswered: what methodological advances are needed to support mandatory prevention-based regulation and how *should* such regulation be structured?

This article addresses those two questions. The first question focuses on building capacity for prevention-based regulation. In other words, are there tools needed to engage in prevention-based regulation? In a conventional risk management regime, the policymaker essentially identifies and then codifies an acceptable exposure level for the chemical without considering whether other chemicals or processes are safer.[10] For a variety of reasons, many prevention-based approaches eschew reliance on a discrete acceptable exposure level however defined, seeking instead to identify and deploy safer alternatives. This perspective is often driven by skepticism regarding government's ability to accurately and fairly identify a safe exposure level. That skepticism is typically coupled with a commitment to "life-cycle" thinking, requiring consideration of a broad range of impacts in judging the safety of a chemical including human impacts, ecological effects, and resource and energy use. A prevention-based approach thus requires a

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Malloy, *Environmental Public Health Law: Three Pillars*, 39 J. L. MED. & ETHICS 34, 35–36 (2011), *available at* stpp.ucla.edu/sites/default/files/Three%20Pillars.pdf; Suzanne Reuben, *Reducing Environmental Cancer Risk: What We Can Do Now*, U.S. DEP'T OF HEALTH AND HUMAN SERV. 103 (2010); Joel Tickner, *Commentary: Barriers and Opportunities to Changing the Research Agenda to Support Precaution and Primary Prevention*, 17 INT'L J. OCCUPATIONAL MED. & ENVTL. HEALTH 163, 163–71 (2004).

10. *See infra* Section II. Admittedly, this characterization over-simplifies conventional regulation; many conventional regulatory programs involve some form of comparative analysis. For example, in technology-based regimes, regulators often compare a range of pollution control technologies to identify the best performing technology on which to base the exposure limit. That said, such evaluations are typically based on just two primary criteria, emission reduction and cost, and do not require sophisticated comparison of multiple, incommensurable criteria.

methodology for the identification and comparative evaluation of potential alternatives. This article describes the state of emerging alternatives analysis methods, and considerations for their use in the regulatory setting.

Regarding the second question, the article presents a typology of structural approaches, and offers a discrete set of normative principles for evaluating and choosing among those approaches. As with most important choices, the decision-maker (be they a policymaker, an academic, or a stakeholder in the regulatory process) will likely value some principles over others, and find that some deeply held principles actually conflict with one another. From a rationalist perspective, the choice of approach should be governed by how well the respective options match up with the decision-maker's preferences regarding those principles. Recognizing that preferences will vary among decision-makers, the article does not attempt to identify the best structure for prevention-based regulation. Instead, it maps the potential approaches and evaluates them against the design principles, leaving it to the reader to consider which approach, and which constellation of principles, they most value.

Of course policymaking is not simply a rational, analytical exercise. It is strategic and political, and compromises are often made so as to secure some reform, even if it is not the decision-maker's most preferred policy approach. Nonetheless, even recognizing the vagaries of real world policymaking, this article's focus on design principles should be of value to all parties engaged in the policy scuffle. Even when compromising, one should know the value of what they have obtained; the mapping of structure against design principles offers one method for making that assessment.

The article begins in Section II with an overview of the existing risk management approach, including examples of lost opportunities for prevention. Section III surveys the limitations of the risk management paradigm as identified by proponents of prevention, and begins to lay the normative groundwork for the prevention-based regulation. In Section IV, the article operationalizes prevention, beginning with discussion of the goals and structure of alternatives analysis. Section IV then sets out a typology of prevention-based approaches to regulation. The article concludes in Section V by presenting a set of design principles against which each of the prevention-based approaches is evaluated.

II. FRAMING THE CONVENTIONAL RISK MANAGEMENT APPROACH

This section distinguishes between two competing regulatory approaches: the dominant risk management approach and the emerging prevention-based approach. Each is intended to protect public health and the

environment, while minimizing the economic impacts of regulatory intervention. Yet the two aim to achieve these goals in fundamentally different ways. The risk management approach implicitly assumes that the use of the toxic chemical should continue, but seeks to control its effects. (In *very* limited circumstances, the risk management approach pursues attainment of the acceptable level by banning or phasing out a chemical.[11]) The prevention-based approach instead seeks first to avoid the use of the hazardous chemical, relying upon control of effects as a secondary strategy.[12]

The risk management approach exhibits two signature features: setting "acceptable" exposure levels and relying on engineering controls to achieve such levels. Regulators develop "acceptable" exposure levels (ACLs) through a variety of methods, some focusing primarily on health effects, and others relying more heavily upon best available control measures. Health-based levels are typically generated using risk assessment, a methodology for characterizing the health risks of chemical exposures. In regulatory programs, risk assessment typically consists of four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization.[13] The statute (or, in some cases, agency officials) make the policy judgment of how much health risk is tolerable, and risk assessment is used to translate that policy choice into a quantifiable exposure level. Technology-based levels are set by reference to the amount of risk reduction achievable by the best control technology available to the relevant industry sector.[14] In many cases, the ACL is a hybrid of health and

11. Richard B. Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 CALIF. L. REV. 1256, 1319 (1981). Typically, however, such bans are *ad hoc* animals, implemented or instigated through legislative action rather than by the independent acts of regulators.

12. ASHFORD & CALDART, *supra* note 8; Malloy, *supra* note 6, at 109.

13. *See* COMMITTEE ON IMPROVING RISK ANALYSIS APPROACHES USED BY THE U.S. EPA, NATIONAL RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 26–53 (2009) [hereinafter NRC, SCIENCE AND DECISIONS]; FRANK B. CROSS, ENVIRONMENTALLY INDUCED CANCER AND THE LAW: RISKS, REGULATION, AND VICTIM COMPENSATION 41–67 (1989). For useful histories of the development and use of risk assessment methodologies in U.S. environmental regulation, *see* Matthew D. Adler, *Against "Individual Risk": A Sympathetic Critique of Risk Assessment*, 153 U. PA. L. REV. 1121, 1133–39 (2005); *see generally* Ellen K. Silbergeld, *Risk Assessment: The Perspective and Experience of U.S. Environmentalists*, 101 ENVTL. HEALTH PERSP. 100 (1993), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1519738/.

14. Gary E. Marchant et al., *Risk Management Principles for Nanotechnology*, 2 NANOETHICS 43, 45 (2008); CROSS, *supra* note 13, at 90–93.

technology factors. For example, a health-based level may be constrained by concerns over technical or economic feasibility.[15]

Beyond its role in setting technology-based standards, control technology is also important in achieving the ACL, regardless of whether that level is health-based or technology-based. Customary controls include engineering measures that capture or divert emissions and discharges (including air pollution control devices or work area ventilation) and work practice standards that minimize emission or exposures (such as mandatory buffer zones around pesticide application areas). In most cases the type of control is largely left to the discretion of the regulated entity, so long as the acceptable level is attained. For a variety of reasons, however, in practice most businesses adopt the control technology relied upon by the regulators in setting the ACL (the "reference technology").[16]

The central principle underlying prevention-based regulation is to avoid the risk by avoiding the chemical. Accordingly, it seeks to minimize the use of toxic chemicals by mandating or directly incentivizing the adoption of safer alternative chemicals or processes wherever feasible.[17] Prevention relies upon a set of strategies, often characterized as substitution, minimization and moderation.[18] Substitution, typically identified as the preferred strategy, refers to the replacement of the hazardous chemical or process with a safer substitute.[19] Where a "drop-in" replacement is not feasible, prevention calls for adjustment of the product (or process) design to minimize the use of the chemical.[20] Alternatively, in a moderation strategy, the chemical itself (or the product or process in which it is used), could be modified so as to reduce the hazards, such reducing the temperature at which a process operates to well below the flashpoint for a flammable chemical used in that process.[21]

The remainder of this section provides an overview of the existing conventional risk management approach in a variety of regulatory programs. Each of these programs presents opportunities to embrace prevention-based regulation, what I call "embedded prevention." In fact, to

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15. *See infra* note 74 and accompanying text (describing standard setting under OSHA).

16. Timothy F. Malloy, *The Social Construction of Regulation: Lessons from the War Against Command and Control*, 58 BUFF. L. REV. 267, 313–17 (2010).

17. Karla Armenti et al., *Joint Occupational and Environmental Pollution Prevention Strategies: A Model For Primary Prevention*, 13 NEW SOLUTIONS 241, 242 (2003); Malloy, *supra* note 6, at 109–10.

18. Malloy, *supra* note 6, at 109–10.

19. *Id.*

20. *Id.*

21. *Id.* at 114.

varying degrees, the statutory language and legislative histories underlying the programs actually call for a prevention-based approach.[22] The preference for prevention is amplified by the explicit language of the 1990 Pollution Prevention Act, which declared that it is "the national policy of the United States that pollution should be prevented or reduced at the source whenever feasible."[23] Yet the statute-specific statements and broader mandate of the Pollution Prevention Act have faded to the background, and for the most part, the opportunities presented by embedded prevention have gone largely untapped, for reasons that I discuss elsewhere.[24]

A. Gatekeeper Programs and Risk/Benefit Balancing

In "gatekeeper programs," the government reviews the safety of chemicals before their introduction into commerce. (Such programs typically also include "delayed gatekeeper" provisions that authorize or even mandate the agency to re-evaluate previously regulated chemicals, as well as chemicals in existence prior to implementation of the review program.)[25] Gatekeeper programs generally adopt the "unreasonable risk" standard in evaluating new chemicals, which requires that the benefits of the chemical outweigh its risks, taking into account any restrictions imposed by the reviewing agency. In practice, however, the risk/benefit balancing tends to focus heavily upon identifying and achieving ACLs, and only rarely involves any balancing or meaningful consideration of safer alternatives.[26] The federal gatekeeper programs for pesticides and for chemicals are illustrative.

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22. *See, e.g.*, 42 U.S.C. § 13101(b) (2012).

23. *Id.*

24. Timothy F. Malloy & Peter S. Sinsheimer, *Innovation, Regulation and the Selection Environment*, 57 RUTGERS L. REV. 183, 212–17 (2004).

25. *See* 15 U.S.C. § 2605 (2012) (delayed gatekeeping under TSCA); Lynn R. Goldman, *Preventing Pollution? U.S. Toxic Chemicals and Pesticides Policies and Sustainable Development*, 32 ELR 11,018, 11,023–29 (2002), *available at* http://www.healthandenvironment.org/%3Fmodule=uploads&func=download&fileId=35 (describing delayed gatekeeping under FIFRA).

26. *See, e.g.*, Pesticides; Procedural Regulations for Registration Review, 71 Fed. Reg. 45,720, 45,725 (2006)

1. Risk Management in Pesticides

New pesticides must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prior to commercial use.[27] FIFRA generally allows for registration for any pesticide that will not cause unreasonable adverse effects on the environment, taking into account any restrictions on its use imposed by EPA as part of the registration decision.[28] "Unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[29]

In theory, the unreasonable risk standard of FIFRA incorporates at least some characteristics of a prevention-based approach. The balancing of economic, social and environment costs against corresponding benefits implicitly calls for consideration of safer alternatives. Assume that a company submits a highly toxic pesticide for registration (the "candidate" pesticide) for use on an important crop. As a first step, EPA would compare the costs (broadly defined to include adverse health, environmental, social, and economic impacts) to the benefits of using the candidate pesticide. In assessing those costs, the agency would take into account the mitigating effect of feasible restrictions such as buffer zones, procedures for applying the pesticide to fields, and emission limits to protect farmworkers. If those costs exceed the benefits, registration would be denied.

Now assume that a viable, substantially safer alternative pesticide exists that can also be used effectively on the crop. Presumably, the benefit accruing from a dangerous chemical is significantly reduced where a viable, safer alternative exists. (Indeed, the Conference Committee report for the Toxic Substances Control Act explicitly adopted that view with respect to the statute's use of the same term, observing that the standard takes into account "the availability of substitutes."[30]) From a prevention perspective, the existence of the significantly safer alternative pesticide shifts the

27. 7 U.S.C. § 136a(a) (2012).

28. 7 U.S.C. § 136a(c)(5) (2012).

29. 7 U.S.C. § 136(bb)(1) (2012). That same standard applies where EPA engages in "delayed gatekeeping" activities under FIFRA, i.e., periodic review of existing registrations, or suspension or cancellation of registrations. *See* 7 U.S.C. § 136d(b) (2012) (describing the cancellation of a chemical's registration); 40 C.F.R. § 155.40 (2009); Environmental Def. Fund v. EPA, 548 F.2d 998, 1003 (D.C. Cir. 1976) (describing the suspension of a chemical's registration).

30. John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 731 (2008) (citing H.R. Rep. No. 94-1341, 13–14 (1976)).

balance against registration. The agency may deny registration, or perhaps impose more stringent restrictions so as to bring risks associated with its use in line with the risks associated with the safer substitute.

Despite the potential for prevention-based implementation of this program, "on-the ground" decision-making under FIFRA has instead strongly embraced a conventional risk management approach. As described in more detail below, EPA structured the registration decision as a two-stage analysis: risk mitigation, followed *(if necessary*) by a balancing of residual risk against benefits. Where control measures are incapable of attaining the acceptable level, approval of the new pesticide is denied unless the social benefits of the chemical outweigh its health risks.

EPA's 2007 registration of the fumigant methyl iodide is striking example of this practice. Methyl iodide is a fumigant used to control destructive insects and worms, soil borne pathogens, and weed seeds for field grown strawberries, peppers, tomatoes, and other plants and trees.[31] In 2007, after performing an extensive human health risk assessment and ecological assessment, EPA concluded that methyl iodide would not create unreasonable risk if the pesticide was applied in accordance with specific restrictions mandated in the registration.[32] In its decision document, EPA identified three health concerns: inhalation toxicity, developmental toxicity, and neurotoxicity.[33] The agency established health-based "levels of concern" for residential and occupational exposures to methyl iodide, i.e., levels above which exposure would be unacceptable.[34] Based upon its human health risk assessment, EPA concluded that absent some type of mitigation measures, application would expose both farm workers and bystanders (meaning people at homes, businesses or schools adjacent to the field) to pesticide emissions above its levels of concern. Accordingly, EPA imposed two control strategies designed to reduce emissions to acceptable levels: the presence of buffer zones around farmland at which methyl iodide is applied to reduce bystander exposure and the use of personal protective

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31. J.M. Duniway, *Status of Chemical Alternatives to Methyl Bromide for Pre-Plant Fumigation of Soil*, 92 PHYTOPATHOLOGY 1337, 1337 (2002).

32. *See Pesticide Fact Sheet*: *Iodomethane*, EPA 20–21 (2007), *available at* http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-000011_01-Jan-07.pdf. Iodomethane is also known as methyl iodide. *Methyl Iodide (Iodomethane)*, EPA (2000), *available at* http://www.epa.gov/ttn/atw/hlthef/methylio.html.

33. *Pesticide Fact Sheet*: *Iodomethane*, *supra* note 32, at 8. Inhalation toxicity refers to tumors of the nasal cavities. Developmental toxicity refers to negative effects to developing humans in the womb through the end of puberty. Neurotoxicity concerns disruptions to the normal activity of the nervous system. *Id.*

34. *Id.* at 8.

equipment (i.e., respirators) for farm workers. EPA believed that these mitigation measures drove exposures sufficiently below the agency's levels of concern, and approved the registration.[35] EPA did not consider the availability or relative efficacy of alternatives to methyl iodide.

The methyl iodide decision reflects EPA's consistent interpretation of FIFRA's registration standard and stands as a stark example of the primacy of risk mitigation over prevention. Despite clear reference to consideration of risks and benefits in FIFRA's definition of "unreasonable adverse effects," the threshold issue for EPA is whether human health and environmental risks posed by a pesticide can be reduced to acceptable levels by the imposition of risk mitigation measures.[36] If so, the analysis is essentially complete and the pesticide is approved without regard to whether safer alternative pesticides or practices exist.[37] Only where risk mitigation is inadequate does EPA seriously consider the benefit side of the equation.

Thus, where the agency concludes that even the use of stringent mitigation measures will not achieve the ACLs, it looks to whether the economic and practical benefits of the pesticide nonetheless justify registration. For example, in reviewing the registration of chlorpyrifos (also known as Lorsban®) for use on food crops, EPA concluded that numerous occupational risks were well above acceptable health-based exposure levels, even with all feasible personal protective equipment or engineering controls in place.[38] Even so, based upon its analysis of the significant benefits of chlorpyrifos for certain uses, EPA confirmed the registration.[39]

Consideration of safer alternatives does creep into the registration process as part of the "back-end" benefits assessment. EPA acknowledges

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35. *Id.* at 11, 15.

36. *See id.*

37. The courts appear to support the EPA's interpretation. *See Environmental Def. Fund*, 548 F.2d at 1012 ("Once the Administrator has found that a risk inheres in the use of a pesticide, he has an obligation to explain how the benefits of continued use outweigh that risk.").

38. *Chlorpyrifos Facts*, EPA (Feb. 2002), http://www.epa.gov/oppsrrd1/REDs/factsheets/chlorpyrifos_fs.htm.

39. *Interim Reregistration Eligibility Decision: Chlorpyrifos*, EPA 80-84 (2002), *available at* http://www.epa.gov/oppsrrd1/REDs/chlorpyrifos_ired.pdf. *See also* EPA, Pesticides; Procedural Regulations for Registration Review, 71 Fed. Reg. 45,720, 45,725 (2006), *available at* http://www.gpo.gov/fdsys/granule/FR-2006-08-09/E6-12904/content-detail.html (expressing and codifying an interpretation that, in the context of reviewing existing registrations, "[w]hen a pesticide poses risks of concern to humans or the environment, the Agency must address these risks. The options for addressing such risks include risk mitigation, determining that the risks are justified in light of the benefits of the pesticide, or initiating regulatory options to modify or cancel the registration.").

that the benefits of a pesticide to the user and society in general are reduced where there are viable safer alternatives to that pesticide.[40] So where the benefits of a pesticide are less significant—as where an alternative pesticide or farming practice provides comparable performance at a comparable cost—exceedance of health-based exposure levels can prevent registration. Such was the case for certain uses of carbofuran, a pesticide used to control insects and worms for a variety of field, fruit, and vegetable crops.[41] Thus, EPA's implementation of FIFRA marginalizes consideration of safer alternatives by relegating consideration of alternatives to the second stage of the two stage analysis: risk mitigation followed, in limited cases in which ACLs cannot be achieved, by a balancing of residual risk against benefits.

2. Risk Management in Chemical Review

For chemicals outside the scope of FIFRA, the Toxic Substances Control Act (TSCA) likewise requires EPA to determine whether a new or existing chemical presents an "unreasonable risk of injury to health or environment."[42] Although TSCA itself contains no definition of this standard, the Conference Committee report for the statute noted that an unreasonable risk determination involves:

> [B]alancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, *taking into account the availability of substitutes for the substance or mixture which do not require regulation*, and other adverse effects which such proposed action may have on society.[43]

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40. *Id.* ("The magnitude of those benefits often depends on the availability of alternative pest control measures, whether chemical, biological or cultural. Benefits are, in general, expected to be higher when there are no viable alternatives.").

41. *See Interim Reregistration Eligibility Decision: Carbofuran*, EPA 31–37 (2006), *available at* www.epa.gov/oppsrrd1/REDs/carbofuran_ired.pdf.

42. 15 U.S.C. § 2604(f)(1) (2007).

43. H.R. REP. NO. 94-1341, at 13–14 (1976) (emphasis added). The Committee went on to observe that

> [t]he balancing process described above does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with a substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful.

While new chemical review under TSCA is driven by a similar "unreasonable risk" standard as FIFRA, the decision-making process is substantially different. The FIFRA pesticide review process typically takes years to complete, with manufacturers performing extensive, expensive toxicity testing and EPA completing complicated risk assessments.[44] By statute, new chemical review under TSCA must generally be completed within ninety days after the manufacturer submits a pre-manufacture notice (PMN), and manufacturers are typically not required to perform extensive health and safety testing.[45] Most notably, unless the EPA takes affirmative action to regulate a new chemical during the ninety-day review period, the manufacturer may introduce it into the market at the expiration of the period.[46] Not surprisingly, EPA developed a streamlined review process under TSCA, making risk management decisions far faster and with substantially less information than it does under FIFRA. Nonetheless, as in FIFRA, chemical review under TSCA relies almost entirely on identification and application of acceptable exposure limits, relegating consideration of safer alternatives to an exceedingly small percentage of cases.

Within the first fifteen days of a PMN submission, the agency ends its review of any chemicals that present low human health and ecological hazards.[47] This is followed by a "Focus Meeting" by the twentieth day at which EPA managers consider a range of regulatory responses after considering the identified risks and benefits of the remaining chemicals.[48] Either at or before the Focus Meeting stage, approximately 80% of all PMN submissions are dropped from further review without any regulatory action.[49] More than 15% of the remaining submissions are regulated under

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In one of the few cases interpreting TSCA, the Fifth Circuit Court of Appeals agreed, stating that EPA "may exercise its judgment without strictly relying upon quantifiable risks, costs, and benefits . . . ." Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1214 (5th Cir. 1991).

44. *Pesticides: Registration Review*, EPA, http://www.epa.gov/oppsrrd1/registration_review/reg_review_process.htm (last updated Dec. 2012).

45. A series of federal court decisions interpreted EPA's authority to require health and safety testing somewhat narrowly, imposing substantial administrative hurdles in the agency's path. *See, e.g.*, Chem. Mfrs. Ass'n v. EPA, 899 F.2d 344, 357–360 (5th Cir. 1990); *see generally* John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 736–39 (2008) (discussing the procedural and administrative burdens the EPA faces).

46. EPA, EPA 744-R-97-003, CHEMISTRY ASSISTANCE MANUAL FOR PREMANUFACTURE NOTIFICATION SUBMITTERS 118 (1997) [hereinafter EPA MANUAL].

47. *Id.* at 27–32.

48. *Id.* at 35.

49. *Id.* at 36.

voluntary consent orders issued under Section 5(e) of TSCA based upon potential hazards or fears of substantial human or ecological exposure.[50] The consent orders typically set out testing requirements, use or volume restrictions, worker protection standards, and in some cases new chemical exposure limits ("NCELs") based upon toxicological data concerning structurally analogous chemicals.[51]

The remaining 3–5% of the cases move on to the third decision point—ironically called "Standard Review"—spanning days twenty through eighty-five.[52] During Standard Review EPA conducts more extensive risk assessment and economic analysis (including identification and review of available substitutes),[53] potentially culminating in either regulatory restrictions or dropping the chemical from further review.[54]

Despite clear differences between FIFRA and TSCA gatekeeper review, the TSCA new chemical review process mirrors that of FIFRA in the dominance of the conventional risk management paradigm. For the vast majority of chemicals, TSCA regulatory review ends within the first twenty days of the ninety-day review period prior to or at the Focus Meeting stage. That review is based solely on a consideration of risk and exposure. For those that reach the Focus Meeting stage, EPA guidance calls for risk/benefit balancing. Nonetheless, there is no indication in EPA's new chemical review manual, guidance documents or published literature that EPA considers the availability of safer alternatives—such as drop-in substitute chemicals or process changes—in evaluating whether the chemical presents an unreasonable risk during the Focus Meeting.[55]

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50. *Id.* at 36–38; *but see* C. Auer & J. Alter, *The Management of Industrial Chemicals in the USA*, *in* RISK ASSESSMENT OF CHEMICALS 556 (C.J. van Leeuwen and T.G. Vermeire eds., 2007) (noting that recent focus meetings tend to call for further analysis and review of 20% of PMN submissions).

51. EPA, RESPONSE TO EXTERNAL COMMENTS ON NEW CHEMICAL EXPOSURE LIMITS IN TOXIC SUBSTANCES CONTROL ACT SECTION 5(E) ORDERS 13–14 (1995).

52. EPA MANUAL, *supra* note 46, at 38–39.

53. *Id.* at 38–39 (noting that as part of Standard Review, staff from Regulatory Impacts Branch (RIB) "perform an economic assessment of the PMN substance that includes comparing the PMN substance to other commercial products that are used for the same purposes"); EPA, EPA 560-3-86-002, NEW CHEMICAL REVIEW PROCESS MANUAL III-2 to III-3 (1986) (explaining that during Standard Review, Health and Environmental Review Division develops a relative hazard finding of the new chemical as compared to the alternatives, if any, identified by the RIB economist).

54. EPA MANUAL, *supra* note 46, at 35–39.

55. That is not to say the agency does not consider safer alternatives at all, simply that it fails to integrate the existence of safer alternatives to the new chemical in the risk/benefit balancing. In the reverse case—where the new chemical itself is viewed as a safer alternative to an *existing* chemical—the agency incorporates that fact into the benefit side of the equation. *See*

Moreover, in establishing restrictions on new chemicals, the agency relies entirely upon NCELs, production and use restrictions, and worker protection standards to address any concerns regarding toxicity and exposure.[56] The NCELs are health-based exposure levels based upon a streamlined risk assessment procedure, and thus fall squarely within the risk management paradigms. The other restrictions and controls are classic engineering and administrative controls so central to the risk management paradigm. It is only for the fraction of chemicals reaching Standard Review that the agency gives alternatives any consideration.[57]

In part, the limited role of alternatives in the PMN process may be attributable to logistical issues related to the short review period of ninety days. The frenetic pace of review leading up to the Focus Meeting by day twenty leaves little time for identification and assessment of alternatives; indeed, it is barely enough time to collect, review and evaluate data regarding the new chemical itself. In addition, the legal obstacles may play a substantial role. In order to ban or comprehensively restrict a new chemical, the agency must use its authority under Section 6 of TSCA, which authorizes such regulatory action in the face of unreasonable risks.[58] Proceeding under Section 6, however, can be treacherous for the agency, as highlighted by EPA's ill-fated efforts to phase out asbestos.[59]

Under Section 6, if EPA concludes that the chemical's manufacture, processing, distribution, use or disposal presents or will present an unreasonable risk, EPA may issue regulations ranging from a ban, to use restrictions, to labeling, disclosure or record-keeping.[60] EPA's activities under Section 6 have been limited; since 1976 the agency has taken substantive regulatory action regarding existing chemicals in only five

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id. at 36 ("Often EPA may identify significant risks of a PMN substance that also has significant benefits to society (e.g., the PMN substance will supplant an existing chemical substance that poses a greater risk). In such instances, it is the practice of EPA to balance these factors in making risk management decisions regarding the PMN substance.") *Id.* Likewise, during the PMN review process, EPA scientists attempt to identify pollution prevention practices for the production of the new chemical, and encourage (but not require) the manufacturer to consider their adoption. *Id.* at 14.

56. EPA, RESPONSE TO EXTERNAL COMMENTS ON NEW CHEMICAL EXPOSURE LIMITS IN TOXIC SUBSTANCES CONTROL ACT SECTION 5(E) ORDERS 13–14 (1995).

57. *See supra* notes 49–52 and accompanying text.

58. 15 U.S.C. § 2605 (2012).

59. Section 6 is used for regulation of new and existing chemicals. For these purposes, an existing chemical is one that EPA placed on its original inventory of chemicals in 1979, or which was subsequently added to the inventory following the PMN review process. *See* TSCA, 15 U.S.C. § 2602(9) (2013) (defining "new chemical substance").

60. 15 U.S.C § 2605(a) (2013).

instances, most famously in the case of asbestos.[61] In 1979, EPA began a ten-year rulemaking process focused on regulating asbestos, an infamous carcinogen, engaging in extensive data collection and evaluation of the risks of asbestos and its existing and emerging substitutes.[62] Those risks were startling: asbestos exposure was linked to asbestosis, lung cancer and mesothelioma.[63] EPA's deliberations also included analysis of the feasibility and costs of substitutes,[64] as well as limited evaluation of their hazards.[65]

In finding an unreasonable risk, EPA did not ask whether the risks could be reduced to an acceptable level via engineering controls or other forms of risk management. Rather the agency engaged in a direct balancing of the risks and benefits, with particular attention to safer substitutes. Concluding that the risks of asbestos were high and the benefits low and shrinking due to existing and emerging safer non-asbestos substitutes, EPA found that asbestos presented an unreasonable risk when used in construction, automotive brake components, piping and numerous other contexts.[66] Accordingly, the agency promulgated a rule phasing out asbestos over a five year period.[67] In the *Corrosion Roof Fittings* case, the Fifth Circuit Court of Appeals vacated the rule on numerous grounds, remanding it to EPA for further proceedings.[68]

For our purposes, two grounds for remand of the rule are particularly important. First is the court's interpretation of language in Section 6 providing that EPA must use "the least burdensome requirements" in responding to unreasonable risks.[69] The court concluded that this language

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61. Lars Koch & Nicholas A. Ashford, *Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and Reach*, 14 J. CLEANER PRODUCTION 31, 31 (2006) (discussing Technology Options Analysis).

62. *See* Asbestos; Proposed Mining and Import Restrictions and Proposed Manufacturing, Importation, and Processing Prohibitions, 51 Fed. Reg. 3740–3744 (proposed Jan. 29, 1986) (to be codified 40 C.F.R. pt. 763); Asbestos; Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions, 54 Fed. Reg. 29,460, 29,460–61 (July 12, 1989) (to be codified at 40 C.F.R. pt. 763).

63. Asbestos; Proposed Restrictions, 51 Fed. Reg. at 3738. Other health effects include cancers of the larynx, pharynx, gastrointestinal tract, kidney and ovary and respiratory diseases such as pneumonia. *Id.* at 3741–42.

64. Asbestos; Proposed Restrictions, 51 Fed. Reg. at 3747; ICF Incorporated, Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products, Appendix H (January 19, 1989).

65. Asbestos; Prohibitions, 54 Fed. Reg. at 29,481–83. *See generally* EPA, HEALTH HAZARD ASSESSMENT OF NONASBESTOS FIBERS (1988).

66. Asbestos; Prohibitions, 54 Fed. Reg. at 29,467–68

67. *Id.*

68. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1207 (5th Cir. 1991).

69. 15 U.S.C. § 2605(a).

placed a heavier burden on the agency "when it seeks a partial or total ban of a substance than when it merely seeks to regulate that product."[70] The opinion provided little guidance on how the burden can be met beyond a vague reference to qualitative consideration of the costs and benefits of regulation under each alternative regulatory approach.[71] By placing a heavier burden on rules adopting a ban, the *Corrosion Proof Fittings* court created a hierarchy among the regulatory options available to the EPA, essentially encouraging restrictions on use rather than mandatory substitution with safer substitutes. Second, the court chided EPA for failing to adequately consider the effectiveness and toxicity of the potential alternatives to asbestos, a point I take up further in Part IV.A.[72]

B. Oversight Programs and Acceptable Exposure Levels

"Oversight programs" focus upon the "downstream" effects of chemicals after their introduction into commerce. They address worker, bystander and end-user exposures to discharges, emissions and other releases associated with the production of the chemical (for example, air emission standards for pesticide manufacturing), the use of the chemical itself (such as worker protection rules for use of chromium in electroplating), or the management of the chemical after use (as in hazardous waste recycling rules for lead-acid batteries). Oversight programs administered by EPA and the Occupational Safety and Health Administration (OSHA) typically establish ACLs, with heavy reliance upon engineering controls to achieve those levels. While both agencies consistently encourage the use of preventative process changes to achieve these levels, neither systematically incorporates safer alternatives into enforceable standards.

In exploring the operation of oversight programs, it is helpful to have a real world example in mind. Consider the case of hexavalent chromium, a known human carcinogen used in decorative electroplating. In that process, a thin layer of chromium is deposited on the surface of metal parts—such as motorcycle and automobile components, household appliances, and plumbing fixtures—for aesthetic appearance and corrosion protection. Yet the electroplating process itself is not nearly as attractive. The parts are dipped and rinsed in a series of large tanks, filled with various acid and chemical baths, including chromic acid. The tanks generate a hazardous

70. *Corrosion Proof Fittings*, 947 F.2d at 1214.
71. *Id.* at 1217, 1222.
72. *Id.* at 1221.

mist, exposing workers and others to hexavalent chromium. Such exposures are linked with lung cancer, nasal tissue damage, asthma, and dermatitis.[73]

OSHA has regulated electroplating operations under the Occupational Safety and Health Act[74] since 1971, updating its standards in 2006.[75] These standards fall directly within the risk management approach, identifying an acceptable level of exposure and permitting use of control measures to achieve that level. Here the acceptable levels take the form of permissible exposure limits or PELs, which typically set out the maximum concentration to which a worker can be exposed over an eight-hour period.[76] Based upon a string of federal appellate and Supreme Court cases from the 1970s and 1980s, OSHA sets the PEL by considering health risk, economic impact and technical feasibility.[77] Health risk is central to the process in two ways: to determine whether the risk posed by the substance is significant enough to justify regulatory intervention,[78] and—if such action is justified—to determine whether a technologically and economically feasible standard will substantially reduce this risk.[79] For OSHA, a risk of 1-in-1000 (or

73. National Emission Standards for Hazardous Air Pollutants; Proposed Standards for Chromium Emissions From Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks, 58 Fed. Reg. 65,768, 65,781 (proposed Dec. 13, 1993) (to be codified as 40 C.F.R. pt. 63); Anil Baral & Robert D. Engelken, *Chromium-based Regulations and Greening in Metal Finishing Industries in the USA*, 5 ENVTL. SCI. & POL'Y 121, 122–23 (2002).

74. The statutory language of OSHA requires the agency to establish reasonably necessary health standards to provide "safe or healthful employment and places of employment." Occupational Safety and Health Act, 29 U.S.C. § 652(8) (2013).

75. National Consensus Standards and Established Federal Standards, 36 Fed. Reg. 10,466 (May 29, 1971) (to be codified at 29 C.F.R. pt. 1910); Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. 10,100 (Feb. 28, 2006) (to be codified at C.F.R. pts. 1910, 1915, 1917, 1918, 1926).

76. 29 C.F.R. § 1910.1000 tbl.Z-1 (2006).

77. Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494 (Jan. 10, 1997) (to be codified at 29 C.F.R. pts. 1910, 1915, 1926); *see also* NICHOLAS A. ASHFORD & CHARLES C. CALDART, TECHNOLOGY, LAW AND THE WORKING ENVIRONMENT 105–160 (rev. ed. 1996) [hereinafter ASHFORD & CALDART, TECHNOLOGY].

78. Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 642 (1980) [hereinafter API] (plurality opinion) (holding that as a threshold matter, OSHA must find the existence of a significant risk prior to establishing any health standard).

79. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. at 10,221. In what has become widely known as the "Cotton Dust case," the Supreme Court defined feasibility as "capable of being done." Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 509 (1981) [hereinafter Donovan]. Regarding technological feasibility, OSHA must show "a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations." *See* United Steelworkers of America v. Marshall, 647 F.2d 1189, 1272 (D.C. Cir. 1980). A standard is economically feasible if it does not endanger the stability of the industry as a whole. *Id.* at 1265.

greater) that a material health effect will occur is significant.[80] The agency relies heavily upon quantitative risk assessment to gauge that risk.[81]

In the case of the 2006 updated PEL for electroplating, OSHA used quantitative risk assessment to evaluate the magnitude of the increased risk of lung cancer facing workers exposed to hexavalent chromium.[82] The risk under the existing PEL ranged between 100 to 350 lung cancer cases per 1000 workers, well above the 1-in-a-1,000 standard for significant risk.[83] Consequently, OSHA found that a revised PEL was necessary.[84] After considering the availability, effectiveness and cost of engineering controls, work practices and personal protective equipment such as respirators, OSHA identified the lowest exposure level that was technologically and economically feasible—or what we have been calling the ACL—as five micrograms per cubic meter of air.[85] Although this revised PEL meaningfully reduced the cancer risk, the risk remaining under the revised PEL was still well above the significant risk level of 1-in-a-1,000, ranging between ten and forty-five cancer cases per 1,000 workers.[86]

The preference of control over prevention—another hallmark of the conventional risk management approach—is likewise present in OSHA's policymaking. As a matter of principle, in rulemaking materials and other pronouncements, OSHA advocates the use of preventive measures such as chemical substitution and process change to attain PELs.[87] It speaks of a

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80. *See* Occupational Exposure to Formaldehyde, 52 Fed. Reg. 46,168, 46,230 (Dec. 4, 1987) (discussing one in a thousand as one measure of significance); Adam M. Finkel & P. Barry Ryan, *Risk in the Workplace*, in RISK ASSESSMENT FOR ENVIRONMENTAL HEALTH 187, 221 (eds. Mark G. Robson and William A. Toscano 2007) (noting OSHA's reliance on the one-in-a-thousand measure); ASHFORD & CALDART, TECHNOLOGY, *supra* note 77, at 139 (observing that OSHA uses the benchmark of one fatality in a thousand as "significant").

81. In API, the Supreme Court emphasized, but did not absolutely require, the use of quantitative risk assessment in evaluating the scope of the risk and the health impact of health standards considered by OSHA. *See* API, *supra* note 78, at 644; Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. at 10,175 (in electroplating standard rulemaking, observing that "[a]lthough the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.").

82. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. at 10,174.

83. *Id.* at 10,224.

84. *Id.*

85. This is measured based upon a time weighted average of eight hours. Thus, so long as the average exposure over any eight hour shift is below 5 ug/m3, the firm is compliant. OSHA, OSHA 3373-10, HEXAVALENT CHROMIUM 6 (2009).

86. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. at 10,195, tbl.VI-7.

87. *See* Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates (Glycol Ethers), 58 Fed. Reg. 15,526-01, 15,599 (proposed Mar. 23, 1993) (to be codified at 29 C.F.R. pt. 1910) ("One of the best ways to keep people from being exposed to a toxic substance

hierarchy of management techniques in which substitution is the most preferred measure for protecting workers from hazardous chemicals, followed by other engineering controls (such as ventilation), work practices (e.g., housekeeping), and finally personal protective equipment (primarily personal respirators) as the least preferred method.[88] In practice, however, in both setting and implementing PELs OSHA relies heavily on conventional engineering controls and work practice standards rather than substitution.[89]

Consider the manner in which OSHA sets the PEL. As noted above, OSHA establishes a PEL largely by reference to the most protective technically feasible control measure used by employers in the relevant industry.[90] Simply put, OSHA will identify the suite of available, feasible control measures and their associated exposure levels, and then set the PEL at the most protective exposure level that can be achieved using those control measures. Despite acknowledging that substitution can substantially reduce exposures—often well below that achieved by conventional engineering control—OSHA does not set the PEL by reference to the exposure levels achieved through substitution. Often, OSHA explains this rejection of substitution by noting that the substitute process cannot be used in all or most industrial operations covered by the standard.[91] Such was the case for hexavalent chromium PEL, and decorative electroplating in particular.[92] Thus, the PEL will often be set at a less protective level for all industrial operations, even those operations within a larger industrial category for which substitution *is* feasible.

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is to stop using it entirely."); Finkel & Ryan, *supra* note 80, at 226–31 (describing OSHA policy preference for elimination and substitution).

88. *See* Occupational Exposire to Cadmium, 57 Fed. Reg. 42,102, 42,340–41 (Sept. 14, 1992) (to be codified at 29 C.F.R. pts. 1910, 1915, 1926) (describing hierarchy of controls); Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. 10,100-01, 10,345 (Feb. 28, 2006) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926) (describing hierarchy).

89. *See* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, OTA-ENV-635, 50–53, GAUGING CONTROL TECHNOLOGY AND REGULATORY IMPACTS IN OCCUPATIONAL SAFETY AND HEALTH—AN APPRAISAL OF OSHA'S ANALYTIC APPROACH (1995).

90. Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494 (Jan. 10, 1997) (to be codified at 29 C.F.R. pts. 1910, 1915, 1926)

91. *See, e.g.*, Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494, 1576 (Jan. 10, 1997) (to be codified at 29 C.F.R. pts. 1910, 1915, 1926) ("In general, however, OSHA has based its findings of feasibility not on the ability of companies in the affected sectors to substitute away from [methyl chloride] but on their ability to implement conventional engineering and work practice controls.").

92. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. at 10,260 ("In most cases OSHA does not rely on material substitution for reducing exposures to Cr(VI) to determine technological feasibility.").

OSHA typically misses another opportunity to embrace its substitution preference when it comes time to implement the PEL. As a general matter, the PEL is a performance standard; that is, with certain exceptions, employers are free to choose their own strategy for meeting the PEL in their particular workplace.[93] Thus, for example, an electroplater could meet the PEL by switching to a trivalent chromium process, by installing ventilation in the affected work areas, or by isolating the operations from other work areas.[94] That said, since 1971 OSHA has routinely set out a mandatory hierarchy of control measures in its PEL rules.[95] Employers are obligated to use engineering controls or work practice standards wherever feasible. Only when such measures are not feasible may employers rely upon personal protective equipment such as respirators, to meet the PEL.[96] In terms of promoting substitution as the primary approach to reducing exposure, this hierarchy is weak indeed. Because OSHA defines substitution as just another type of engineering control, it is preferred over only personal protective equipment. All other conventional measures (such as emission control, ventilation, isolation, good housekeeping, and employee training) are likewise within the definitions of either engineering controls or work practices, and thus on equal footing with substitution.[97]

The story is much the same with EPA's activities under the Clean Air Act, both with respect to setting ACLs and reliance upon control rather than prevention. That statute directs EPA to promulgate emission standards for specified hazard air pollutants (HAP), of which chromium is one.[98] As with OSHA's PEL-setting process, EPA considers health effects, economic impacts and technical feasibility in establishing its acceptable exposure limits, although in a significantly different configuration.[99] The emission

93. *See* 29 U.S.C. § 655(b)(5) (2012) ("Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.").

94. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. at 10,256.

95. *See* Am. Iron & Steel Inst. v. OSHA, 182 F.3d 1261, 1265 (11th Cir. 1999); AFL-CIO v. OSHA, 965 F.2d 962, 985 (11th Cir. 1992) (describing adoption of control of hierarchy policy).

96. *See* 29 C.F.R. § 1910.1026(f)(1)(i) (2012) (establishing preference for engineering controls and work practice standards in the health standard for hexavalent chromium).

97. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. at 10,345.

98. 42 U.S.C. § 7412(b)(1) (2012).

99. One twist here is staged manner of regulation. The statute calls for at least two sequential stages of regulation—the technology-based MACT standard and the health-based residual risk standard—with each stage using different criteria for ACLs. 42 U.S.C. § 7412(d)(2); 42 U.S.C. § 7412(f)(2)(A). The technology-based MACT standard is described above. *See infra* notes 101–09 and accompanying text. Having ensured a basic level of protection through the technology-based MACT, in the second stage EPA revisits each MACT standard to address any residual health risks. *See* 42 U.S.C. § 7412(f)(2)(A). EPA will consider

standard for a given HAP focuses on technical feasibility tempered by other considerations.[100] This so-called "MACT standard" (for maximum achievable control technology) does not incorporate notions of health risk.[101] Instead, it is based upon the maximum achievable reduction in emissions.[102] At a minimum, the standard must reflect "best practices" in emissions control for the relevant industry, without consideration of cost.[103] EPA also has the discretion to go beyond this best practices floor to require additional technologically achievable reductions, but in doing so must evaluate cost, the energy requirements, and other environmental impacts.[104]

The text and legislative history of the Clean Air Act both favor pollution prevention approaches over control strategies in setting MACT standards. Clean Air Act Section 101(c) identifies promoting pollution prevention as a fundamental goal of the statute.[105] The Act's MACT provisions explicitly charge EPA with eliminating HAP emissions where possible "through process changes, substitution of materials, or other modifications . . . ."[106] Confirming this point, in discussing MACT standards, the Senate Committee on Environment and Public Works stated:

> The technologies, practices or strategies which are to be considered in setting emission standards under this subsection go beyond the traditional end-of-the-stack treatment or abatement

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additional regulatory intervention only where the health risks exceed a risk level of 1-in-a-1,000,000 risk of cancer. 42 U.S.C § 7412(f). As with OSHA's PEL, that risk level is simply a trigger for action, and the resulting regulation need not reduce the risk to 1-in-a-1,000,000. Rather, the health-based regulation need only "provide an ample margin of safety to protect public health." Natural Res. Def. Council v. EPA, 529 F.3d 1077, 1081 (D.C. Cir. 2008) (holding that 1-in-a-1,000,000 level was a trigger only). EPA defines the ample margin of safety to mean a standard under which as many people as possible face excess lifetime cancer risks no greater than one-in-one million, and that no single person faces a risk greater than 100-in-one million (one-in-ten thousand). *Id.* at 1082. Also like OSHA, EPA relies upon quantitative risk assessment to assess the health risk both for purposes of determining if the trigger is exceeded, and in determining whether an ample margin of safety is achieved. *See id.* at 1084–85.

100. National Emission Standards for Hazardous Air Pollutants and Proposed Standards for Chromium Emissions, 58 Fed. Reg. 65,768, 65,770 (proposed December 16, 1993) (to be codified at 40 C.F.R. pt. 63).

101. *See* National Emission Standards for Hazardous Air Pollutants Phosphoric Acid Manufacturing and Phosphate Fertilizers Production, 64 Fed. Reg. 31,358, 31,359 (June 10, 1999) (to be codified at 40 C.F.R. pts. 9, 63).

102. 42 U.S.C. § 7412(d)(2).

103. *Id.*; Nat'l Lime Ass'n v. EPA, 233 F.3d 625, 640 (D.C. Cir 2000).

104. 42 U.S.C. § 7412(d)(2); Nat'l Lime Ass'n, 233 F.3d at 640. The EPA is also required to consider non-air quality health and environmental impacts and energy requirements. 42 U.S.C. § 7412(d)(2).

105. 42 U.S.C. § 7401(c).

106. 42 U.S.C. § 7412(d)(2)(A).

> system. The Administrator is to give priority to technologies or strategies which reduce the amount of pollution generated through process chances or the substitution of materials less hazardous. Pollution prevention is to be the preferred strategy wherever possible.[107]

Despite this directive, EPA has been reluctant to consider process change in setting MACT standards. The courts have repeatedly forced EPA to honor the preference for pollution prevention set out in the Clean Air Act and the Pollution Prevention Act.[108] EPA's reticence towards embedded prevention is reflected in the electroplating rulemaking. In setting the MACT standard, the agency considered a number of engineering control alternatives such as mist eliminators, scrubbers and tank enclosures. The agency also considered substitution in the form of trivalent chromium electroplating. Its comparative analysis showed that trivalent chromium electroplating reduced emissions of hexavalent chromium by greater than 99%, and resulted in substantially less total chromium in process wastewaters and less sludge generation.[109]

Notwithstanding those results, EPA declined to use trivalent chromium-based processes as the basis for the MACT standard for two reasons. First, as did OSHA in the PEL rulemaking, EPA concluded that trivalent systems could not be used for every decorative electroplating application. Second, the total chromium emissions from trivalent systems it tested were greater than those from a well-controlled hexavalent system even though hexavalent chromium emissions were much lower.[110] Nonetheless, EPA

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107. S. REP. NO. 101-228, pt. 2, at 168 (1989), *reprinted in* 1990 U.S.C.C.A.N. 3385, 3553.

108. Cement Kiln Recycling Coal. v. EPA, 255 F.3d 855, 859 (D.C. Cir. 2001) (standards for hazardous waste combustors); *Nat'l Lime Ass'n*, 233 F.3d at 634 (emission limits for cement plants); Monsanto Co. v. EPA, 19 F.3d 1201, 1208 (7th Cir. 1994) (extension of compliance waiver under Section 112 for a company seeking to implement a pollution prevention strategy). Which is not to say that the agency *never* bases MACT standards on process changes. *See* National Emission Standards for Hazardous Air Pollutants for Industrial Process Cooling Towers, 59 Fed. Reg. 46,339-01, 46,339–40 (Sept. 8, 1994) (to be codified at 40 C.F.R. pts. 9, 63) (prohibiting chromium-based water treatment in industrial process cooling towers); Kenneth A. Zarker & Robert L. Kerr, *Pollution Prevention through Performance-Based Initiatives*, 16 J. CLEANER PROD. 673, 680 (2008). Only that in most cases it appears reluctant to do so.

109. National Emission Standards for Hazardous Air Pollutants and Proposed Standards for Chromium Emissions, 58 Fed. Reg. 65,768, 65,77–80 (proposed December 16, 1993) (to be codified at 40 C.F.R. pt. 63).

110. National Emission Standards for Chromium Emissions From Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks, 60 Fed. Reg. 4,948, 4,954–55 (Jan. 25, 1995) (to be codified at 40 C.F.R. pts. 9, 63).

encouraged new decorative chromium electroplating sources to use the trivalent process because of its "overall multi-media benefits."[111]

III. THE CASE AGAINST CONVENTIONAL RISK MANAGEMENT

Having mapped out the nature of conventional risk management in Part II, I turn now to its limitations as asserted by proponents of prevention.[112] The most common critiques fall into four general categories: *protectiveness*, *overall effectiveness*, *cost-effectiveness*, and *dynamic efficiency*.[113] While my purpose here is mainly descriptive, it is worthwhile noting that some of

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111. National Emission Standards for Hazardous Air Pollutants and Proposed Standards for Chromium Emissions, 58 Fed. Reg. 65,768, 65,797 (proposed December 16, 1993) (to be codified at 40 C.F.R. pt. 63). The statute requires that EPA conduct a technology review of each MACT standard at least every eight years to determine if developments in practices, processes and control technologies necessitate revisions. 42 U.S.C. § 7412(d)(6) (2012). The EPA proposed technology review for decorative chromium electroplating did not consider or even mention trivalent chromium systems or any other process changes as relevant developments. National Emission Standards for Hazardous Air Pollutant Emissions: Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks, 75 Fed. Reg. 65,068, 65,093–94 (proposed Oct. 21, 2010) (to be codified at 40 C.F.R. pt. 63). The EPA also performed a residual risk evaluation for decorative chromium electroplating, including an extensive risk assessment, as part of the proposed rulemaking. *Id.* at 65,076. The agency investigated the efficacy and cost of high-efficiency particulate air filters and the retrofitting of composite mesh pad systems for decorative chromium electroplating, but did not consider the adoption of process changes such as use of trivalent systems. *Id.* at 65,092. Due to the low cost-effectiveness of the control options (ranging between 486–367 million dollars per ton of chromium removed), EPA found that the existing standards provide an ample margin of safety. *Id.* at 65,091–93.

112. There is no shortage of articles critiquing conventional "command and control" regulation more generally on a variety of grounds. *See generally* Malloy, *supra* note 16 (collecting and categorizing critiques). Here I focus primarily upon challenges raised by proponents of prevention-based regulation.

113. These categories are a subset of a broader array of factors often used to evaluate environmental regulation more generally. *See* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, OTA-ENV-634, 50–53, ENVIRONMENTAL POLICY TOOLS: A USER'S GUIDE (1995) (using cost-effectiveness and fairness, demand on government, assurance of meeting goals, pollution prevention, environmental equity and justice, adaptability, and technology innovation and diffusion); Peter Bohm & Clifford S. Russell, *Comparative Analysis of Alternative Policy Instruments*, *in* 1 HANDBOOK OF NATURAL RESOURCE AND ENERGY ECONOMICS 395, 399–402 (A.V. Kneese & J.L. Sweeney eds., 1985) (discussing static efficiency, information intensity, ease of monitoring and enforcement, flexibility, dynamic efficiency, and political considerations); Robert W. Hahn & Robert N. Stavins, *Economic Incentives for Environmental protection: Integrating Theory and Practice*, 82 ECON. ENV'T 464, 464–466 (1992) (identifying static efficiency, dynamic efficiency, overall effectiveness, ease of implementation, equity, information needs, monitoring and enforcement capabilities, political feasibility, and clarity to the public).

the criticisms asserted against conventional risk management could be fairly made against prevention-based regulation, particularly with respect to cost-effectiveness and dynamic efficiency. I touch upon those points briefly where relevant in the discussion below, and revisit them with more detail in Section V while evaluating different forms of prevention-based regulation. But first things first: why shift from risk management?

A. Limited Protectiveness

Perhaps the most prevalent critique of conventional risk management is that it provides illusory protection. This claim can be parsed into three distinct yet related threads: the dynamic character of judgments regarding acceptable risk and toxicity, the pliable nature of risk assessment, and the downstream impacts of control strategies. The first facet of this claim challenges the notion that a single safe level (or even range of safe levels) can be identified and attained. Experience has demonstrated that as scientific knowledge advances, previously "safe" exposure levels often turn out to be inadequately protective. Examples of this phenomenon (such as lead, arsenic, and ionizing radiation) are plentiful; counterexamples are few.[114] Lead in particular serves as a powerful example: recent studies appear to confirm the view that there is no "safe" threshold for lead; lead affects intellectual development among children at blood lead levels well below the ten micrograms/deciliter standard commonly viewed as acceptable in the United States.[115] This skepticism about our ability to identify safe levels has intensified over the last decade or so as more and more studies have linked a range of diseases and conditions to extremely low level chemical exposures, including cancer, cardiovascular disease, asthma, autism, and obesity.[116] Thus, identifying static safety standards can result in limited and ultimately transient protection.

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114. Peter Montague, *Reducing the Harms Associated with Risk Assessments*, 24 ENVTL. IMPACT ASSESSMENT REV. 733, 744 (2004) ("The history of numerical exposure limits reveals that they tend to be set more strictly as time passes."); MARY O'BRIEN, MAKING BETTER ENVIRONMENTAL DECISIONS: AN ALTERNATIVE TO RISK ASSESSMENT 9–12 (2000); Allan H. Smith et al., *Arsenic Epidemiology and Drinking Water Standards*, 296 SCIENCE 2145, 2145–46 (2002).

115. Bruce P. Lanphear et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSPS. 894, 894 (2005).

116. NICHOLAS A. ASHFORD & CLAUDIA S. MILLER, LOW-LEVEL CHEMICAL EXPOSURES: A CHALLENGE FOR SCIENCE AND POLICY 74–84 (2d ed. 1998); James E. Trosko & Brad L. Upham, *A Paradigm Shift is Required for the Risk Assessment of Potential Human Health After*

The second related strand of this claim addresses the use of quantitative risk assessment itself, contending that despite the appearance of objectivity and precision, the outcomes of risk assessment tend to be malleable. Historically, due to the pervasive problems of uncertainty of data and the variability of the attributes under study (such as exposure and dose response), EPA has used of a broad range of assumptions and scientific judgments—sometimes termed "inference options"—to fill gaps or provide tractability.[117] The assumptions involved and the discretion afforded to the risk assessor can produce widely variable conclusions, thus providing ample opportunity to shape the desired results.[118] While EPA has made meaningful strides in standardizing its inference options, two recent studies conclude that there are continuing significant problems concerning clarity and transparency.[119] Likewise, the risk assessment process for rulemaking is often excessively time consuming.[120] Many assessments require from ten to twenty years to complete, due in large part to scientific controversy, political priorities, and economic factors.[121]

This assault on risk assessment is closely aligned with the dissatisfaction with the very concept of safe exposure limits. Policymakers use risk assessment to either trigger the development of an exposure limit (particularly where the exposure limit will be technology-based rather than health-based) or to generate the acceptable exposure limit itself in whole or in part. Proponents of prevention seek to avoid the transience of exposure levels and the uncertainty, politicization, and delays attributed to risk assessment by engaging instead a comparative analysis of regulated chemical or process to potential alternatives. The goal is to select the safest viable alternative from the set; thus, there is no need to identify an absolute

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Exposure to Low Level Chemical Exposures: A Response to the Toxicity Testing in the 21st Century Report, 29 INT'L J. TOXICOLOGY 344, 344 (2010).

117. NRC, SCIENCE AND DECISIONS, *supra* note 13, at 7–8; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-595, HUMAN HEALTH RISK ASSESSMENT: EPA HAS TAKEN STEPS TO STRENGTHEN ITS PROCESS, BUT IMPROVEMENTS NEEDED IN PLANNING, DATA DEVELOPMENT, AND TRAINING 19 (2006) [hereinafter GAO, HUMAN HEALTH RISK ASSESSMENT]; NAT'L RESEARCH COUNCIL, COMM'N ON LIFE SCIS., RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 31–40 (1983).

118. Aniello Amendola et al., *Uncertainties in Chemical Risk Assessment: Results of a European Benchmarking Exercise*, 29 J. HAZARDOUS MATERIALS 347, 362–363 (1992); Daniel Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 572–573 (1992).

119. NRC, SCIENCE AND DECISIONS, *supra* note 13, at 207–208, 270; GAO, HUMAN HEALTH RISK ASSESSMENT, *supra* note 117, at 24.

120. Koch & Ashford, *supra* note 61, at 32–33.

121. NRC, SCIENCE AND DECISIONS, *supra* note 13, at 17; GAO, HUMAN HEALTH RISK ASSESSMENT, *supra* note 117, at 62.

safe level, but rather simply to develop some sort of relative ranking of the regulated chemical and the alternatives.[122]

These two aspects of the limited protectiveness criticisms are tempered by several factors. Not all—nor perhaps even most—exposure limits are based solely on "safe" levels established using quantitative risk assessment. Clearly, gatekeeper programs ostensibly balancing of risks and benefits engage in the articulation of safe (or rather, safe enough) levels. However, as we have seen, oversight programs are often technology-based, meaning that the exposure limits are based upon the "state of the art" in engineering controls in the relevant industry sector.[123] The technology-based MACT standard is an example of such a case. Also, embracing prevention will not entirely displace the "moving target" concern. What is the safest viable alternative today may be not be so tomorrow, and the actual health impacts on affected populations will depend heavily upon the prevention-based program's agility in responding to advances in technology. Lastly, as I discuss below with respect alternatives analysis methodologies, depending upon its design, the methodology for identifying safer alternatives itself could raise the same concerns of malleability, opaqueness and delay associated with risk assessment.

The third element of the limited protectiveness claim focuses upon the consequences of control in terms of downstream impacts to current and future generations. The choice to control risks rather than prevent them often leads to risk shifting, particularly in the case of oversight programs. For example, capturing hazardous air emissions from a production facility is only the first step of a control strategy. The toxic particulates collected from the exhaust air become a waste disposal problem, exacerbated by the fact that the collection process typically concentrates the particles. The dusty waste may be transported for treatment or disposal, operations that create their own risks to workers and to other environmental media.[124] This is compounded by the accumulation of contaminants in the ecosystem stemming from allowable emissions and discharges. Thus even well-

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122. O'BRIEN, *supra* note 114, at 6–7; Joel A. Tickner & Ken Geiser, *The Precautionary Principle Stimulus for Solutions- and Alternatives-Based Environmental Policy*, 24 ENVTL. IMPACT ASSESSMENT REV. 801, 805–06 (2004); Montague, *supra* note 114, at 741.

123. *See supra* pp. 124–131.

124. O'BRIEN, *supra* note 114, at 6–7; Joel Hirschhorn et al., *Towards Prevention: The Emerging Environmental Management Paradigm*, *in* CLEAN PRODUCTION STRATEGIES: DEVELOPING PREVENTIVE ENVIRONMENTAL MANAGEMENT IN THE INDUSTRIAL ECONOMY 125, 127, 132 (Tim Jackson ed. 1993); Kurt A. Strasser, *Cleaner Technology, Pollution Prevention and Environmental Regulation*, 9 FORDHAM ENVTL. L.J. 1, 15 (1997).

designed risk management leaves behind landfills, containment structures and residual air, water and soil contamination.

The legacy of these cross-media transfers impacts future generations in multiple ways; for example, subjecting them to risks from exposure, restricting their use of resources contaminated or otherwise spoiled by wastes and discharges, and imposing on them future costs of response.[125] Emerging science regarding epigenetic effects of some chemicals raises the stakes from the intergenerational perspective even further. DNA alterations occurring from exposure to such chemicals can be transmitted to offspring, causing health impacts to children and grandchildren of the exposed individual.[126]

B. Ineffectiveness of Control Measures

Because the conventional approach relies upon control measures to reduce risk, its effectiveness in managing risk depends directly upon the efficacy of such measures. Here there are two related concerns. First, risk mitigation strategies such as engineering controls—including air pollution controls, wastewater treatment, pesticide application equipment, and the like—can be technically complex and prone to failure, even where the regulated party is acting reasonably and in good faith. The phenomena of the "normal accident"—the inevitability of failures within complex technical systems—is well documented (although not uncontested).[127]

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125. *See* EDITH BROWN WEISS, IN FAIRNESS TO FUTURE GENERATIONS AND SUSTAINABLE DEVELOPMENT: INTERNATIONAL LAW, COMMON PATRIMONY, AND INTERGENERATIONAL EQUITY 38 (Richard Falk ed. 1989) (discussing the impacts on and interests of future generations); Braden Allenby, *Supporting Environmental Quality: Developing an Infrastructure for Design*, 2 ENVTL. QUALITY MGMT. 303, 303 (1993). The treatment of benefit accruing to future generations in economic analysis of environmental policy—particularly in the context of climate change—is controversial. In this regard scholars in economics, law, philosophy and other disciplines have wrangled over the moral and technical aspects of discounting future benefits in cost-benefit analysis. *See, e.g.*, Daniel Farber, *From Here To Eternity: Environmental Law and Future Generations*, 2003 U. ILL. L. REV. 289 (discussing controversy).

126. Mark A. Rothstein, Yu Cai & Gary E. Marchant, *The Ghost in our Genes: Legal and Ethical Implications of Epigenetics*, 19 HEALTH MATRIX 1, 4–11, 14–17 (2009) (discussing transgenerational effects of endocrine disrupting chemicals, ionizing radiation, and air pollution).

127. CHARLES PERROW, NORMAL ACCIDENTS: LIVING WITH HIGH-RISK TECHNOLOGIES (1984); SCOTT D. SAGAN, THE LIMITS OF SAFETY: ORGANIZATIONS, ACCIDENTS AND NUCLEAR WEAPONS 14–44 (1993) (contrasting high reliability organization theory with normal accident theory); David L. Cooke & Thomas R. Rohleder, *Learning from Incidents: From Normal Accidents to High Reliability*, 22 SYS. DYNAMICS REV. 213, 215 (2006) (describing the thesis

Second, consistent and effective operation of engineering controls and work practice standards is heavily dependent upon the conscientious, effective implementation of such measures by businesses, workers and consumers. Here again, experience teaches us that the implementation of such controls and practices is highly variable, whether because of intentional noncompliance, negligence or confusion on the part of the responsible party.[128] Substitution of a hazardous chemical with a safer alternative can, at least to some degree, avoid such concerns. As one pioneer of prevention in industrial hygiene observed, "What you don't have, can't leak."[129]

C. Lack of Cost-Effectiveness

Cost-effectiveness is one measure often used to evaluate the relative efficiency of regulatory approaches, the other being social efficiency (or maximization of social welfare). Cost-effectiveness analysis estimates the cost of achieving a specified goal under alternative policies, allowing identification of the least cost approach.[130] The targeted goal itself is a given, and thus cost-effectiveness measures say nothing regarding the wisdom of pursuing the goal.[131] By contrast, social efficiency measures both the costs and benefits of alternative options, comparing those options in terms of net benefits produced.[132] Prevention proponents such as advocates of pollution prevention, toxics use reduction, clean production, and other similar movements tend to focus upon cost-effectiveness concerns in assailing the risk management paradigm. Accordingly, I concentrate on that point here, taking up social efficiency as a design principle later in Section V.E.

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that "accidents are a normal consequence of interactive complexity and close coupling of an organizational system").

128. Hirschhorn et al., *supra* note 124, at 127.

129. Trevor A. Kletz, *What You Don't Have Can't Leak*, 6 CHEMISTRY & INDUSTRY 287 (1978) (discussing the principles of inherently safer design in industrial processes).

130. HENRY M. LEVIN & PATRICK J. MCEWAN, COST-EFFECTIVENESS ANALYSIS: METHODS AND APPLICATIONS 10–11 (C. Deborah Laughton ed. 2d ed. 2000); EPA, GUIDELINES FOR PREPARING ECONOMIC ANALYSES 1–5 (2010).

131. Frank Ackerman, Lisa Heinzerling & Rachel Massey, *Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea*? 57 ADMIN. L. REV. 155, 175 n.116 (2005).

132. NATIONAL RESEARCH COUNCIL, VALUING HEALTH RISKS, COSTS, AND BENEFITS FOR ENVIRONMENTAL DECISION MAKING 7 (P. Brett Hammond & Rob Coppock eds., 1990); Kenneth J. Arrow et al., *Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?*, 272 SCIENCE 221 (1996).

The argument here is that the pollution and hazardous exposures resulting from typical production processes and products reflect inherent inefficiencies of those processes and products.[133] Production wastes such as sludges and still bottoms, air emissions like NOx and PAHs, and wastewater discharges are all evidence of the inefficient use of raw materials and energy. Risk management approaches aggravate the wastefulness by layering on costly add-on controls, administrative requirements and remediation obligations intended to capture, manage and cleanup the pollutants and wastes.[134] Indeed, the cost of pollution controls can go beyond the expense of installation and operation; for example, add-on controls can decrease the thermodynamic efficiency of a production process even further, leading to higher energy costs.[135]

In theory, prevention-based approaches address the environmental impacts of processes and products by removing or reducing the inefficiencies that create those impacts.[136] Recall that prevention covers a set of strategies: *substitution* of a hazardous chemical or process with a safer replacement, *adjustment* of the product or process design to minimize the use of the chemical, and *moderation* in which the chemical itself (or the product or process in which it is used) is modified so as to reduce the hazards, such as mixing an additive with a volatile toxic gas to reduce its mobility.[137] Now consider the example of an adjustment strategy as compared to a risk management approach for dealing with emissions of a toxic pollutant from a production process. Rather than capturing and incinerating the toxic emissions, a preventative adjustment strategy would adopt process improvements that substantially reduce the amount of the raw material needed in the first place—minimizing emissions and also reducing raw material costs.[138]

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133. Kirsten U. Oldenburg & Kenneth Geiser, *Pollution Prevention and . . . or Industrial Ecology?* 5 J. CLEANER PRODUCTION 103, 106 (1998); Mark Dorfman, Allen White, Monica Becker, & Tim Jackson, *Profiting from Pollution Prevention*, *in* CLEAN PRODUCTION STRATEGIES: DEVELOPING PREVENTIVE ENVIRONMENTAL MANAGEMENT IN THE INDUSTRIAL ECONOMY 189, 189–91 (Tim Jackson ed. 1993).

134. Mark Dorfman et al., *supra* note 133, at 189–191.

135. *Id.* at 190 n.3.

136. LEO BASS, CLEANER PRODUCTION AND INDUSTRIAL ECOLOGY: DYNAMIC ASPECTS OF THE INTRODUCTION AND DISSEMINATION OF NEW CONCEPTS IN INDUSTRIAL PRACTICE 26–27 (2005); Mark Dorfman et al., *supra* note 133, at 189–191.

137. Malloy, *supra* note 6, at 114.

138. *Id.*; BASS, *supra* note 136, at 26–27; Carlos Montalvo, *General Wisdom Concerning the Factors Affecting the Adoption of Cleaner Technologies: A Survey 1990-2007*, 16 J. CLEANER PRODUCTION S7, S9 (2008).

Prevention strategies can also shrink or even entirely avoid the often substantial regulatory compliance costs such as permitting, monitoring, training and reporting costs for industry (and associated enforcement costs for government) that almost inevitably accompany risk management strategies.[139] Here take the case of a substitution strategy from the dry cleaning sector. Adoption of a water-based professional garment care process eliminates emissions of the toxic cleaning solvent used by traditional dry cleaners while freeing the operator from onerous permitting and compliance costs regarding air emissions.[140]

Despite anecdotal accounts in the literature of the cost-reduction benefits associated with prevention efforts, there is apparently no systematic evidence demonstrating that prevention strategies are necessarily or even generally more cost-effective than risk management approaches.[141] Indeed, the question of cost-effectiveness is likely to be highly contextual and results will vary from chemical to chemical, and process to process. While cost reduction appears to occur in some cases, there is no reason to believe that safer substitutes or process changes will as a rule be more cost-effective than engineering controls. In fact, a safer substitute chemical could easily be more expensive than the more hazardous material it replaces; for example, lead-free solder, lithium-ion batteries, and steel wheel weights are all more expensive than their lead-dependent counterparts.

D. Inferior Dynamic Efficiency

Dynamic efficiency refers to the capacity to encourage innovation, defined as the development, commercialization, and adoption of new technology.[142] Innovation in environmental technologies—sometimes referred to as social innovation—has long been hailed as a primary goal of effective, efficient regulation.[143] Innovation allows environmental engineers

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139. Montalvo, *supra* note 138, at S9; Margaret M. Quinn et al., *Sustainable Production: A Proposed Strategy for the Work Environment*, 34 AM. J. INDUS. MED. 297, 300 (1998).

140. Malloy & Sinsheimer, *supra* note 24, at 207–211.

141. *See* Oldenburg & Geiser, *supra* note 133, at 104; James Lis & Kenneth Chilton, *Limits of Pollution Prevention*, 30 SOC'Y 49, 55 (1993).

142. Adam B. Jaffe & Robert N. Stavins, *Dynamic Incentives of Environmental Regulations: The Effects of Alternative Policy Instruments on Technology Diffusion*, 29 J. ENVTL. ECON. & MGMT. S-43, S-44 (1995).

143. Nicholas A. Ashford, *An Innovation-Based Strategy for the Environment*, *in* WORST THINGS FIRST: THE DEBATE OVER RISK-BASED NATIONAL ENVIRONMENTAL POLICIES 275, 291 (Adam M. Finkel & Dominic Golding eds., 1994) [hereinafter Ashford, *Innovation-Based Strategy*]; Timothy F. Malloy, *Regulating by Incentives: Myths, Models and Micro-Markets*, 80 TEX. L. REV. 531, 540–41 (2002).

to keep pace with the growing technological demands placed upon them by economic growth and industrial development. Likewise, environmental innovations can also reduce production costs and improve operating efficiencies, thus providing added value to the business itself.[144]

Proponents of prevention-based approaches contend that such approaches enhance dynamic efficiency of regulation, both in terms of the rate of innovation and the social value of those innovations. Regarding the *rate* of innovation, the claim here is that the conventional risk management approach's reliance on engineering controls coupled with a static exposure level tends to lock in existing technology. Once compliance is reached, firms will have no incentive to pursue improvement.[145]

In contrast, prevention-based regulation that focuses on the product or process itself, rather than on discharges and add-on controls, will engender more creative engagement by process engineers, managers and other personnel beyond the firm's compliance staff. Moreover, the opportunities for cost reductions associated with preventative measures would likewise encourage firm staff and management to seek out innovative alternatives.[146] Concerning the nature of the innovations flowing from prevention, the contention is that traditional regulation generates innovation in control technologies, if at all, while prevention-derived innovations are likely to result in product or process improvements having beneficial spillover benefits such as increased competitiveness.[147]

As with cost-effectiveness, the rate and nature of innovation flowing from alternative regulatory approaches is likely to be highly contextual. A variety of factors such as market distortions, information asymmetries in the market, organizational features of the firm, and the specific attributes of the new technology affect innovation.[148] In many cases, these factors and others can create a technological inertia that consistently dampens the impact of regulation on the development and spread of new and emerging

144. *Id.* at 292.

145. Malloy, *Social Construction*, supra note 16, at 291–92; Neil Gunningham et al., SMART REGULATION: DESIGNING ENVIRONMENTAL POLICY 39 n.5 (Keith Hawkins ed. 1998); Cass R. Sunstein, *Congress, Constitutional Moments, and the Cost-Benefit State*, 48 STAN. L. REV. 247, 260 (1996).

146. BASS, *supra* note 136, at 26–27; Quinn et al., *supra* note 139, at 300; Kurt A. Strasser, *Cleaner Technology, Pollution Prevention and Environmental Regulation*, 9 FORDHAM ENVTL. L.J. 1, 3 (1998).

147. Dorfman et al., *supra* note 133, at 190.

148. *Id.* at 191–93; Malloy & Sinsheimer, *supra* note 24, at 192–98; Ashford, *Innovation-Based Strategy*, *supra* note 143, at 291.

technologies.[149] This inertia has been demonstrated in the context of both add-on control technologies and prevention strategies such as substitution and process change.[150]

E. Summing Up

So what can we say about the charges against conventional risk management? The limited protectiveness of ACLs and the ineffectiveness of control measures are significant concerns. Standing alone they justify shifting towards the prevention paradigm. That said, the design of prevention-based programs, and the methodologies they use, must take heed of the lessons from conventional risk management. Otherwise they may find themselves stymied by the very same problem of limited protectiveness. The factors of cost-effectiveness and dynamic efficiency appear too contextual to form a compelling basis for embracing prevention in all settings. Both factors are relevant, however, in evaluating the performance of the various forms of prevention-based regulation—a subject I take up in Part V. But first I turn to operationalizing prevention in the regulatory setting.

IV. OPERATIONALIZING PREVENTION

The plethora of government reports, advocacy pieces, and academic articles that embrace prevention offer no systematic account of the choices available to policymakers willing to take up the prevention mantle. So what does it mean to say that a regulatory program should use "prevention-based" approaches to advance the adoption of "safer alternatives"? The central principle underlying prevention-based regulation is to avoid the risk by avoiding the chemical. It seeks to minimize the use of toxic chemicals by mandating or directly incentivizing the adoption of safer alternative chemicals or processes wherever feasible. This section addresses the challenge of prevention-based regulation in two parts. First, it sketches out the broad outlines of alternatives analysis, a method that government agencies and businesses will need in the regulatory setting to identify and evaluate safer, viable alternatives. Second, it sets out a typology of specific

149. Malloy, *supra* note 143, at 531; CARLOS C. MONTALVO, ENVIRONMENTAL POLICY AND TECHNOLOGICAL INNOVATION: WHY DO FIRMS ADOPT OR REJECT NEW TECHNOLOGIES (Edward Elgar ed. 2002).

150. Malloy & Sinsheimer, *supra* note 24, at 198–207.

prevention approaches that could be adopted in gatekeeper and oversight programs to mandate or encourage adoption of such safer alternatives.

A. Alternatives Analysis: The Threshold Methodology

By now it is clear that any prevention-based approach, whatever its form, requires the evaluation of alternatives against which the regulated chemical or process is to be compared. Is a petroleum-based solvent "safer" than perchloroethylene when used for dry cleaning? As viable? Is a silver/tin/copper solder a better choice than a lead-based solder? Typically, the concept of a "viable safer alternative" incorporates several features. Of course, safety is central to the concept, and generally includes consideration of human health, ecological and environmental impacts.[151] Viability focuses upon both technical performance and economic feasibility; an alternative which cannot satisfactorily serve the role filled by the baseline chemical or process, or which can do so only at substantially increased cost may not be viable.[152] It follows that regardless of whether the potential alternatives involve substitution, process change, or moderation, some evaluation is needed to evaluate their relative safety, technical performance and economic feasibility. Thus alternatives analysis—a method for identification, assessment and comparative evaluation of alternatives—will be a central element of any prevention-based approach.[153]

Government agencies have engaged in various forms of alternatives analysis in a wide range of contexts for decades.[154] Examples include evaluation of federal projects under the National Environmental Policy Act,[155] selection of clean-up strategies for contaminated sites under the Comprehensive Environmental Response, Compensation and Liability Act

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151. *See* Timothy F. Malloy, Peter J. Sinsheimer, Ann Blake, & Igor Linkov, *Use of Multi-Criteria Decision Analysis in Regulatory Alternatives Analysis: A Case Study of Lead Free Solder*, 9 INTEGRATED ENVTL. ASSESSMENT & MGMT. 652, 653 (2013) (*hereinafter* Malloy et al., *Case Study*); ECHA, Guidance for the Preparation of an Annex XV Dossier for Restrictions at 69 (June 2007); Rossi et al., *supra* note 8, at 5.

152. *See* ASHFORD & CALDART, *supra* note 8; ECHA, Guidance on the Preparation of an Application for Authorisation 56–61 (ECHA-11-G-01, January 2011); Rossi et al., *supra* note 8, at 18–20.

153. Malloy et al., *Case Study*, *supra* note 151; O'BRIEN, *supra* note 114, at 3–15.

154. O'BRIEN, *supra* note 114, at 147–169; Oliver Houck, *Hard Choices: The Analysis of Alternatives under Section 404 of the Clean Water Act and Similar Environmental Laws*, 60 U. COLO. L. REV. 773 (1989).

155. *See* 40 C.F.R. § 1502.14 (setting out general requirements for alternatives analysis under NEPA).

(commonly referred to as "Superfund"),[156] and identification of best available control technologies in Clean Air Act permitting.[157] However, agencies have had significantly less experience in the chemical regulation area.[158] Perhaps the most infamous example of regulatory alternatives analysis occurred as part of EPA's ill-fated attempted regulation of asbestos-containing products under TSCA.[159] The court faulted EPA's hazard evaluation of the substitutes for asbestos, concluding that the agency's comparative analysis of the hazards was superficial: "EPA, in its zeal to ban asbestos, cannot overlook, with only cursory study, credible contentions that substitute products actually might increase fatalities."[160]

Businesses and academics have engaged in alternatives analysis of chemicals and chemical processes in a variety of non-regulatory contexts, including chemical safety, process design, and consumer product evaluation.[161] While these private efforts provide valuable background for development of a regulatory alternatives analysis methodology, they cannot be applied directly in a regulatory context. Integration of alternatives analysis into a formal regulatory program must take into account normative issues (such as legitimacy,[162] accountability,[163] and transparency[164]) not

156. 40 C.F.R. § 300.430.

157. ENVTL. PROT. AGENCY, NEW SOURCE REVIEW WORKSHOP MANUAL: PREVENTION OF SIGNIFICANT DETERIORATION AND NONATTAINMENT AREA PERMITTING B-4–55 (1990).

158. In the European Union, the European Chemical Agency has issued guidance for alternative analysis of certain regulated chemicals under REACH, but there has been little experience implementing that guidance. *See* EUR. CHEMS. AGENCY, ECHA-11-G-01, GUIDANCE ON THE PREPARATION OF AN APPLICATION FOR AUTHORISATION 3–7 (2011); EUR. CHEMS. AGENCY, GUIDANCE FOR THE PREPARATION OF AN ANNEX XV DOSSIER FOR RESTRICTIONS 17 (2007).

159. ICF INCORPORATED, REGULATORY IMPACT ANALYSIS OF CONTROLS ON ASBESTOS AND ASBESTOS PRODUCTS, Appendix H (1989); *see also* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1221–28 (5th Cir. 1991).

160. *Corrosion Proof Fittings*, 947 F.2d at 1224.

161. *See* Koch & Ashford, *supra* note 61, at 36–37 (discussing Technology Options Analysis); CENTER FOR CHEMICAL PROCESS SAFETY (CCPS), INHERENTLY SAFER CHEMICAL PROCESSES: A LIFE CYCLE APPROACH 1–2 (1996); TOXICS USE REDUCTION INST. UNIV. OF MASS. LOWELL, FIVE CHEMICALS ALTERNATIVES ASSESSMENT STUDY 2 (2006); Xiaoying Zhou & Julie M. Schoenung, *An Integrated Impact Assessment and Weighting Methodology: Evaluation of the Environmental Consequences of Computer Display Technology Substitution*, 83 J. ENVTL. MGMT. 1 (2007).

162. By legitimacy, I refer to whether the government action is procedurally fair. *See* Timothy F. Malloy, *Regulation, Compliance and the Firm*, 76 TEMP. L. REV. 451, 467–470 (2003) (discussing the social psychology literature regarding compliance with law as it relates to perceived legitimacy of regulation); Craig A. McEwen & Richard J. Maiman, *In Search of Legitimacy: Toward an Empirical Analysis*, 8 LAW & POL'Y 257, 258–59 (1986).

163. *See* Tony Prosser, *Democratisation, Accountability and Institutional Design: Reflections on Public Law*, *in* LAW, LEGITIMACY AND THE CONSTITUTION 182 (Patrick

necessarily present in the private setting. For example, the legitimacy of government action depends, among other things, on the consistency and rigor of the action taken.[165] Thus, in a regulatory program mandating that manufacturers of nail polish perform alternatives analyses of their products, the principle of consistency requires that similar products should be treated in a similar fashion.[166] Regulatory responses should not vary as a result of solely private business decisions about the nature, scope, or methodology of the alternatives analysis process selected by the manufacturer. Likewise, the standard of rigor mandates that government action be grounded in science, with well-articulated standards and methodologies.[167] As the D.C. Circuit's *Corrosion Proof Fittings* decision regarding EPA's alternatives analysis under TSCA demonstrates, *ad hoc* decision-making is vulnerable to political and judicial challenge.[168] With this distinction between private and regulatory alternatives analysis in mind, I turn now to consider the objectives of and approaches to alternatives analysis.

Existing alternatives analysis approaches and frameworks provide the basic elements of this methodology,[169] of which elements fall into two major steps. The first step, *alternatives assessment*, includes (1) identification of the key criteria for comparison (e.g., technical, health and safety, environmental, and economic attributes) and the metrics for measuring performance on those criteria; (2) identification of potentially viable

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McAuslan & John F McEldowney eds., 1985) (defining accountability as "the development and institutionalisation of the means for obtaining and publicly testing information forming reasons for decisions.").

164. Leeka Kheifets et. al, *Risk Governance for Mobile Phones, Power Lines and Emerging Technologies*, 10 RISK ANALYSIS 1481, 1482 (2010); NATIONAL RESEARCH COUNCIL, PUBLIC PARTICIPATION IN ENVIRONMENTAL ASSESSMENT AND DECISION MAKING 1 (Thomas Dietz & Paul C. Stern eds., 2008).

165. *See* Gerald S. Levanthal, *What Should Be Done with Equity Theory*, *in* SOCIAL EXCHANGE: ADVANCES IN THEORY AND RESEARCH 27, 39 (Kenneth J. Gergen et al. eds., 1980) (arguing that procedural justice in the allocation of resources includes the principles of consistency and accuracy).

166. *See* Todd S. Aagaard, *Environmental Law as a Legal Field: An Inquiry into Legal Taxonomy*, 95 CORNELL L. REV. 221, 224 (2010) ("Justice requires consistency.").

167. NRC, SCIENCE AND DECISIONS, *supra* note 13, at 68 (calling for the use of best scientific evidence and methods in regulatory risk assessment). Of course, the rigor principle, despite its validity, is subject to strategic manipulation. *See* Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 1650–51 (1995).

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

169. Malloy et al., *Case Study*, *supra* note 151, at 653–57; Zhou & Schoenung, *supra* note 136, at 3; Rossi et al., *supra* note 8, at 3–4 (2006); TOXICS USE REDUCTION INSTITUTE, ALTERNATIVES ASSESSMENT FOR TOXICS USE REDUCTION: A SURVEY OF METHODS AND TOOLS, 1–2 (2005); ENVTL. PROT. AGENCY, EPA 744-R-95-002, CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT: A METHODOLOGY AND RESOURCE GUIDE (1996).

alternatives; and (3) collection and compilation of data regarding performance of the regulated product and alternatives for each criterion.[170] Most forms of alternatives assessment generate some type of a "performance matrix," a table, chart, or other graphic setting out the relative performance of each alternative across all comparison criteria.

The alternatives assessment step is fairly well developed, and there appears to be broad consensus regarding how it should be conducted.[171] Methodological and implementation issues clearly remain, however. For example, in terms of methods, while practitioners agree that human health impact is a critical criterion, there are a range of approaches as to which impacts should be assessed and how they should be measured and reported.[172] Regarding implementation, the scope and volume of information needed for a comprehensive alternatives assessment can be formidable. To engage in rigorous, defensible comparisons of existing chemicals and their alternatives, regulators will need information about the relative hazards and risks associated with each.[173]

The practical problem here is that existing methodologies for hazard identification and risk assessment are time-consuming and expensive.[174] Indeed, the paucity of information about the majority of existing chemicals is due in large part to this very problem. Ironically, adoption of a comparative, preventive approach exacerbates the challenges presented by conventional risk management and risk assessment by increasing the focus from a single regulated chemical to that chemical *and* its alternatives. Predictive toxicology, which uses a variety of computational approaches, high throughput assays, and other methods to predict human health and ecological impacts with minimal testing and cost, offers a potential solution

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170. Malloy et al., *Case Study*, *supra* note 151, at 653–55; BRANDON KUCZENSKI & ROLAND GEYER, CAL. DEP'T OF TOXIC SUBSTANCE CONTROL CONTRACT REPORT # 08-T3629, CHEMICAL ALTERNATIVES ANALYSIS: METHODS, MODELS, AND TOOLS 30 (2010).

171. KUCZENSKI & GEYER, *supra* note 170, at 31.

172. Kathryn H. Winnebeck, *An Abbreviated Alternatives Assessment Process for Product Designers: A Children's Furniture Manufacturing Case Study*, 19 J. CLEANER PROD. 464, 465–68 (2011).

173. Likewise, the scope of information required will be broader in a prevention-based approach. Existing chemical regulatory programs typically call for considerable data regarding a limited range human health and economic impacts of one chemical, and a smattering of data regarding environmental, energy and resource impacts. Alternatives assessment ostensibly could require substantially more data—much which would have to be generated for the assessment—concerning *all* those impacts for the baseline chemical *and* all the relevant alternatives.

174. *See* Thomas Hartung, *Toxicology for the Twenty-First Century*, 460 NATURE 208, 208 (2009); NATIONAL ACADEMY OF SCIENCE, TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND A STRATEGY, 1 (2007).

to this dilemma.[175] In any event, the potentially paralyzing data-intensive nature of the alternatives assessment will have to be confronted, most likely by streamlining the data needs as well as relying upon emerging predictive toxicology methods.

The second component of alternatives analysis is *alternatives evaluation*, largely but not entirely conducted after the alternatives assessment is completed. It moves beyond the collection and presentation of data to the determination of whether viable, safer alternatives are available. Its goal is essentially to rank the baseline and alternatives in the relative order of how well each option fits the decision criteria guiding the evaluator.[176] In some cases, this may be a relatively straightforward exercise. Consider the case of a cheaper, commercially available alternative that neither contains a chemical of concern nor has any other negative health, environmental, or resource impacts. Likewise, the judgment is fairly clear where the baseline chemical/product and alternative exhibit the same hazards but at substantially different magnitudes.

Most cases, however, will likely be much more difficult, presenting thorny trade-offs within decision criteria (for example, within the human health criteria comparing carcinogenicity with endocrine disruption) or between them (such as balancing an adverse health impact against an environmental impact). The balancing of such incommensurables is by nature a subjective process driven by the decision-maker's values, essentially forcing the decision-maker to explicitly or implicitly weight the relative importance of the various decision criteria.

While the alternatives evaluation is inherently subjective, the principles of rigor,[177] consistency,[178] and transparency[179] that underlie risk regulation require that the decision-making process be directed by clearly articulated program expectations and decision rules. The Superfund statute and implementing regulations establish a more explicit array of program expectations coupled with set of nine narrative decision criteria.[180] Selection among remedial alternatives in the Superfund programs is driven

175. *See* Daniel Krewski et al., *New Directions in Toxicity Testing*, 32 ANN. REV. PUB. HEALTH 161, 163 (2011); Douglas W. Bristol, et al., *The NIEHS Predictive-Toxicology Evaluation Project*, 104 ENVTL. HEALTH PERSPS. 1001, 1002 (1996).

176. Malloy et al., *Case Study*, *supra* note 151, at 655–57.

177. *See supra* notes 175–76 and accompanying text.

178. *See supra* notes 175–76 and accompanying text.

179. *See* NRC, SCIENCE AND DECISIONS, *supra* note 13.

180. 40 C.F.R. § 300.430(a)(1)(iii) (2009). For example, Superfund program expectations include use of treatment rather than containment where practical; return groundwater to beneficial uses; use innovative technology where comparable to conventional technology. *Id.*

through a balancing of five criteria: long-term effectiveness, reduction of toxicity through treatment, short-term effectiveness, implementability, and cost-effectiveness.[181] The approach adopted in the Superfund—the balancing of narrative decision criteria—could be adopted in regulatory alternatives analysis as well.

Yet there is reason for concern over leaving decision-making in such complex cases solely to narrative decision rules and *ad hoc* determinations by agency staff and managers. Alternatives analysis can be extremely challenging even in relatively straightforward circumstances; it can require consideration of a broad range of criteria, some of which are qualitative in nature and many of which are incommensurable. The data to be considered will be quite diverse in nature; some will be qualitative and other quantitative. So, for example, in comparing the use of a lead-tin solder to a tin-silver-copper formulation in consumer electronics, the analyst must consider a trade-off between lead contamination from landfill disposal and substantially increased energy consumption in solder production. Likewise, in assessing the dangers of alternative plasticizers in a teething ring, the regulator may face choice between endocrine disruption and cancer. These challenges are intensified by the fact that data regarding toxicity, exposure, functionality, and economic impact are typically incomplete and often highly uncertain.

The resulting decision environment is thus decidedly complex. Cognitive psychology and decision theory both recognize that humans have substantial difficulty managing and synthesizing such diverse, rich streams of information in a consistent and coherent fashion. We adapt by adopting cognitive heuristics—rules of thumb that tend to simplify data and emphasize biases.[182] In the regulatory setting, concerns regarding consistency and transparency are also raised; ill-considered or even self-interested decision-making can flourish in the shadows of a complex decision environment. For example, commentators have noted the deficiencies in the transparency, consistency, and rigor of the Superfund remedy selection decision process.[183]

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181. 40 C.F.R. §300.430. Each of these criteria is further broken down into underlying factors or sub-criteria. *Id.*

182. *See* Gregory A. Kiker et al., *Application of Multicriteria Decision Analysis in Environmental Decision Making*, 1 INTEGRATED ENVTL. ASSESSMENT & MGMT. 95, 95 (2005); Timothy L. McDaniels et. al., *Democratizing Risk Management: Successful Public Involvement in Local Water Management Decisions*, 19 RISK ANALYSIS 497, 498 (1999); AMOS TVERSKY & DANIEL KAHNEMAN, JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 3 (1982).

183. *See* Joel S. Hirschhorn, *Definition and Analysis of Stubborn Superfund Problems*, *in* WORKING PAPERS ON SUPERFUND REFORM: PROBLEM DEFINITION AND POLITICAL MAPPING 55,

Decision analysis tools can assist policy makers and stakeholders facing such complex decision environments. One type of decision analysis aid that has been used increasingly in many fields is multi-criteria decision analysis (MCDA).[184] MCDA methods allow decision-makers to analyze multiple streams of incommensurable data (such as economic costs expressed in dollars, health impacts expressed in cancer potency factors, and ecological impacts measured in habitat loss) in a standardized, objective manner.[185] MCDA uses a variety of mathematical methods to sort through the performance of each alternative across a range of attributes, taking into account the relative importance of those attributes to the decision-maker. There are a variety of MCDA methods available, reflecting a range of theoretical foundations.[186] Some MCDA methods generate a complete ranking of the alternatives; i.e., a ranking in which all alternatives are ranked relative to one another. Others simply identify the "best" alternative, or a set of acceptable alternatives[187]. Some are compensatory—allowing a high "score" in one attribute to offset a low score in another, while others are partially compensatory.[188]

MCDA is not intended to supplant the decision-maker, nor is it a "black box" from which a selected alternative emerges. It is simply a tool for systematizing the decision-process, and is driven by the preferences and values of the decision-maker which are incorporated into the algorithms of the particular MCDA approach chosen. Thus, it attempts to provide a comparative evaluation of the alternatives based upon the criteria provided by the decision-maker, taking into account the relative importance of those

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66–67, 71–72 (1992) (criticizing clarity of decision framework and noting inconsistent remedy choices for similar contaminated sites); Aaron A. Jennings, et al., *Superfund Decision Analysis in Presence of Uncertainty*, 120 J. ENVTL. ENGINEERING 1132, 1144–47 (1994) (describing lack of clarity and transparency of the process); U.S. Congress, Office of Technology Assessment, *Coming Clean: Superfund's* Problems *Can Be Solved* . . . , OTA-ITE-433175–177 (Washington, DC: U.S. Government Printing Office, Oct. 1989).

184. *See* Gregory A. Kiker et al., *supra* note 182.

185. Igor Linkov et al., *Multi-Criteria Decision Analysis: A Framework for Structuring Remedial Decisions at Contaminated Sites*, *in* COMPARATIVE RISK ASSESSMENT AND ENVIRONMENTAL DECISION MAKING 15, 17 (Igor Linkov & Abou Bakr Ramadan eds., 2004).

186. *See generally* VALERIE BELTON & THEODOR J. STEWART, MULTIPLE CRITERIA DECISION ANALYSIS: AN INTEGRATED APPROACH 331–43(2002); IGOR LINKOV & EMIL MOBERG, MULTI-CRITERIA DECISION ANALYSIS: ENVIRONMENTAL APPLICATIONS AND CASE STUDIES (2012).

187. Jyri Seppälä et al., *Decision Analysis Frameworks for Life-Cycle Impact Assessment*, 5 J. INDUS. ECOLOGY 45, 47 (2001).

188. Igor Linkov et al., *From Comparative Risk Assessment to Multi-Criteria Decision Analysis and Adaptive Management: Recent Developments and Applications*, 32 ENVT. INT'L 1072, 1075–76 (2006).

criteria to the decision-maker.[189] Properly used, MCDA methods could provide consistency across cases, and provide transparency for stakeholders.[190] For example, MCDA can visualize for stakeholders how an alternative's performance on each decision criteria contributed to its overall ranking. See Figure 1 below for an illustration of that feature in an MCDA comparison of lead solder (labeled as "SnPb") to a set of non-lead alternatives.[191] It also allows for sensitivity analysis, which permits decision-makers and stakeholders to see how changes in the data or the weighting accorded to various decision criteria affect the outcome.[192] It also offers a variety of systematic, transparent approaches for dealing with uncertain or missing data.[193]

189. C.D. Gamper and C. Turcanu, *On the Governmental Use of Multi-Criteria Analysis*, 62 ECOLOGICAL ECON. 298, 299–300 (2007).

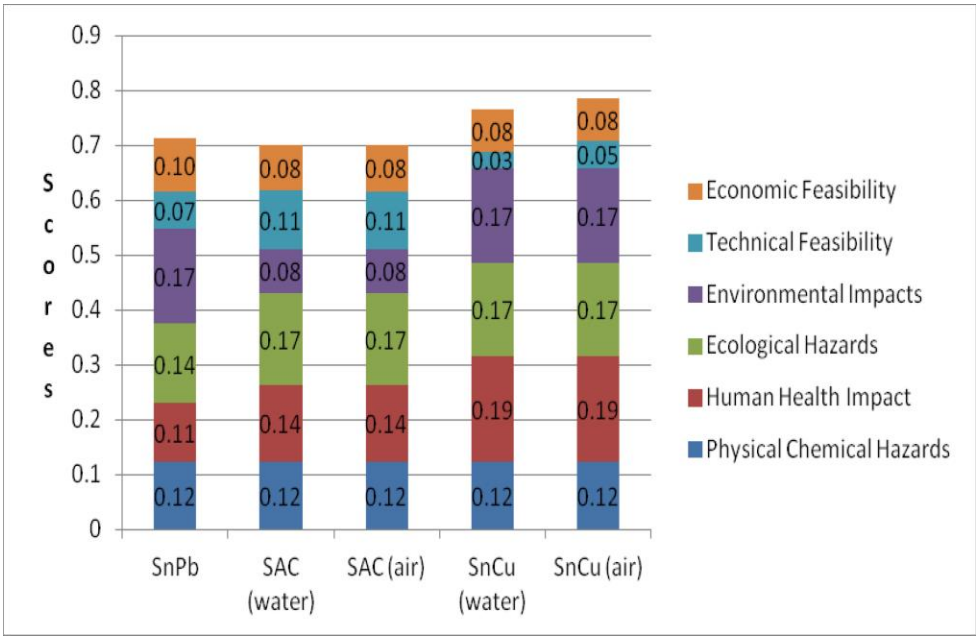
190. Malloy et al., *Case Study*, *supra* note 151, at 662.

191. *See infra* Figure 1.

192. Kylie Hyde, Holdger R. Maier, and Christopher Colby, *Incorporating Uncertainty in the PROMETHEE MCDA Method*, 12 J. MULTI-CRITERIA DECISION ANALYSIS 245, 246 (2003).

193. LINKOV & MOBERG, *supra* note 186, at 3–7, 109–111.

Figure 1
MCDA Output for Lead Solder (SnPb) and Alternatives



That said, MCDA is a formal, specialized methodology and, much like risk assessment, can obscure implicit assumption and value choices within that formal framework. Moreover, even the selection of a particular MCDA approach itself can affect the ultimate outcome. Accordingly, the decision of whether and how to use MCDA as a decision tool as part of regulatory alternatives analysis requires careful consideration.[194]

B. The Prevention Typologies

Alternatives analysis provides the means for identifying "safer" viable alternatives; prevention-based regulation supplies the vehicle for spreading those alternatives. This section sets out a descriptive typology of prevention-based regulatory approaches.[195] As with any general typology,

194. Malloy et al., *Case Study*, *supra* note 151, at 661–63.

195. The term "typology" refers to a range of methods for describing, classifying and explaining sets of objects, phenomena, institutions and other objects of study in a variety of disciplines, including sociology, linguistics, law and political science. A descriptive typology of the sort I employ defines distinct types to use as descriptive characterizations. *See* Colin Elman,

the groupings are somewhat imprecise.[196] In seeking to group the approaches by reference to major distinctions among them, the typology necessarily loses resolution, becoming fuzzy around the edges. There is admittedly overlap across some of the types, and of course analytical simplification which leaves out various potential combinations of approaches. This diminished nuance and incompleteness is unfortunately a necessary one in generating a tractable typology. That said, where relevant, the discussion below attempts to clear up some fuzziness and complicate some simplifications.

Before embarking on this tour of prevention-based approaches, it is important to emphasize three themes that underlie them. First, one can adopt a prevention-based approach without embracing the precautionary principle. For many, the precautionary principle is the third rail of environmental policy. There is substantial debate about exactly what the precautionary principle actually is; indeed, one of the primary challenges raised by its critics is the amorphous, underdeveloped nature of the concept, what David Dana terms the indeterminacy critique.[197] The Rio Declaration provides one of the earliest formulations of the precautionary principle, vague yet constrained enough in its reach to attract relatively broad support: "Where there are threats of serious or irreversible damage, lack of full scientific uncertainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[198] Other formulations would extend the principle in various directions, such as loosening or even dropping the constraints of irreversibility and cost-effectiveness, or shifting conventional burdens of proof.[199] There is considerable debate within and outside academia, and it is fair to say that

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Explanatory Typologies in Qualitative Studies of International Politics, 59 INT'L ORG. 293, 295–298 (2005) (providing a typology of typologies, including descriptive, classificatory and explanatory typologies). For a discussion of the distinction between a typology and a taxonomy, *see* Donald C. Hambrick, *Taxonomic Approaches to Studying Strategy: Some Conceptual and Methodological*, 10 J. MGMT. 27, 28–29 (1984).

196. Shaker A. Zahra & John A. Pearce II, *Research Evidence On The Miles-Snow Typology*, 16 J. MGMT. 751, 753 (1990).

197. David A. Dana, *A Behavioral Economic Defense of the Precautionary Principle*, 97 NW. U. L. REV. 1315, 1317 (2003).

198. United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3–14, 1992, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/5/Rev.1 (Vol. I), Annex I (Aug. 12, 1992), *reprinted in* 31 I.L.M. 874 (1992).

199. *See* Bernard D. Goldstein & Russellyn S. Carruth, *Implications of the Precautionary Principle for Environmental Regulation in the United States: Examples from the Control of Hazardous Air Pollutants in the 1990 Clean Air Act Amendments*, 66 LAW & CONTEMP. PROBS. 247, 249–50 (2003).

the precautionary principle itself has become deeply politicized and polarized.

Adoption of prevention-based regulation can proceed without engaging the precautionary principle debate. While there is a tendency among some commentators and advocates to link prevention and the precautionary principle or even use the terms interchangeably, the two are conceptually distinct. Simply put, one can engage in prevention without espousing precaution, and vice versa. For example, a regulator could delay action concerning a chemical until the risk of harm was absolutely clear (thus rejecting the precautionary principle), but require substitution of that chemical rather than control when finally acting (engaging in prevention). Conversely, the regulator may take precautionary action based upon early but uncertain indications of harm, but choose engineering controls designed to reduce the risk to acceptable levels.[200]

Second, prevention-based regulation and conventional risk management are not mutually exclusive. The classic example of prevention in action is the case in which an environmentally-benign, viable alternative exists for a hazardous chemical or process. In that case, prevention is a complete solution. While such cases do occur, the far more likely scenario is that safer, but not completely safe, alternatives will be available. A halogenated solvent is replaced with a water-based solvent for metal parts cleaning, or a hexavalent chromium electroplating processes is phased-out in favor of a safer trivalent chromium process. In both cases, the substitution is a significant improvement, but still exhibits some residual risks which must be addressed through conventional risk management measures such as engineering controls.[201] Alternatively, in other cases, no viable, safer alternative (or moderation or minimization strategies) may be available. In such cases, risk management is a second-best but still appropriate approach.

Third, prevention-based regulation is not completely uncoupled from notions of risk (i.e., the probability of harm taking into account the hazard of a chemical and the extent of exposure to that chemical). Some proponents of prevention-based regulation characterize it as obviating, or at

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200. *See* Geert van Calster, *Risk Regulation, EU Law and Emerging Technologies: Smother or Smooth?*, 2 NANOETHICS 61, 66–68 (2008) (distinguishing between the prevention and precautionary principles with respect to whether a risk is certain (prevention principle) or uncertain (precautionary principle)).

201. *See* Emi Kikuchi, Yasunori Kikuchi, & Masahiko Hirao, *Analysis of Risk Trade-Off Relationships between Organic Solvents and Aqueous Agents: Case Study of Metal Cleaning Processes*, 19 J. CLEANER PROD. 414, 422–23 (2011) (wastewater treatment needed for aqueous cleaning solvents).

least substantially reducing, the need to assess risk.[202] While quantitative risk assessment would most certainly become less important in a prevention-based regime, a practical program implemented in a world of limited resources will require consideration of the relative risk of chemicals at two points: (1) the initial prioritization of chemicals and (2) as part of the alternatives analysis itself.

With tens of thousands of chemicals in the marketplace, regulators will have to prioritize their regulatory resources in some manner, choosing which chemicals to address in what order. Focusing only upon the hazards of the various chemicals will not necessarily capture those presenting the most troubling public health or environmental threats. For example, a moderately hazardous chemical in a widely-used household cleaning spray could do significantly greater harm than a substantially more hazardous chemical in limited commercial use, or embedded in the printed circuit board of a wireless telephone. Thus, even in a prevention-based program, some attention to the relative risks presented by chemicals will be needed to allocate regulatory attention so as to minimize overall harm.

The need to account for relative risk will also be required where the regulator is determining whether a safer substitute or alternative for the regulated chemical exists. As noted above, most potential alternatives are unlikely to be completely benign—many will no doubt present concerns of their own. Alternatives analysis is a comparative exercise, and just as in the case of prioritization of chemicals, meaningful comparison of the public health threat requires consideration of both hazard and exposure—in other words, consideration of risk in some form. While this consideration need not be a formal quantitative risk assessment, it should account for the relative exposure potential as well as the relative hazard.

Prevention-based regulatory approaches can be broken into two major types. The first are direct, mandatory approaches that expressly incorporate safer alternatives in a design or performance standard. A design standard requires adoption of a specific technology, material or process, in this case being the safer alternative.[203] It may also prohibit the use of a specified technology, as in a ban or phase-out of a specified technology or material. A

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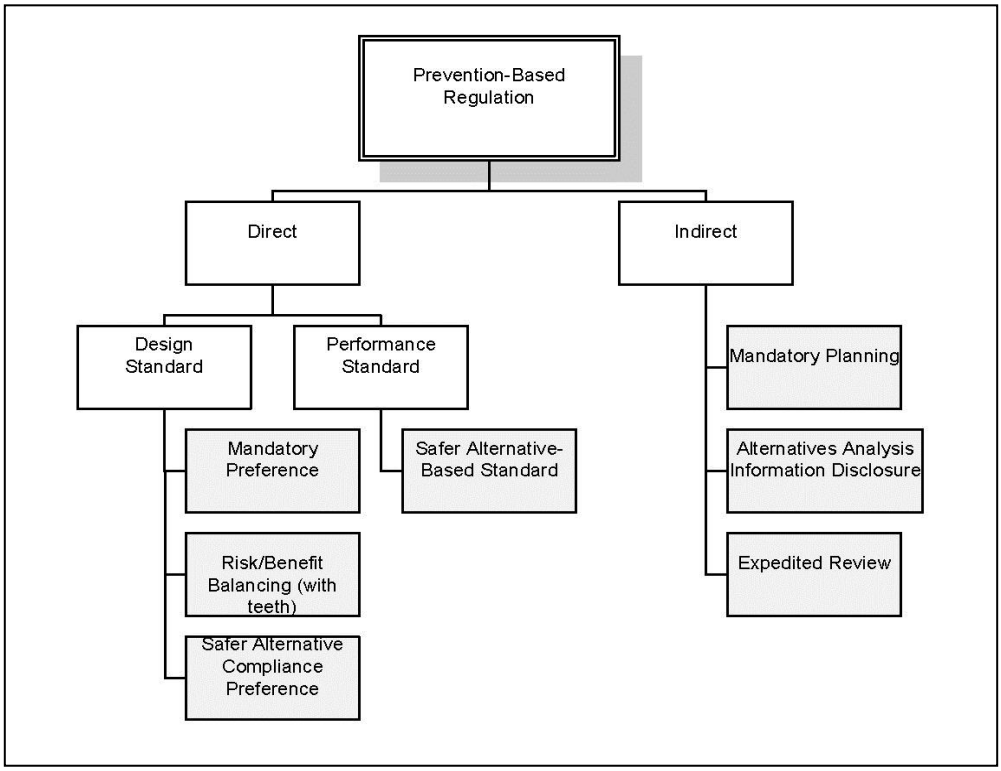
202. Mark Rossi, Cheri Peele & Beverly Thorpe, *How to Select Safer Alternatives to Chemicals of Concern to Human Health or the Environment*, BIZNGO 10 (Nov. 30, 2011), *available at* http://www.biznngo.org/resources/entry/chemical-alternatives-assessment-protocol; Beverley Thorpe & Mark Rossi, *Background Paper for Reform No. 1 of the Louisville Charter for Safer Chemicals* 3 (August 2005), *available at* http://www.cleanproduction.org/static/ee_images/uploads/news/Charter_sub_Thorpe2005.pdf.

203. Malloy & Sinsheimer, *supra* note 24, at 196–98.

performance standard sets out a specified level of performance but which may be attained through other effective means.[204] The second are indirect approaches which encourage, but do not require, adoption of safer alternatives by regulated entities. See Figure 2.

Figure 2
The Prevention Typology



1. Direct Design Standards

Mandatory Preference for Viable, Safer Alternatives. In this approach, use of a chemical or process would be prohibited if a safer viable alternative is available. In its weaker form, the mandatory preference would simply prohibit the use of the baseline chemical or process given the existence of the safer alternative. This weak form would most likely arise in the gatekeeper context, in which the regulated entity is seeking approval for a new chemical or process. The stronger form, which would require the

204. *Id.*

regulated entity to adopt the safer alternative, would most likely be used in the oversight context. The regulatory process, whether an application review in a gatekeeper program or a rulemaking proceeding in an oversight program, would include an alternatives analysis of the type discussed above intended to identify and evaluate potential alternatives. In the absence of a safer, viable alternative, conventional risk management approaches would apply.

The European Union's 2006 comprehensive chemical regulation, known as the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),[205] demonstrates the use of a mandatory preference in the gatekeeping context. That regulation applies the preference to a particular subset of formally listed "substances of very high concern" (SVHC). SVHCs include substances exhibiting a range of hazards, such as carcinogenicity, mutagenicity, or reproductive toxicity (known collectively as CMRs), endocrine disruption, persistence in the environment, and bioaccumulation.[206] Manufacturers of articles containing such chemicals must obtain authorization from the European Commission in order to market the articles in the European Union.[207] REACH sets out special authorization standards for two categories of SVHCs: CMRs and endocrine disrupters for which a "safe" level cannot be determined, and substances that are persistent, bioaccumulative and toxic.[208] For these particularly worrisome SVHCs, manufacturers must perform alternatives analyses. If the analysis identifies a safer alternative, the manufacturer must prepare and implement a substitution plan for phasing-in the alternative. If no alternative exists, authorization is available only if the manufacturer demonstrates that the socio-economic benefits of the chemical use outweigh the risks (taking into account the application of the most protective, technically practical control measures).[209]

The REACH regime melds this prevention-based approach for SHVCs of heightened concern with a more conventional risk management approach

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205. Commission Regulation 1907/2006, 2006 O.J. (L 396) 1 (EC).

206. Commission Regulation 1907/2006, art. 57 (a)–(f), 2006 O.J. (L 396) 1, 141–42. A substance becomes subject to the authorisation process upon being listed as a SVHC in Annex XIV to REACH. The listing process is quite involved, with new candidate substances identified at least every two years. Commission Regulation 1907/2006, art. 58, 2006 O.J. (L 396) 143 (EC).

207. Commission Regulation 1907/2006, art. 56.1, 2006 O.J. (L 396) 139 (EC).

208. Commission Regulation 1907/2006, art. 57, 2006 O.J. (L 396) 141–42 (EC).

209. Commission Regulation 1907/2006, art. 60.4, 60.10, 2006 O.J. (L 396) 150, 152 (EC); *see* ECHA, *Guidance on the Preparation of an Application for Authorisation* 16–19 (ECHA-11-G-01, Jan. 2011).

for the remaining SVHCs and other chemicals. Under the risk management approach, the manufacturer (and downstream users) must "adequately control" the "risk to human health or the environment from the use of the substance."[210] For example, human health risks are adequately controlled where the risk management measures avoid exposures at levels "above which humans should not be exposed."[211]

California's draft Safer Consumer Products regulations, to be promulgated under AB Assembly Bill 1879 and Senate Bill 509 (collectively AB 1879), adopt a similar regime. These bills mandated a comprehensive chemicals regulatory scheme having three steps: identification and prioritization of consumer products containing chemicals of greatest concern; performance of alternative analyses for those products; and selection of regulatory responses ranging from outright bans to no action at all and everything in between. The California draft regulations explicitly embrace the prevention principle:

> In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection. For these purposes, "inherent protection" refers to avoidance or reduction of adverse impact . . . that is achieved through the redesign of a product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern. . . .[212]

The Department of Toxic Substances Control (DTSC) may ban or phase-out a "Priority Product" where alternatives analysis demonstrates the existence of an alternative that is functionally acceptable and technically and economically feasible. Even where no safer alternative exists, DTSC may ban or phase-out products unless the manufacturer demonstrates that the benefits and utility of the product significantly outweigh its overall

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210. *See* Commission Regulation 1907/2006, art. 14.6, 2006 O.J. (L 396) 79 (EC) (requiring manufacturers registering chemicals produced in volumes exceeding ten tons per year to identify and apply the appropriate measures to adequately control the risks associated with the substance and to recommend them in the safety data sheets provided to downstream users); Commission Regulation 1907/2006, art. 37.5, 2006 O.J. (L 396) 118 (EC) (requiring identification and application of adequate controls by downstream users); Commission Regulation 1907/2006, art. 60.2, 2006 O.J. (L 396) 149 (EC) (concerning authorisation standards for SVHCs not falling within the prevention-based regime).

211. Commission Regulation 1907/2006, annex I, Section 1.0.1, 2006 O.J. (L 396) 242 (EC), Likewise, with respect to environmental risks, concentrations of the substance must be kept below the level at which "adverse effects in the environmental sphere of concern are not expected to occur." Commission Regulation 1907/2006, Annex I, Section 3.0.1, 2006 O.J. (L 396) 248 (EC).

212. CAL. CODE REGS. tit. 22, § 69506(b) (2011).

adverse impacts, and that exposure controls can adequately protect human health and the environment.[213] DTSC has the discretion to impose less intrusive regulatory responses in lieu of a ban, including use restrictions and information disclosure requirements.[214] Apart from the general adoption of the prevention principle, the proposed regulations provide no specific direction as to when a ban rather than a use restriction or other regulatory response should be selected.

In the context of oversight programs, the County of Contra Costa's Industrial Safety Ordinance in California adopts a mandatory preference for safer alternatives in dealing with chemical plants and oil refineries. In accordance with federal process safety management requirements under Occupation Safety and Health Act and the Clean Air Act, the ordinance requires such facilities to regularly evaluate the safety of production processes and identify available mitigation measures.[215] The ordinance also expands the conventional process safety management requirements at such facilities, directing them to "consider the use of *inherently safer systems*" in existing and new processes and facilities.[216] The notion of "inherently safer systems" embraces prevention wholeheartedly, referring to equipment, processes, and procedures intended to avoid or reduce risk of chemical accidents by modifying a process rather than adopting "layers of protection."[217] Mandating consideration of inherently safer systems is unusual in its own right, yet remarkably the ordinance goes even further to require that facilities "select and implement inherently safer systems to the greatest extent feasible."[218]

Stated so starkly, the mandatory preference approach sounds draconian, raising legitimate concerns regarding the personal autonomy, economic

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213. CAL. CODE REGS. tit. 22, § 69506.5(b) (2011).

214. *See, e.g.*, CAL. CODE REGS. tit. 22, § 69506.3 (2011) (providing consumer information); CAL. CODE REGS. tit. 22, § 69506.4 (2011) (use restrictions); CAL. CODE REGS. tit. 22, § 69506.7 (2011) (end-of-life management requirements); CAL. CODE REGS. tit. 22, § 69506.8 (2011) (funding further research to develop safer alternatives).

215. *See* Malloy, *supra* note 6, at 110–11 (describing the process safety management program).

216. CONTRA COSTA COUNTY, CAL., Ordinance Code, tit. 4, div. 450, § 450-8.016(d)(3) (2006) (emphasis added).

217. *Id.* § 450-8.014(g).

218. *Id.* § 450-8.016(d)(3). The ordinance defines feasibility quite broadly: "capable of being accomplished in a successful manner within a reasonable period of time, taking into account economic, environmental, legal, social and technological factors." *Id.* § 450-8.014(c). Guidance issued by the County Health Department elaborates on this definition. Contra Costa Health Services, *Industrial Safety Ordinance Guidance Document*, at D-12 to D-13 (June 15, 2011), *available at* http://cchealth.org/hazmat/iso/guidance.php.

freedom and the proper role of government. I take those and other concerns up below in Part V. For now, however, it is worth noting that the mandatory preference approach is subject to several significant qualifications. First, the strength of the stated preference for safer, viable alternatives is highly dependent upon the definitions of "safer" and "viable" embedded in regulation and its alternative analysis methodology. For example, a definition of "viable" which requires that a lead-free solder equal or exceed the performance of the existing lead-based solder on *every* measure of functionality, even where the consumer application in question would tolerate less, diminishes the impact of a preference.

Second, the particular design of a mandatory preference approach can temper its ostensible harshness. Consider the case of an industrial process such as decorative electroplating in which an agency determines that hexavalent chromium processes should be replaced with a trivalent chromium process. In that event, an immediate ban on hexavalent chromium processes would be very unlikely. Instead, the ban would likely be phased in over time, providing electroplating businesses the opportunity to time to recoup the capital costs invested in the existing equipment. Such was the case in Southern California in 2002 when the South Coast Air Quality Management District began a phase-out of perchloroethylene dry cleaning processes based on the existence of viable, safer alternatives.[219]

Risk/Benefit Balancing (With Teeth). Under this approach, the overall health, environmental and societal risks of using the baseline chemical or process would be balanced against the corresponding overall benefits of its use. The benefits analysis would explicitly include consideration of safer alternatives. As the capacity of the alternative chemical or process to perform similar functions as the baseline increases, the baseline's benefits correspondingly shrink. If the risks exceed the expected benefits, the regulator would ban or phase out the baseline chemical or process. The strongest version of this approach rejects any consideration of potential exposure controls in assessing the risks of the baseline chemical. This reflects the prevention approach's skepticism regarding the effectiveness of mitigation controls. A weaker version of risk/benefit balancing (with teeth) would take into account the risk reduction achievable through exposure controls, weighing the net risk against the benefits.

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219. Malloy & Sinsheimer, *supra*, note 24, at 230–231 (adopting a phase out period based upon the expected useful life of existing equipment).

The "teeth" of this approach lies in the emphasis it accords to safer alternatives in the balancing. Risk/benefit balancing (with teeth) is based upon the unreasonable risk standard found in many gatekeeper programs such the TSCA and FIFRA, which likewise requires a balancing of the risks and benefits of the chemical. In practice, however, both the TSCA and FIFRA programs heavily favor risk management by focusing their review first on whether mitigation measures bring exposures below the ACL.[220] Risk/benefit balancing (with teeth) rejects the threshold question of whether mitigation can achieve an ACL, ensuring that safer alternatives will be considered in every case.

One may fairly ask how risk/benefit balancing (with teeth) differs from the mandatory preference. At first glance, it appears that outcomes under each should be the same. The mandatory preference bans or phases-out a chemical or process whenever a safer, viable, economically feasible alternative capable of performing the same function exists. In such cases, would not the risks of the chemical use always exceed its benefits? The answer to that question depends on the congruence between the criteria considered in alternatives analysis in identifying "safer, viable, economically feasible alternatives" and those considered as part of risk/benefit balancing.

The clearest example of this concerns the treatment of economic impact. The alternatives analysis typically takes a firm-centric form, limiting consideration of economic impacts to those experienced by the individual firm. Thus, the analysis would not consider the broader impacts on trade, competition, economic growth, inflation, taxes and other macro-economic features. This is consistent with an approach to alternatives analysis under REACH in the authorization process.[221] Risk/benefit balancing would take a more expansive approach, considering broader economic and societal effects. Thus, an alternative may be deemed safer and economically viable from the manufacturer's perspective, yet not fare well in risk/benefit balancing due to substantial adverse impacts on the larger economy. Where the criteria in the alternatives analysis track the type of criteria used in risk/benefit balancing, the mandatory preference may be the functional equivalent to risk/benefit balancing.

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220. *See supra* text accompanying notes 42–47.

221. *See* EPA, CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT—A METHODOLOGY AND RESOURCE GUIDE 10-1 to 10-27 (EPA/744-R-95-002, Dec. 1996); ECHA, *Guidance on Socio-Economic Analysis–Restrictions* 17, 86–97 (2008).

Safer Alternative Compliance Preference. Under this approach, the preference for safer alternatives would arise not in the standard-setting process, but rather in the implementation process. As in conventional technology-based standard setting, here the agency would conduct a technology review to identify the most protective risk reduction technology. However, in this case, that technology review would include an alternatives analysis. The emission standard, however, would be set by reference to the best level achieved by conventional controls. A regulated facility would be required to use the safer alternative to achieve compliance with the emission level, unless the facility demonstrated that the alternative was not appropriate for the specific conditions of that facility.

This approach is useful in situations involving a generally applicable rulemaking in which the agency concludes that the safer alternative is viable for some but not all applications in a particular industry sector. For example, both EPA and OSHA reached just such a conclusion in their separate analyses of trivalent chromium electroplating.[222] In a sector with many heterogeneous firms, it may be difficult to establish a generally applicable prevention-based performance standard. Recognizing this, the alternative-based compliance preference allows for consideration of the safer alternative at the firm level.

This approach is similar to OSHA's Hierarchy of Control Policy, a compliance preference in the PEL setting in which firms must demonstrate that engineering controls are infeasible before relying upon personal protective equipment.[223] As noted previously, that policy characterizes prevention-based strategies like substitution as just another form of engineering control. The policy, which has withstood multiple challenges in the courts over the past four decades,[224] could be modified to place prevention at the apex of the hierarchy, allowing exposure controls only to the extent that substitution with safer chemicals is not infeasible. The reasoning relied upon by OSHA for the existing preference for engineering controls over respirators applies with equal force when considering the relative value of preventive measures over traditional exposure control. In the preamble to the electroplating standard, OSHA explained:

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222. *See supra* pp. 22–26.

223. *See supra* text accompanying notes 95–97.

224. *See* Public Citizen Health Research Grp. v. U.S. Dep't of Labor, 557 F.3d 165, 176–77 (3d Cir. 2009); Chao v. Gunite Corp., 442 F.3d 550, 560 (7th Cir. 2006); American Iron and Steel Inst. v. OSHA, 182 F.3d 1261, 1265–71 (11th Cir. 1999); United Steelworkers of America v. Marshall, 647 F.2d 1189, 1269–72 (D.C. Cir. 1980).

> Engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored, allow for predictable performance levels, and can efficiently remove a toxic substance from the workplace. Once removed, the toxic substance no longer poses a threat to employees. The effectiveness of engineering controls does not generally depend to any substantial degree on human behavior, and the operation of equipment is not as vulnerable to human error as is personal protective equipment.[225]

Preventive measures are generally superior to exposure controls on each of the criteria relied upon by OSHA for the existing hierarchy—reliability, consistency and predictability, ease of monitoring, permanence, and freedom from human error. Indeed, OSHA suggested as much later in that preamble, noting that

> [s]ubstitution can be an ideal control measure. One of the best ways to prevent workers from being exposed to a toxic substance is to stop using it entirely. . . . In those cases where substitution of a less toxic material is not possible, substituting one type of process for another process may provide effective control of an air contaminant.[226]

2. Direct Performance Standard

Safer Alternative-Based Performance Standard. This approach is a variation on the theme of conventional technology-based standards. As Section II.B discussed, performance standards are often set by reference to the best performing control technology; regulated sources are required to achieve the same level of control as the reference technology. In most cases, the source is free to adopt the control technology of their choice so long as it can achieve the specified control level. The safer alternative-based performance standard simply grafts the preference for safer alternatives onto that conventional structure.

As with the alternative-based performance standard, the agency would engage in technology review of conventional emission controls and an alternatives analysis of potentially viable, safer alternatives. If a safer viable alternative were identified, rather than mandating its use, the agency would set the emission limit or other standard for the relevant chemical or process by reference to the performance of the alternative. Suppose that trivalent

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225. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. 10,100, 10,345 (2006).
226. *Id.*

chromium electroplating processes emit very low levels of hexavalent chromium; in that case, the MACT standard (or OSHA PEL) would be set to that level, leaving the facility owner the discretion to attain the level either by controlling emissions from the hexavalent chromium process or by adopting the alternative.

Two features of the safer alternative-based performance standard are worth noting. First, in some cases, the emissions reductions achievable through a safer alternative may be 100%. This was the case under California's Airborne Toxics Control Measure (ATCM) program as applied to crushed rock used for surfacing unpaved roads. The statute in that case required the California Air Resources Board (CARB) to reduce emissions of toxic air contaminants "to the lowest level achievable through application of best available control technology or a more effective control method."[227] In making that determination, CARB is required to consider "availability, suitability, and relative efficacy of substitute compounds of a less hazardous nature."[228] In evaluating options for dealing with asbestos-containing rock, CARB determined that the safer alternative of asbestos-free rock justified an emission level for asbestos of zero, and banned the use of asbestos-containing rock for surface paving.[229] In such cases, the safer alternative-based standard functions as a mandatory preference.

Second, the safer alternative-based standard might also be paired with a conventional health-based standard (*i.e.*, an acceptable exposure level based on health risks). Here the regulator would set a generally applicable health-based standard that, at a minimum, must be attained in all cases to secure regulatory approval. However, in any case in which a viable alternative would be more protective than the default health-based standard, that standard would be made more stringent to reflect the level associated with the alternative. The regulated entity would be free to use the baseline chemical or process so long as such use would achieve the more stringent adjusted standard, taking into account the impact of enforceable exposure controls.[230] Why use a standard that is *more* demanding than the default health-based standard? After all, if we are satisfied that the health-based standard in fact is safe, what purpose is served by ratcheting the standard

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227. CAL. HEALTH & SAFETY CODE, § 39666(c) (West 1992).

228. CAL. HEALTH & SAFETY CODE, § 3966(b)(6) (West 1992).

229. CAL. CODE REGS. tit. 17, § 93106(c) (2001); Coalition for Reasonable Regulation of Naturally Occurring Substances v. California Air Res. Bd., 122 Cal. App. 4th 1249, 1261 (Cal. Ct. App. 2004);

230. Here again if the program *requires* use of the safer alternative in such cases, it would be more akin to a mandatory preference.

lower when a safer alternative is available? The answer goes to the assumption embedded in the question itself, that we are satisfied that the health-based standard is safe. For those concerned about the transience of safe levels or skeptical of the risk assessment process that generates such levels, the safer alternative floor serves as a public health backstop. Where a safer alternative is available, its use in setting regulatory levels provides additional assurance that public health is protected "on the ground."

3. Indirect Standards

Mandatory Prevention-Based Planning. This approach moves away from centralized agency rule-making, instead placing the facility more centrally in the regulatory process through management-based regulation. Management-based regulation attempts to influence behavior not by imposing emission limits but rather by directly penetrating the regulated entity's decision-making processes.[231] In the case of mandatory planning, it ensures facility managers pay attention to and actively evaluate specific operational matters. In mandatory prevention-based planning, the regulated entity would be required to evaluate its use of specified chemicals or processes, performing an alternatives analysis to identify any viable, safer alternatives. This form of prevention-based regulation would not mandate the adoption of any alternatives, leaving that decision to the firm's discretion.[232]

Prevention-based planning has been on the scene for almost twenty-five years at the state level. Between 1989 and 1994, twenty-four states established mandatory pollution prevention programs with some notable success.[233] However, the classic example of mandatory prevention-based planning is Massachusetts' Toxic Use Reduction Act (TURA).[234] Enacted in

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231. *See* Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC'Y REV. 691, 698 (2003); Malloy, *supra* note 6, at 110, 118–20.

232. Of course, a mandatory prevention-based planning regime could also include the obligation to implement identified safer alternatives. The Contra Costa County Industrial Safety Ordinance is an example of such an approach. *Id.* at 120. Inclusion of mandatory implementation, however, would convert this regime into a mandatory preference for safer, viable alternatives.

233. Zarker & Kerr, *supra* note 108, at 676. *See also* National Pollution Prevention Roundtable, FACILITY POLLUTION PREVENTION PLANNING REQUIREMENTS: AN OVERVIEW OF STATE PROGRAM EVALUATIONS (1997).

234. Toxics Use Reduction Act, MASS. GEN. LAWS ch. 21I (2006).

1989, TURA requires that "large quantity toxics users"[235] periodically complete a toxics use reduction plan for processes using or manufacturing a listed toxic substance.[236] The plan, which is certified by a state-approved planner, must include a comprehensive technical and economic evaluation of appropriate toxic use reduction options, and an implementation schedule for the options, if any, selected by the firm.[237] Appropriate options for toxic use reduction include: input substitution, product reformulation, production unit redesign or modification, production unit modernization, improved operations and maintenance, and in-process recycling, reuse or extended use of production materials.[238]

TURA does not require that firms adopt any toxics use reduction option, even if the plan demonstrates that the option is a safer, viable alternative.[239] Instead, in addition to the planning requirement, TURA attempts to build the awareness, technical knowledge and capacity needed for individual firms to appreciate the opportunities for and value of toxics use reduction in their operations.[240] It relies upon training, technical assistance, demonstration sites, and other activities offered by the Massachusetts Department of Environmental Protection (DEP), the Toxics Use Reduction Institute (TURI), and the Office of Technical Assistance and Technology (OTA).[241]

Alternatives Analysis Information Disclosure. Alternatives analysis information disclosure is a form of information-based regulation, which is designed to spur behavior through the dissemination of information to

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235. Large quantity toxics user are firms within specified industry sectors that use listed toxic substances above certain volumes. Toxics Use Reduction Act, MASS. GEN. LAWS ch. 21I, § 2 (2006).

236. *Id.* § 11.

237. *Id.* § 11(A)(3).

238. *Id.* § 2.

239. Dana O'Rourke & Eungkyoon Lee, *Mandatory Planning for Environmental Innovation: Evaluating Regulatory Mechanisms for Toxics Use Reduction*, 47 J. ENVTL. PLANNING & MGMT., 181, 185 (2004), *available at* http://www.cnr.berkeley.edu/orourke/PDF/TURA.pdf. In certain circumstances, the Massachusetts Department of Environmental Protection may establish performance standards applicable to industry segments limiting the generation of byproducts per unit of production. Toxics Use Reduction Act, MASS. GEN. LAWS ch. 21I, § 15 (2006).

240. Jennifer Nash, *The Massachusetts Toxics Use Reduction Act: A Model for Nanomaterials Regulation?*, 14 J. NANOPART RES. 1070, 1073 (2012), *available at* http://link.springer.com/article/10.1007%2Fs11051-012-1070-7.

241. Rachel I. Massey, *Program Assessment at the 20 Year Mark: Experiences of Massachusetts Companies and Communities with the Toxics Use Reduction Act (TURA) Program*, 19 J. CLEANER PROD. 505, 505 (2011); O'Rourke & Lee, *supra* note 239, at 185.

various actors.[242] Information-based regulation may have a variety of goals, depending upon the context.[243] In the environmental arena, it typically serves three major functions. First, it may be designed to enhance decision-making by the private recipient of the information. The disclosure ensures that the end-user has all relevant information needed in making purchasing decisions, particularly for those businesses and individuals who incorporate health and safety, environmental, and liability concerns into such decisions.

Second, the obligation to provide disclosure could also influence the behavior of product manufacturers.[244] As a threshold matter, the very act of generating the information needed to provide disclosure will make certain that the manufacturer is itself aware of the hazards and corresponding liabilities associated with the materials it produces or distributes. As management scholars acknowledge, you manage what you measure.[245] Indeed, if the actual or anticipated reactions of customers or government regulators to the information are sufficiently negative, the manufacturer may even choose to avoid the relevant behavior.

Third, disclosure may also affect the behavior of government regulators or other third parties in a position to exert pressure on the manufacturer. For example, third party non-governmental organizations such as environmental advocacy groups can rely upon manufacturer disclosures in seeking voluntary commitments by manufacturers for improvement in practices, or to support advocacy campaigns directed at regulators, legislators, or the general public to leverage market forces in support of safer alternatives.[246]

In the case of alternatives analysis information disclosure, the regulated entity—whether the manufacturer of a chemical-containing product or the operator of an industrial process—would be required to perform an alternatives analysis of potential alternatives. If the analysis uncovers viable, safer alternatives, the firm must either adopt the alternative or notify relevant interested parties (e.g., workers, adjacent landowners, or end-users) of its decision to forgo the alternative. So for example, the manufacturer of

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242. *See* Bradley C. Karkkainen, *Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm*?, 89 GEO. L.J. 259, 270–80 (2001); O'Rourke & Lee, *supra* note 239, at 182.

243. Timothy F. Malloy, *Disclosure Stories*, 32 FLA. ST. U. L. REV. 617, 629–30 (2005); David Weil et al., *The Effectiveness of Regulatory Disclosure Policies*, 25 J. POL'Y ANALYSIS & MGMT. 155, 160 (2006).

244. Depending upon the labeling regime, the term manufacturers may include distributors and/or importers.

245. *See* Louis Lowenstein, *Financial Transparency and Corporate Governance: You Manage What You Measure*, 96 COLUM. L. REV. 1335, 1342–1345 (1996).

246. Malloy, *Disclosure Stories*, *supra* note 243, at 628–36.

a household cleaning product might be obligated to provide information regarding the alternative on the product label or on a website. Alternatively, a facility using toxic materials in a production process would inform workers of safer alternative processes, perhaps through a notation on the relevant material safety data sheets or through notice to the union. This alternative combines the value of management-based regulation in focusing management attention on an issue with the added external pressure for alternative adoption that third party notification could bring to bear.[247]

The proposed regulations for California's Safer Consumer Products program include a weaker version of alternatives analysis information disclosure. Those regulations do not mandate direct disclosure of safer alternatives to third parties. However, they do provide for public disclosure of the results of a firm's alternatives analysis via posting on the DTSC website of the firm's alternatives analysis report.[248] In addition, one of the regulatory responses available to DTSC based on the alternatives analysis is the disclosure of product information to consumers.[249] If directed by DTSC, the firm must make specified information available to the consumer prior to product purchase, including a list of chemicals of concern in the product, known hazards of those chemicals, and a website address where the consumer can obtain additional information about the product and its adverse impacts identified in the alternatives analysis report.[250]

Expedited Review of Safer Alternatives. This last approach affords safer alternatives in gatekeeper programs with less expensive, more nimble review. Expedited review serves two purposes. From a strategic perspective, it provides manufacturers with the incentive to develop safer alternatives through the competitive advantage of quicker registration and approval.[251] From a public health perspective, it minimizes the time involved in getting a safer alternative to market.

EPA has significant experience with expedited review. For example, FIFRA's expedited review program is an alternative to conventional pesticide registration, which can take between six to ten years to complete at a cost of $50–70 million for a single pesticide. Expedited review under FIFRA covers applications for pesticides that "may reasonably be expected

247. *Id.*

248. CAL. CODE REGS. tit. 22, § 69501.5(b)(3)(F)(2) (2013).

249. *Id.* § 69506.3.

250. *Id.* § 69506.3(b)(7).

251. Lynn R. Goldman, *Managing Pesticide Chronic Health Risks*, 12 J. AGROMEDICINE 67, 72 (2008).

to . . . [r]educe the risks of pesticides to human health."[252] First initiated as a policy in 1993, expedited review for "reduced risk" pesticides was mandated by statute in 1996. Under the program, EPA gives priority in the registration process to pesticides that meet the reduced risk criteria: low-impact on human health; low toxicity to non-target organisms (birds, fish, and plants); low potential for groundwater contamination; lower use rates; low pest resistance potential; and compatibility with Integrated Pest Management.[253] In the TSCA new chemicals program, the Sustainable Futures initiative offers a speedy review for low hazard or low exposure chemicals, but requires prior training and demonstrated experience in safer chemical design.[254]

V. DESIGN PRINCIPLES AND EVALUATION

This section evaluates the prevention-based approaches against a set of design principles drawn from three sources. One source is the general literature on regulatory design, which identifies a commonly recognized menu of criteria for evaluating regulation.[255] Another source is the prevention literature, which identifies justifications for adopting prevention-based regulation.[256] The same factors also serve as measures in differentiating the value of competing prevention-based approaches. The last source is what I call the anti-regulatory literature. The criticisms it raises—interference in the market, respect for individual autonomy and the capacities of government—should be taken seriously in evaluating the relative merit of prevention-based approaches. Despite the rhetoric that often accompanies them, each of these three points reflects long-standing and often deeply held values in the United States. They are important on substantive grounds and from the strategic perspective as well.

This section examines each principle and its relevance to prevention-based regulation, and qualitatively assesses how well each of the prevention approaches fares on it as compared to the other approaches. I assess the

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252. 7 U.S.C. § 3(c)(10)(B) (current version at 7 U.S.C.A. 136a(c)(10)(B) (1996)).

253. EPA, Pesticide Registration (PR) Notice 97-3: Guidelines for Expedited Review of Conventional Pesticides under the Reduced-Risk Initiative and for Biological Pesticides (Sept. 4, 1997).

254. Maggie Wilson, *Sustainable Futures: Encouraging Risk Screening of Industrial Chemicals at the R&D Stage*, ENVTL. QUALITY MGMT. 37, 47 (2004); Sustainable Futures — Voluntary Pilot Project Under the TSCA New Chemicals Program; Notice, 67 Fed. Reg. 76,285 (Dec. 11, 2002).

255. *See supra* Part II.

256. *See supra* Part III.

strength of the relative performance on a scale of one to five, with a score of five representing very high performance and a score of one indicating very low performance.[257] Separate bar charts for each principle reflect the qualitative (and admittedly subjective) scores. Each chart is followed by a narrative discussion explaining the ranking. A summary chart appears at the end of the section.

Keep in mind that I am assessing generic formulations of these prevention-based approaches. In the real world, actual performance will vary with the specific details of the regulatory program, the setting and other factors. The comparisons thus focus upon the respective approaches' defining structural aspects; that is, those attributes that would not substantially change depending upon specific program design.

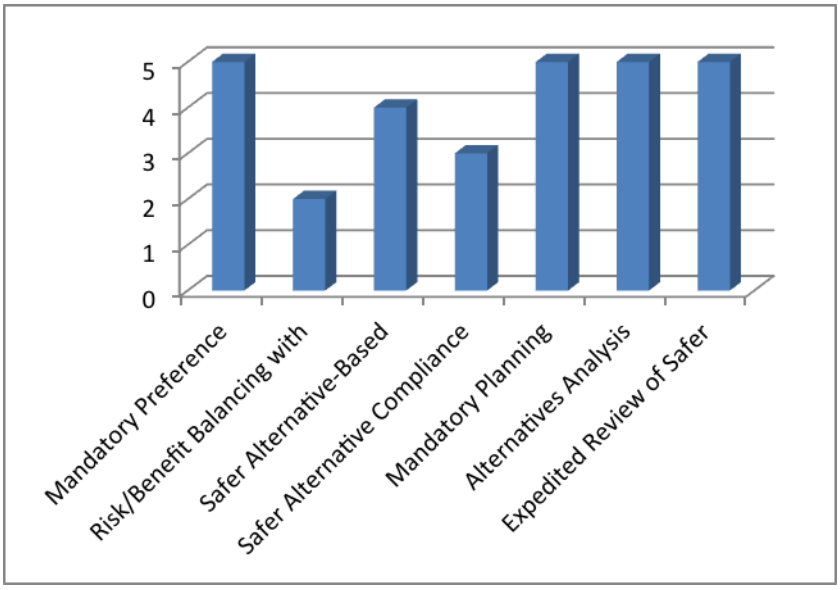
A. Protectiveness

Protectiveness focuses on whether the standard avoids reliance upon ACLs. The ACLs are transient, changing as science advances. They are vulnerable to strategic and political considerations buried within the risk assessment/risk management process. Protectiveness also includes consideration of the standard's capacity to minimize risk shifting across media and across generations.[258]

257. The remaining scores reflect the following relative performance: two (low), three (moderate), and four (high).

258. All prevention-based approaches inherently allow some level of risk shifting in that alternatives analysis typically considers risk trade-offs made among alternatives. For example, switching from a toxic solvent to a non-toxic petroleum-based solvent may increase smog formation. The assessment here focuses on risk shifting associated with the use of control measures rather than prevention measures.

Figure 3
Relative Protectiveness



The *mandatory preference*, *mandatory planning*, *alternatives analysis information disclosure*, and *expedited review of safer alternatives* perform best here. Each of them relies upon identification of safer alternatives without consideration of any ACLs.[259] The next best performer is the *safer alternative-based performance standard*. Although this approach avoids reliance on acceptable exposure limits and risk assessment in setting the performance standard, some risk shifting across media and across generations may occur where the compliance method chosen by the regulated entity is exposure control.

The *safer alternative compliance preference* performs only moderately well; consideration of acceptable exposure is central to setting the underlying performance standard. The worst performer is *risk/benefit balancing (with teeth)*. The risk portion of the balancing will likely rely upon quantitative risk assessment, including consideration of the effects of exposure controls upon the baseline risk presented by the chemical/process. A safer, viable alternative will not always "trump" the more risky baseline

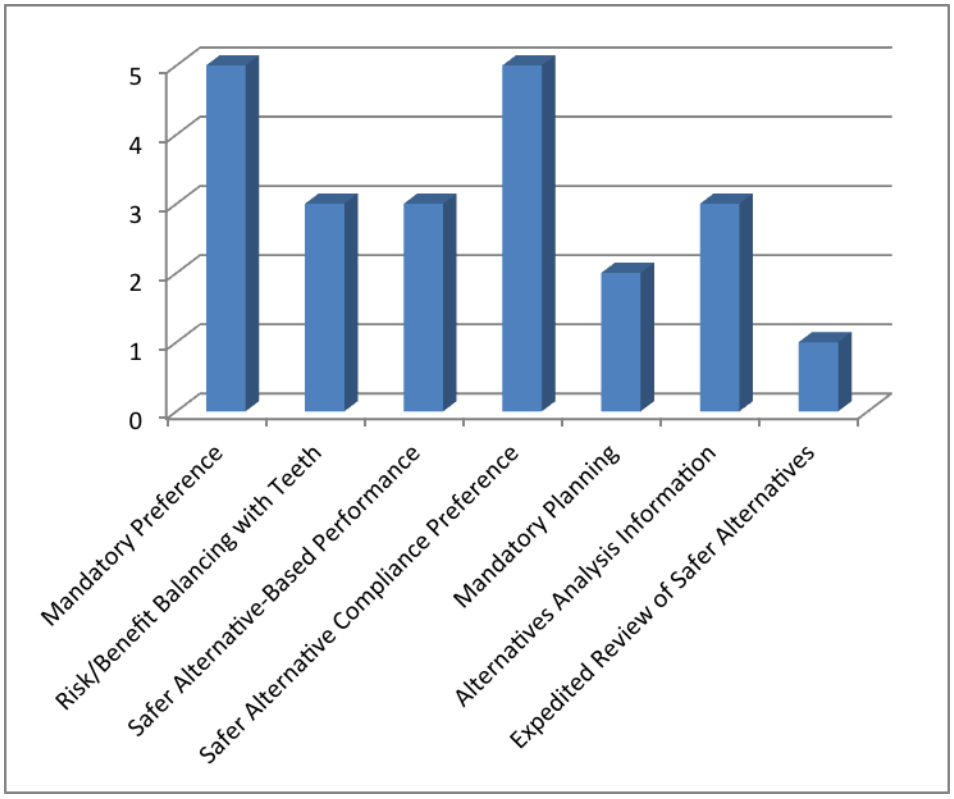
259. Of course, in the absence of a safer alternative, regulated entities would fall back to convention risk management, including use of ACLs.

chemical/process where other factors such as impact on the broader economy are taken into account in the balancing.

B. Effectiveness

As noted previously in Section III, effectiveness essentially concerns the reliability of the measures adopted to reduce or avoid risk. Engineering or administrative measures used to control exposure are vulnerable to both technology and operator failure. Safer alternatives are considered more effective because they avoid the use of the material of concern and thus the need to rely upon control measures. To evaluate the relative effectiveness of the prevention-based approaches, I assess the likelihood that each respective approach would lead to the use of safer alternatives rather than a control technology.

Figure 4
Relative Effectiveness



The *mandatory preference* and *safer alternative compliance preference* approaches perform best in terms of effectiveness. In each, if a safer alternative exists it would be adopted, obviating or reducing reliance on control technologies. The *risk/benefit balancing (with teeth), safer alternative-based performance standard,* and *alternatives analysis information disclosure* approaches are the next highest performers. Each places emphasis on safer alternatives, albeit in different ways. In *risk/benefit balancing,* the existence of a safer viable alternative will reduce the benefits associated with the chemical or process in question, and thus lead to the use of that safer alternative instead. However, in some cases conventional exposure control could allow that chemical or process to attain the same or ostensibly better level of protection as the safer alternative. In such cases it is possible (and, considering the deeply embedded nature of conventional risk management, perhaps even likely) that the chemical/process will be approved, subject to use of exposure controls.

Regarding the *safer alternative-based performance standard*, while adoption of the performance standard itself may lead to greater protectiveness (see above), its openness to compliance through control technologies raises concerns about technology or operator failure.

Alternatives analysis information disclosure will likely have "reflexive" effects within the firm,[260] causing managers and staff to be more attentive to opportunities for safer alternatives, and legitimizing prevention as a company goal. The addition of disclosure provides increased incentive, as external stakeholders may pressure for adoption of alternative. However, this enhanced effect is dependent on the attention and power of those external stakeholders.

Mandatory planning performs somewhat well. As in *alternatives analysis information disclosure*, it may well have a reflexive effect on the firm, but without disclosure it will lack external drivers for adoption. *Expedited review* is the worst performer as it provides no assurance that end users will actually adopt the safer alternative following completion of the expedited regulatory review. Thus, control measures could still be the dominant response to potential risks.

C. Cost-Effectiveness

As discussed previously, cost-effectiveness is used as a comparative measure to identify the least expensive means of achieving a desired outcome.[261] For all but one of the prevention-based approaches, the desired outcome is the adoption of the safest viable alternative by the set of regulated entities. In the case of the safer alternative-based performance standard, the desired goal is adoption of measures that achieve a level of protection equivalent to that provided by the safer alternative.

While the types of costs considered in cost-effectiveness analysis can vary,[262] in the context of regulation two categories of costs dominate: the regulated entity's compliance costs and the regulatory agency's

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260. *See* Eric W. Orts, *Reflexive Environmental Law*, 89 NW. U. L. REV. 1227, 1269–1271 (1995).

261. *See supra* text accompanying note 130; Kenneth J. Arrow et al., *Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?*, 272 SCIENCE 221, 222 (1996).

262. *See* Tammy O. Tengs et al., *Five-Hundred Life-Saving Interventions and their Cost-Effectiveness*, 15 RISK ANALYSIS 369, 373–84 (1995) (including a broad range of societal costs).

administrative and enforcement costs.[263] It is difficult to identify significant differences in the agency's costs across prevention-based approaches without more detail regarding specific program design and setting.[264] Accordingly, I focus the comparison of prevention-based approaches on the firm's costs of compliance. Regarding industry compliance costs, regulatory programs that provide flexibility to businesses to adopt the least costly compliance strategy are *potentially*[265] the most cost-effective. Thus, potential cost-effectiveness for our purposes depends upon the extent to which a given prevention-based approach provides the regulated entity with the discretion to select the least costly route to compliance.

One caveat is in order here. To a varying degree depending upon its particular design, alternatives analysis inherently engages in some evaluation of cost-effectiveness. One criterion typically included in alternatives analysis is economic feasibility, often measured in terms of the increase (or decrease) in the firm's costs of adopting a particular alternative.[266] Thus, alternatives analysis provides a comparison across the alternatives with respect to cost. Inclusion of relative cost as a decision criterion in the alternatives analysis, however, does not inevitably lead to the conclusion that the safer alternative is cost-effective. It may well be that other decision criteria outweigh cost or otherwise dilute its impact in the alternatives analysis, such that the highest ranked alternative is not the least costly.

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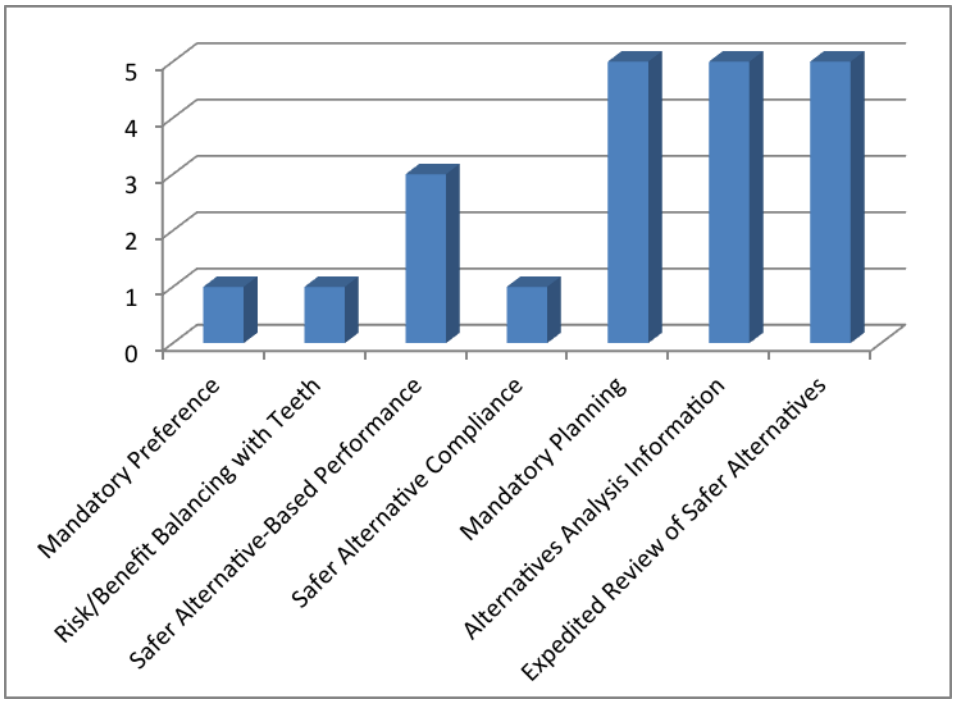
263. Tom Tietenberg, ENVIRONMENTAL ECONOMICS & POLICY 44–45 (5th ed. 2007); South Coast Air Quality Management District, BEST AVAILABLE CONTROL TECHNOLOGY GUIDELINES 30 (2003).

264. It appears that the major costs to the agency will be the initial design of the program, the evaluation of alternative analyses submitted by regulated firms (or the actual performance of the alternatives analyses if the agency takes on that responsibility itself), and follow-up to ensure or encourage implementation of the alternative. Those costs would likely be similar across all approaches. On face, it may seem that the mandatory planning approach would be least costly, as little follow-up by the agency may be involved. But recall that cost-effectiveness analysis assumes that the program will achieve the desired outcome, which I have defined as adoption of the safer alternative. In a mandatory planning regime ensuring adoption of safer alternative may require substantial intervention by agency, with costs approaching those of a mandatory preference program.

265. Whether the regulation actually results in the most cost-effective action depends upon what the businesses do with the flexibility. It is possible that a firm may *not* select the least costly compliance strategy, either because of flawed decision analysis on the firm's part, or because factors other than cost (as defined by the cost-effectiveness analysis methodology) drive the decision.

266. Malloy et al., *Case Study*, *supra* note 151, at 652.

Figure 5
Relative Potential Cost-Effectiveness



The *mandatory planning*, *alternatives analysis information disclosure*, and *expedited review* approaches perform best here. In the first two approaches, firms face no obligation beyond performing the alternatives analysis. Should they choose to act (as the policymakers hope they will), the firms again may choose from the full range of control and prevention options. Of course, the very feature that enhances cost-effectiveness—the discretion to use cheaper control measures—diminishes the effectiveness. Whether such a trade-off is acceptable is a judgment with which prevention-minded policymakers must grapple. *Expedited review* is perhaps the very best performer, in that it leaves the threshold decision of whether to even consider alternatives completely to the business.

The *mandatory preference*, *risk/benefit balancing (with teeth)*, and *safer alternative compliance preference* are the worst performers. Each places substantial constraints on the firm's ability to select the least costly compliance approach. As explicit design standards, both the *mandatory preference* and the *risk/benefit balancing (with teeth)* approaches direct or prohibit use of particular alternatives, respectively. The *safer alternative*

compliance preference likewise mandates use of a particular alternative. The *safer alternative-based performance standard* approach lies somewhere between these two groups of best and worst performers. Under this approach, the firm is free to rely on conventional engineering controls so long as those controls provide protection equivalent to that of the safer alternative.[267]

D. Dynamic Efficiency

As noted in Section III.D,[268] innovation includes both the generation (or invention) of new technologies and products, and their broad diffusion throughout the relevant market. Regulation can increase both the generation and diffusion of new technology through at least two mechanisms. First, regulation acts directly, creating demand for new and existing technology. Technology-forcing regulation sets standards beyond the reach of existing technology, creating market pressure for new innovation.[269] More often, however, regulation sets performance standards achievable through existing but under-used "state of the art" (SOTA) technology. SOTA performance standards increase diffusion of those technologies, and may also trigger generation of new, less costly technology capable of achieving the standards.[270] The latter effect, however, may be substantially limited by the reluctance of cautious firms and rigid regulators alike to accept anything but the reference SOTA technology.[271] Design standards *requiring* adoption of SOTA likewise spark diffusion, but largely remove the incentive to search for less costly innovative alternatives to SOTA.[272]

Second, regulation acts indirectly, focusing firms on the opportunities for cost-saving innovation. The innovation literature has documented numerous market and organizational barriers to innovation by business firms, including imperfect information, deficient organization structure and

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267. One could even imagine a *safer alternative-based performance standard* approach which incorporates a market-based element such as emissions trading to further enhance the cost-effectiveness. No doubt such an approach would raise the full panoply of concerns relating to emissions trading more generally, including formation of toxic hot spots, which could undermine other principles of prevention.

268. *See supra* text accompanying notes 142–50.

269. Malloy, *supra* note 143, at 549–50.

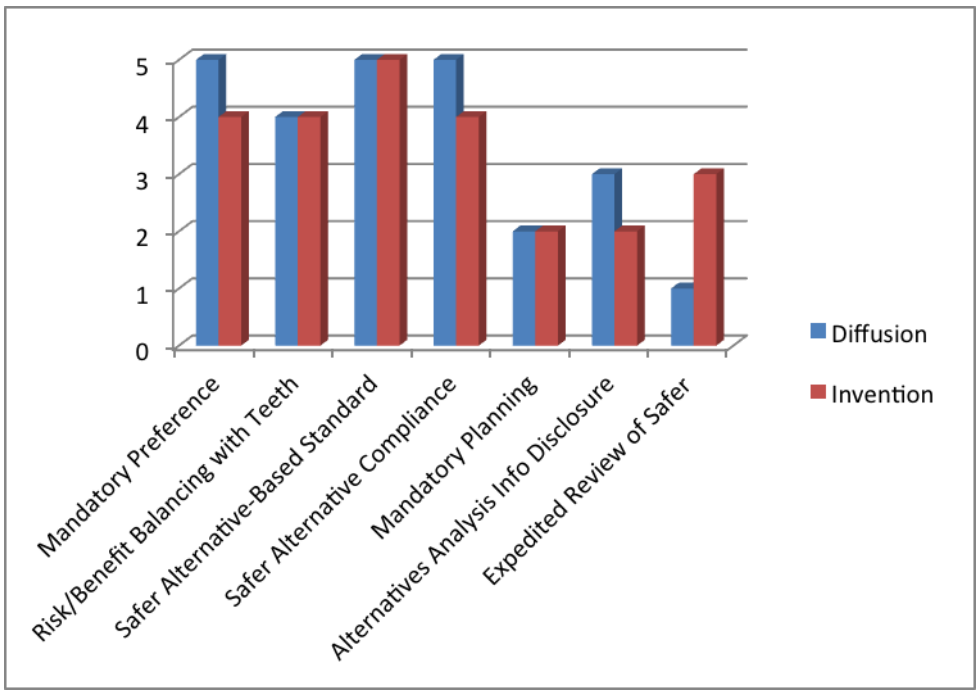
270. Malloy & Sinsheimer, *supra* note 24, at 197.

271. *Id.* at 198.

272. *See, e.g.*, *id.* at 196–98; Stewart, *supra* note 11, at 1281–83; Byron Swift et al., *Barriers to Environmental Technology Innovation and Use*, 28 ENVTL. L. REP. 10,202, 10,213 (1998).

cognitive limits of managers.[273] Under management-based regulation, firms engage in systematic analysis and planning regarding health and environmental impacts of their operations. By shifting firm attention and resources, such regulation can help firms to overcome the market and organizational barriers that impede innovation.

Figure 6
Relative Dynamic Efficiency
(Diffusion and Invention)



The *mandatory preference*, *safer alternative compliance preference* and *safer alternative-based performance standard* are the best performers regarding diffusion of safer alternatives. The first two essentially require adoption of the alternative, thus guaranteeing diffusion within the affected market sector. Under the *safer alternative-based performance standard*, while not mandated, it is likely that at least some portion of the industry sector will adopt the alternative as means of compliance. *Risk/benefit balancing (with teeth)* applied to existing products or processes could also

273. Malloy, *supra* note 143, at 555–86; RENE KEMP, ENVIRONMENTAL POLICY AND TECHNICAL CHANGE 96–99 (1997).

enhance diffusion of safer alternatives, by removing the existing product or process from the market place.[274] The resulting demand for a replacement coupled with the implied agency imprimatur of the safer alternative could encourage diffusion. The *mandatory planning* and *alternatives analysis information disclosure* are the next best performers. Both potentially enhance diffusion by ensuring that firms meaningfully evaluate the alternatives.[275] *Alternatives analysis information disclosure* offers the further push towards adoption in the form of pressure from informed third parties such as consumers or non-governmental organizations. *Expedited review* marginally improves diffusion by getting the alternative to the market more quickly.

Turning now to the development and commercialization of new technologies and products, the impacts of the prevention-based approaches are more complicated and contextual. For example, impacts depend to some extent on whether an existing product has already been evaluated and regulated under the prevention-based program. Take the case of a pesticide that has been identified for future regulation under one of these four approaches: *mandatory preference*, *safer alternative compliance preference*, *safer alternative-based performance standard*, and *risk/benefit balancing (with teeth)*. Given the potential market for a safer alternative embraced by the alternatives analysis, firms and researchers would have significant incentive to generate an innovative alternative to the pesticide. Once a safer alternative is identified and subsequently drives the regulatory outcome (either as a mandate, a reference technology, or a spoiler in a risk/benefit analysis), there will be substantial demand for it.

However, for the *mandatory preference*, *safer alternative compliance preference*, and *risk/benefit balancing (with teeth)* approaches, innovation incentives drop off after the initial regulation. The selected alternative is essentially "locked-in" until the regulators revisit the decision.[276] A *safer alternative-based performance standard* would not necessarily face the lock-in problem; in theory firms may use any technology to meet the alternative-based standard. In practice, however, there is some evidence that

274. This would occur in the "delayed" gatekeeping situation in which an existing product or process is periodically reevaluated after an initial approval or registration.

275. O'Rourke & Lee, *supra* note 239, at 190–94 (2004).

276. Malloy & Sinsheimer, *supra* note 24, at 197.

firms and regulators tend to rely on the reference technology in achieving performance based standards.[277]

Expedited review is likely to have a moderate impact on invention. The reduced time and cost of regulatory review provides some reason for firms to skew their research and development efforts towards safer alternatives. Experience under EPA's expedited review of reduced risk pesticides suggests that such incentives are somewhat effective.[278] *Mandatory planning* and *alternatives analysis information disclosure* have the weakest effect on generations of new technology. The incentive for investing in research and development—the chance that a firm may consider and select the resulting innovation—can be speculative.

E. Social Efficiency

As a theoretical matter, a particular policy or regulatory program is socially efficient when its marginal social costs and marginal social benefits are equal.[279] Developing measures of social efficiency has proven both difficult and controversial. The classic criterion for a Pareto efficient policy—no adjustment to the policy could make at least one person better off without making anyone worse off—is nearly impossible to attain in the real world of policymaking.[280] Most economists have "settled" for the more practical Kaldor-Hicks formulation, which essentially asks whether the total

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277. NEIL GUNNINGHAM ET AL., SMART REGULATION: DESIGNING ENVIRONMENTAL POLICY 39, n.5 (1998) ("[A]gency [technology] guidance becomes *de facto* requirement and technological lock-in occurs.").

278. Lynn R. Goldman, *Managing Pesticide Chronic Health Risks*, 12 J. AGROMEDICINE 67, 73 (2008).

> It would appear that incentives for industry to bring forward new, safer chemical and biological pesticides are beginning to achieve success. What this demonstrates is a willingness of industry to develop new and safer products, if given appropriate market incentives in the regulation of pesticides. What is unknown at this time is the extent to which these newer safer pesticides are being widely adopted by pesticide.

Id.

279. Richard B. Howarth & Bo Andersson, *Market Barriers to Energy Efficiency*, 15 ENERGY ECON. 262, 270 (1993); David de Meza & J. R. Gould, *The Social Efficiency of Private Decisions to Enforce Property Rights*, 100 J. POL. ECON. 561, 564 (1992) (noting that private decisions regarding property right enforcement are socially efficient if and only if "no other set of decisions to enforce property rights yields an allocation of resources that is a potential Pareto improvement.").

280. Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165, 170 (1999); Robert N. Stavins, *Environmental Economics* 1–2 (Nat'l Bureau of Econ. Res., Working Paper No. 13574, 2007), *available at* http://www.nber.org/papers/w13574.

social benefits of a policy exceed the total social costs. This efficiency measure lies at the heart of cost-benefit analysis (CBA), a method often employed in evaluating the efficiency of environmental and other regulations. In the classic and most widely-used version of CBA, the costs and benefits of the program are quantified in monetary terms, with future costs and benefits discounted at some appropriate rate.[281] A regulatory intervention is socially efficient if discounted benefits exceed its discounted costs; in other words, if it has a positive net present value. CBA is also used to evaluate the relative efficiency of alternative regulatory actions by comparing the alternatives on the basis of the respective net present values.[282]

CBA is not the only tool available for assessing the social efficiency of alternative policy choices. Others are trade-off analysis and multidimensional assessment. The former presents costs and benefits of each choice in a non-aggregated form, using quantitative and qualitative measures depending upon the particular economic, environmental, health or other effect. It leaves it to the policymakers to informally balance the trade-offs in selecting a policy option.[283] The latter aggregates the impacts (positive and negative) for all the relevant decision criteria, allowing for trade-offs in performance across the criteria.[284] Multidimensional assessment typically uses formal decision tools such as multi-criteria decision analysis to generate the aggregated assessment, taking into account the full range of economic, environmental, health, social and other criteria relevant to overall social welfare.[285]

The relevance of social efficiency in environmental health policy—and the efficacy, wisdom and ethics of the associated assessment methodology—continues to be ably debated by legal scholars, economists,

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281. David Pearce, *Cost-Benefit Analysis and Environmental Policy*, 14 OXFORD REV. ECON. POL'Y 84, 86–7 (1998).

282. VALUING HEALTH RISKS, COSTS, AND BENEFITS FOR ENVIRONMENTAL DECISION MAKING: REPORT OF A CONFERENCE 1, 7 (P. Brett Hammond & Rob Coppock eds., 1990).

283. *See* ASHFORD & CALDART, *supra* note 8, at 168–69 (describing trade-off analysis); Adler & Posner, *supra* note 280, at 233–34 (describing "qualitative" multidimensional assessment).

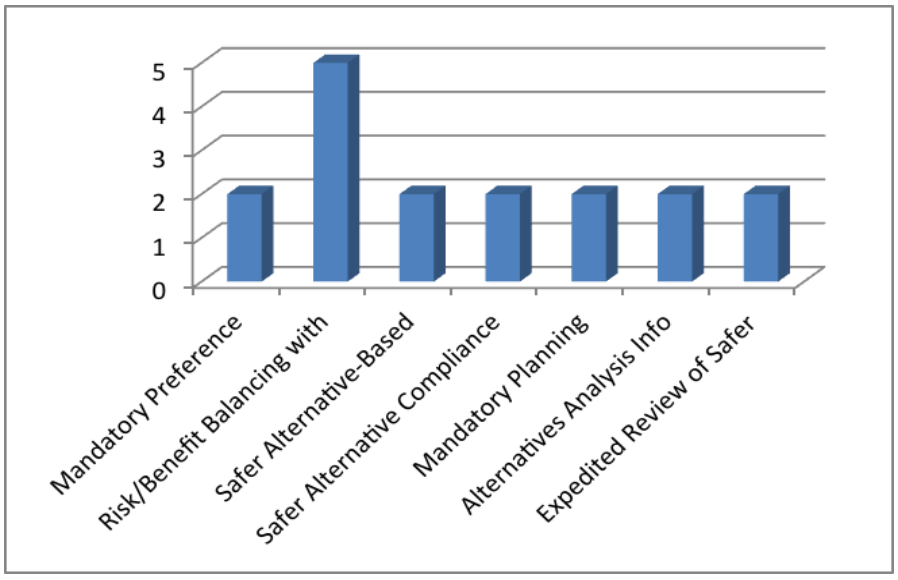
284. Adler & Posner, *supra* note 280, at 229–35.

285. D. Diakoulaki & F. Karangelis, *Multi-Criteria Decision Analysis and Cost–Benefit Analysis of Alternative Scenarios for the Power Generation Sector in Greece*, 11 RENEWABLE & SUSTAINABLE ENERGY REV. 716, 718–20 (2007); Alejandro Tudela, Natalia Akiki & Rene Cisternas, *Comparing the Output of Cost Benefit and Multi-Criteria Analysis: An Application to Urban Transport Investments*, 40 TRANSP. RES. 414, 415 (2006). Use of MCDA in the context of alternatives analysis is discussed above. *See supra* text accompanying notes 210–23.

ethicists, philosophers, and others.[286] For purposes of this article, the debate need not be resolved nor a substantive position staked out. Instead I am interested only in assessing how well the respective prevention-based approaches may perform in terms of efficiency. I leave the judgment of just how important efficiency is to the policymakers and stakeholders.

Without specific program designs before us, it is difficult to assess the efficiency of each of the prevention-based approaches.[287] Accordingly, I consider the extent to which each may incorporate measures of social efficiency in standard setting.

Figure 7
Relative Incorporation of Social Efficiency Measures



Risk/benefit balancing (with teeth) exhibits the greatest potential to incorporate social efficiency. Its central goal is to identify the alternative having the greatest net social benefit, whether that is determined through classic CBA, qualitative trade-off analysis, or formal MCDA. None of the remaining prevention-based approaches consider net social benefit in that way. The *mandatory preference*, *safer alternative-based performance*

286. *See* ASHFORD & CALDART, *supra* note 8, at 151–165; Adler & Posner, *supra* note 319, at 171–72; Pearce, *supra* note 281, at 92–97.

287. Individual autonomy and economic freedom, which are central elements of socially efficient governance, are discussed below. *See infra* text accompanying notes 290–312.

standard, and *safer alternative compliance preference* each impose obligations on regulated firms without systematically evaluating the net social value of that policy choice. The firm itself controls decision-making in *mandatory planning*, *alternatives analysis information disclosure*, and *expedited review*, but likewise does not necessarily engage in comprehensive evaluation of net social welfare.

In some cases it may be that the alternatives analysis itself may roughly approximate the outcome of a comprehensive CBA or MCDA. Alternatives analysis does engage in evaluation and balancing of the adverse and beneficial impacts of each alternative across a range of criteria, all in search of the alternative with the best overall performance. However, existing alternatives analysis methodologies generally do not incorporate the broad range of criteria typically considered in assessing social efficiency, such as macroeconomic or social impacts.[288] Thus, the correspondence between the alternatives analysis outcome and an evaluation of net social benefit will not necessarily occur consistently.

F. Individual Autonomy

This principle focuses on the extent to which a regulatory approach constrains the choices available to the individual, including choices that may cause the individual injury. Examples include non-commercial artists committed to white lead-based paint for its unique aesthetic qualities, recreational pilots depending on leaded aviation fuel, and homeowners swearing by conventional weed-killers for a beautiful lawn. Public health policy has long wrestled with the tension between the interests of the individual and the authority of the government to protect population health. Individual autonomy has a variety of normative grounds, most notably notions of economic efficiency and personal liberty.

Welfare economics seeks to advance social welfare, which itself is defined as the optimization of individuals' preferences.[289] Government

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288. California Department of Toxic Substances Control, Proposed Safer Consumer Product Regulations, Section 69505.6(a)(2)(C) (R-2011-02, January 2013) (limiting economic impact to monetized health and environmental impacts and administrative costs to agencies); ECHA, Guidance on the Preparation of an Application for Authorisation 74 (ECHA-11-G-01, January 2011) (setting out a narrow set of relevant criteria, specifically excluding macroeconomic impacts.).

289. K. Calman, *Beyond the Nanny State: Stewardship and Public Health*, 123 PUB. HEALTH e6, e7 (2009); Ted Gayer & W. Kip Viscusi, *Overriding Consumer Preferences with Energy Regulations* (Vanderbilt Law & Econ., Working Paper No. 12-24, 2012), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2111450.

policies that rebuff personal preferences thus tend to reduce social welfare. From an economic efficiency perspective, such policies are to be avoided unless needed to deal with market imperfections.[290] One relevant imperfection is the creation of negative externalities; namely, costs associated with one individual's preference that fall upon other individuals. So for example, recreational pilots enjoying enhanced engine performance from leaded aviation fuel expose residents near airports to elevated lead exposures.[291] Another imperfection occurs where the individual has limited access to information regarding impacts of and alternatives to his or her choices.[292] Limited information can result in inefficient choices where complete information would lead to different choices. Thus, a homeowner interested in both reducing their environmental footprint and in controlling aggressive ivy may reject a hazardous weed-killer when made aware of a safer, equally effective product.

Rights-based views of personal liberty value autonomy as a good in itself without regard to efficiency effects.[293] Under this view, government intervention should not restrict personal choice absent some significant overriding justification.[294] The most common justification is the need to prevent behavior that causes harm to another.[295] The precise nature and scope of the so-called "harm principle" is subject to some debate, but the general notion itself is widely accepted.[296] Another generally accepted justification for intervention is the protection of those with diminished mental capacity, such as children or adults with substantial intellectual or cognitive disabilities.[297] Some commentators expand this justification to include situations in which an individual's choice is not substantially voluntary, as when made under coercion, with insufficient information, or

290. ASHFORD & CALDART, *supra* note 8, at 131; Gayer & Viscusi, *supra* note 289, at 2–3.

291. Marie Lynn Miranda, Rebecca Anthopolos, & Douglas Hastings, *Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels*, 119 ENVTL. HEALTH PERSPECT. 1513, 1513 (2011).

292. ASHFORD & CALDART, *supra* note 8, at 135–36.

293. Calman, *supra* note 289, at e7; LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 48–49 (2d ed., 2008).

294. GOSTIN, *supra* note 293, at 48.

295. JOHN STUART MILL, ON LIBERTY, THE SUBJECTION OF WOMEN & UTILITARIANISM 68 (2002); Calman, *supra* note 289, at e7.

296. GOSTIN, *supra* note 293, at 47–49; JOEL FEINBERG, THE MORAL LIMITS OF CRIMINAL LAW: HARM TO OTHERS, 11–12 (1984); Thaddeus Mason Pope, *Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulations*, 61 U. PITT. L. REV. 419, 433–54 (2000).

297. GOSTIN, *supra* note 293, at 49–59.

without adequate understanding.[298] A third justification—protecting individuals from self-inflicted harm—is substantially more controversial. The "harm to self" principle, also referred to as paternalism, is rarely asserted as a primary justification for public health interventions.[299] Whichever of the three justifications one invokes, the principle of individual autonomy requires that the intervention be narrowly crafted so as to achieve its goal with as little impact on individual choice as possible.[300]

I evaluate impact on autonomy by assessing the extent to which each prevention-based approach potentially constrains or enhances individual choice. In doing so, I focus upon the most likely scenario in which individuals acting in their personal capacity are affected:[301] the selection of a particular consumer product.

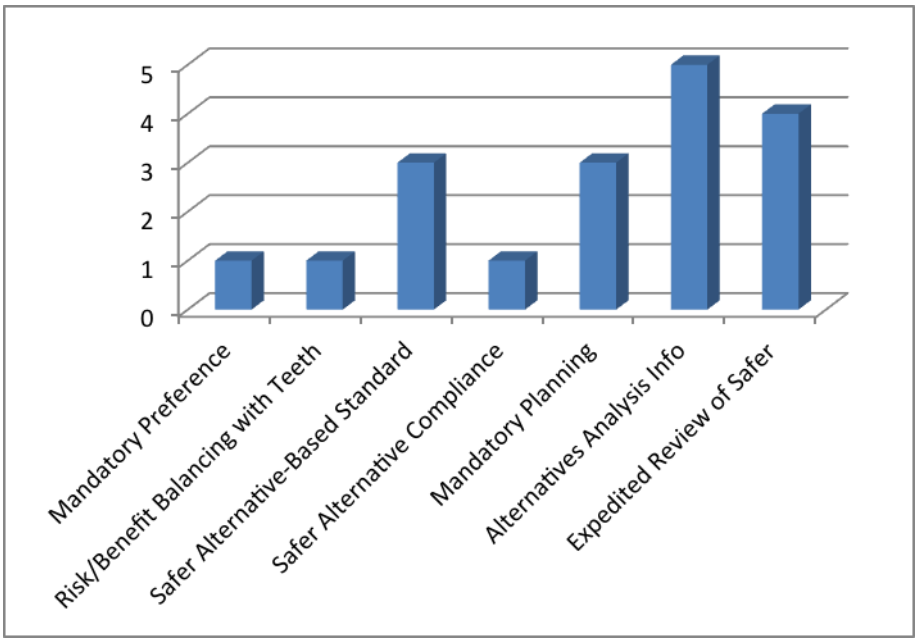
298. Pope, *supra* note 296, at 454–469. Pope calls this "soft paternalism," a categorization rejected by Gostin. GOSTIN, *supra* note 293, at 527 n.21.

299. GOSTIN, *supra* note 293, at 50–51; Pope, *supra* note 296, at 454–69; FEINBERG, *supra* note 296, at 27. Traditionally public health proponents have relied upon the first two justifications for government interventions such as vaccination, infectious disease quarantines, motor cycle helmet laws, and seat belt laws. For example, in upholding motorcycle helmet laws and seat belt laws, courts have uniformly relied upon the harm principle, citing direct and indirect harms to society in the form of traffic dangers, medical costs, disability payments, and lost productivity. James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of Jacobson v. Massachusett*s, 4 AM. J. PUB. HEALTH 571, 574 (2005); Melissa Neiman, *Motorcycle Helmet Laws: The Facts, What Can be Done to Jump Start Use, and Ways to Cap Damages*, 11 J. HEALTH CARE L. & POL'Y 217, 218–19 (2008).

300. GOSTIN, *supra* note 293, at 68 ("Public health agencies should adopt the policy that is most likely to promote health and prevent disease while incurring the fewest possible personal burdens."); Pope, *supra* note 296, at 431–32.

301. I deal with individuals selecting goods or services for use in business activities in Section G., *Economic Autonomy*.

Figure 8
Relative Individual Autonomy



The *mandatory preference*, *risk/benefit balancing (with teeth)* and *safer alternative compliance preference* are the worst performers on individual autonomy. Each restricts the choices available to the consumer by essentially directing manufacturers to produce a particular good, regardless of consumer preference.[302] Relatively speaking, the *safer alternative-based performance standard* and *mandatory planning* have substantially less discernable effect upon individual autonomy. Each leaves the manufacturer with discretion as to whether the safer alternative should be adopted, the latter significantly more than the former.

The best performers are *alternatives analysis information disclosure* and *expedited review*, both of which have the potential to increase individual autonomy. *Alternatives analysis information disclosure* enhances autonomy by providing individuals with new and/or more reliable information regarding the range of choices available to them. The artist, the pilot and the

302. It is worth noting that the impact may be dulled where the alternatives analysis itself takes consumer acceptance of an alternative into account in evaluating whether an alternative is "viable."

amateur landscaper may, for a variety of reasons, be unaware of relevant safer alternatives or skeptical of information regarding alternatives available in the marketplace. Information drawn from an "official" alternatives analysis and disseminated by the government, alternative manufacturers, or third party non-governmental organizations could credibly fill knowledge gaps and thus affect consumer choice. *Expedited review* acts more directly to boost individual autonomy. It can enhance consumer choice by clearing the regulatory path for introduction of new, safer products to the market, without restricting availability of other existing products.

G. Economic Autonomy

This principle reflects the laissez faire view that, as a normative matter, government intrusion in the market should be minimized.[303] It has an instrumental basis; that is, that the market will operate better absent government interference.[304] It also has a rights-oriented basis, grounded in principles of economic freedom and autonomy.[305] It overlaps with the principle of individual autonomy in that consumer sovereignty is a central (but not sole) element of laissez faire ideology, the others including protection of private property, freedom of contract, and limited government.[306] Moreover, purchasing, production and other decisions by a business firm are the result of individual choice, whether by one person in a sole proprietorship or a group in a large firm. Therefore government constraints on a firm's economic freedom necessarily affect individual autonomy as well.

As with the individual autonomy principle, proponents of laissez faire typically acknowledge that government intervention is appropriate in certain circumstances. The nature and scope of those circumstances has been contested for centuries, but common examples are interventions to

303. John F. Henry, *The Ideology of the Laissez Faire Program*, 42 J. ECON. ISSUES 209, 210 (2008) (describing the "soft" laissez faire ideology of Adam Swift and other early economists and the "hard" ideology of the French school); Jacob Viner, *The Intellectual History of Laissez Faire*, 3 J.L. & ECON. 45, 45–46 (1960) (discussing the historical strategic use of notions of individual liberty and freedom to justify and gain acceptance of laissez faire).

304. K. Sabeel Rahman, *Conceptualizing the Economic Role of the State: Laissez Faire, Technocracy, and the Democratic Alternative*, 43 POLITY 264, 272–74 (2011); Viner, *supra* note 303, at 64–65.

305. *See* Henry, *supra* note 303, at 219–22 (discussing the historical strategic use of notions of individual liberty and freedom to justify and gain acceptance of laissez faire).

306. Richard A. Epstein, *The Assault That Failed: The Progressive Critique of Laissez Faire*, 97 MICH. L. REV. 1697, 1699 (1999).

correct for market imperfections or to respond to emergencies such as war or natural disaster.[307] Hayek himself recognized that government intervention in the form of performance-based regulation may be necessary based on the harm principle.[308] That said, laissez faire proponents contend that interventions should be designed so as to minimize impacts on economic freedom.

In assessing the respective impacts of the prevention-based approaches upon economic freedom, I consider the potential effects on the business' capacity to order its operations and make business decisions without interference.[309] Here it is helpful to think about the two roles that a business may play in the supply chain for a particular chemical or product: manufacturer/vendor or consumer. Imagine the case of a prevention-based mandatory preference rule directed at automotive brake pads containing copper. In its role as the manufacturer/vendor, the parts supplier would perform an alternatives analysis and adopt a safer viable alternative if found. No doubt this would be a substantial intrusion into the business' management and operations. The automobile manufacturer is the consumer of those brake pads. While not directly subject to the regulation itself, the auto maker's freedom of choice regarding brake pads would nonetheless be affected.[310] The impacts of the respective prevention-based approaches on the firm as consumer mirror those on individual consumers, as described in Section V.F, above. Here I focus on the impacts on the firm as manufacturer/vendor.

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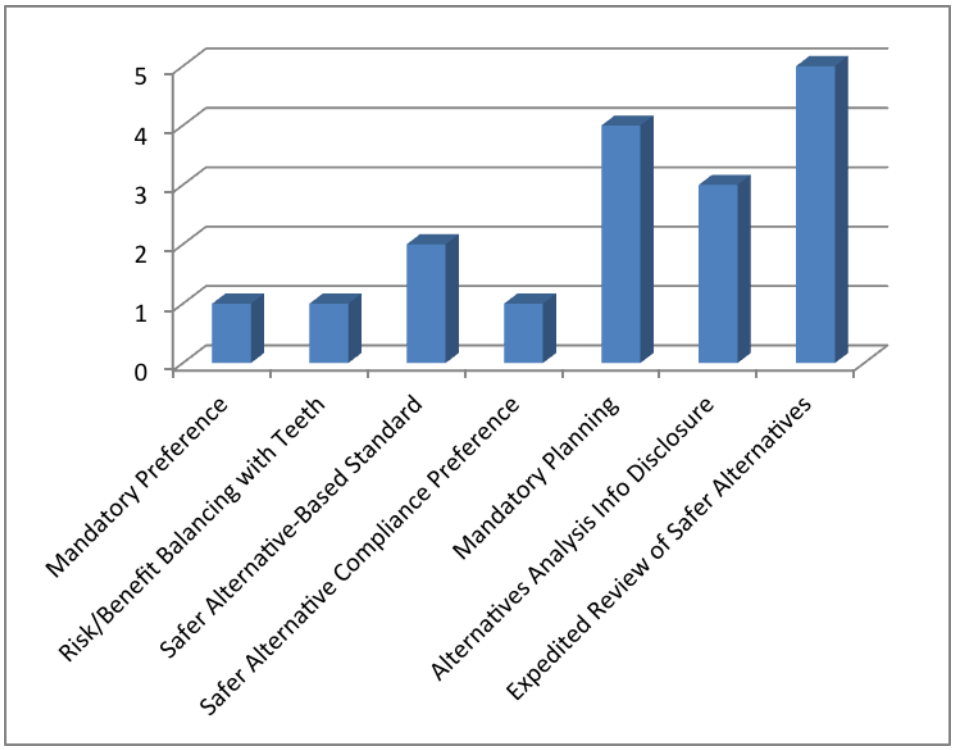
307. *Id.* at 1699; Viner, *supra* note 303, at 45–46.

308. FREIDRICH A. HAYEK, THE CONSTITUTION OF LIBERTY 354–55 (1960) (justifying building codes based on the "the now familiar consideration of the harm that may be done to others by the erection of buildings which constitute fire or health hazards").

309. The analysis regarding impact on decision-making here essentially tracks the analysis regarding flexibility in the section on cost-effectiveness. I used flexibility as a surrogate for cost-effectiveness because of the highly contextual nature of cost. It is possible that in an actual case the evaluation under cost-effectiveness would diverge from the evaluation of interference in firm decision-making.

310. Of course, depending upon how the regulatory program is defined, a business may find itself in either category. For example, the regulation might identify the automobile as the regulated product, with particular focus on the copper in its brake pads or lead in its battery. The auto maker may then be burdened with preparation of an alternatives analysis, but the brake pad manufacturer would no doubt still face impacts on its manufacturing choices.

Figure 9
Relative Economic Autonomy



Not surprisingly, the *mandatory preference*, *risk/benefit balancing (with teeth)* and *safer alternative compliance preference* are the worst performers given their extensive incursion within the firm, both as to firm operations and to decision-making. In terms of operations, like all the prevention-based approaches save *expedited review*, the obligation to perform alternatives analysis imposes procedural strictures and resource allocations on the firm. The firm must harmonize its product development and process design procedures with regulatory alternatives analysis. Personnel from multiple firm units such as engineering, environmental, health and safety, and finance must devote time and effort to the process. With respect to decision-making, the firm loses control over certain aspects of its products or processes, forced to adopt safer alternatives. The *safer alternative-based performance standard* is the next worst performer. While this approach does not require that the firm switch to a particular alternative, it still intrudes significantly in decision-making concerning product or process design.

The remaining three approaches perform significantly better. None of them directly encroach on firm decision-making regarding product or process design. *Mandatory planning* and *alternatives analysis information disclosure* each affect firm management by requiring alternatives analysis. *Alternatives analysis information disclosure* compounds this interference in management by mandating disclosure of the results to outside parties. *Expedited review* is the best overall performer. It simply provides benefits to those firms who have independently decided to pursue government approval/review of a safer alternative.

H. Limitations of Government

This principle considers the capacity of government bureaucracies to implement prevention-based regulation. The pertinent concern is whether government agencies are well suited to make decisions regarding the safety and viability of alternative products and processes. Critics of conventional technology-based regulation have long questioned the ability of EPA and other agencies to make appropriate judgments regarding control technologies for regulated firms.[311] The argument against government competency rests largely on the notion that firms have superior explicit and tacit knowledge and experience regarding their business, technologies and customers.[312] Fair enough, but sophisticated government agencies have skills, resources and information sources of their own that will be important in the prevention-based setting. The central question is whether those skills, resources and information sources are sufficient for effective action under the various prevention-based approaches.

In answering that question, one must remember that alternatives analysis, which lies at the heart of prevention-based regulation, involves consideration of human health and environmental effects, economic

311. *See* Malloy, *Social Construction*, *supra* note 16, at 335–36; Daniel J. Fiorino, *Toward a New System of Environmental Regulation: The Case for an Industry Sector Approach*, 26 ENVTL. L. 457, 469 (1996); Bruce A. Ackerman & Richard B. Stewart, *Reforming Environmental Law*, 37 STAN. L. REV. 1333, 1343 (1985).

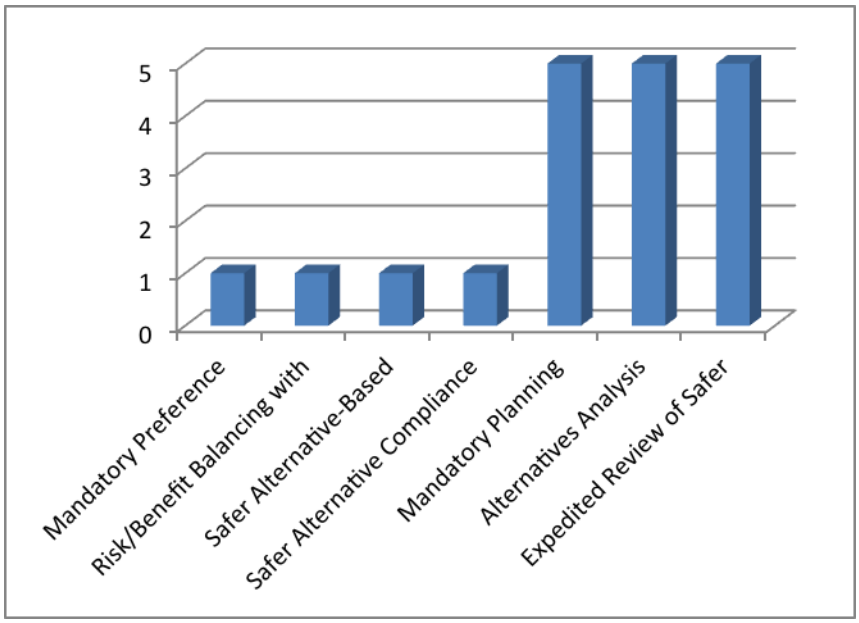
312. *See, e.g.*, David M. Driesen, *Is Emissions Trading an Economic Incentive Program?: Replacing the Command and Control/Economic Incentive Dichotomy*, 55 WASH. & LEE L. REV. 289, 297 (1998) ("[T]he polluter knows its facility better than the regulator and can determine how to deliver any given decrease in pollution more efficiently than the regulator."); Ackerman & Stewart, *supra* note 311, at 1343 ("Instead of giving the job of economic and technological assessment to bureaucrats, the marketable rights mechanism would put the information-processing burden precisely where it belongs: upon business managers and engineers who are in the best position to figure out how to cut back on their plants' pollution costs.").

feasibility and technical feasibility. Environmental regulators have substantial experience and expertise in the areas of health and environmental assessment, as well as both micro- and macroeconomic analysis.[313] Agency engineers and scientists likewise engage in sophisticated analyses of technological feasibility in permitting and rulemaking setting. That experience, however, is largely limited to assessment of pollution control technologies and practices. It is one thing to judge the effectiveness and impacts of equipment that is added at the tail end of a production process to capture emissions. It is quite another more challenging matter to step into the production process itself from outside the firm. Which is not to say that agencies are inherently unable to understand or evaluate process and product changes—federal and state agencies and academic researchers assists firms and trade associations in pollution prevention efforts on a regular basis. But we should recognize that integrating such efforts into a mainstream regulatory program requires a "scaling up" of that capacity in terms of expertise, staffing and resources.

In evaluating the principle of limited government capacity in the prevention-based regulation context, I consider the extent to which an approach calls for a direct determination by the agency regarding the technical feasibility of an alternative. For these purposes, technical feasibility includes both the functionality of the alternative as well as its acceptability to end-users.

313. Malloy, *Social Construction*, *supra* note 16, at 337–44.

Figure 10
Limitations of Government



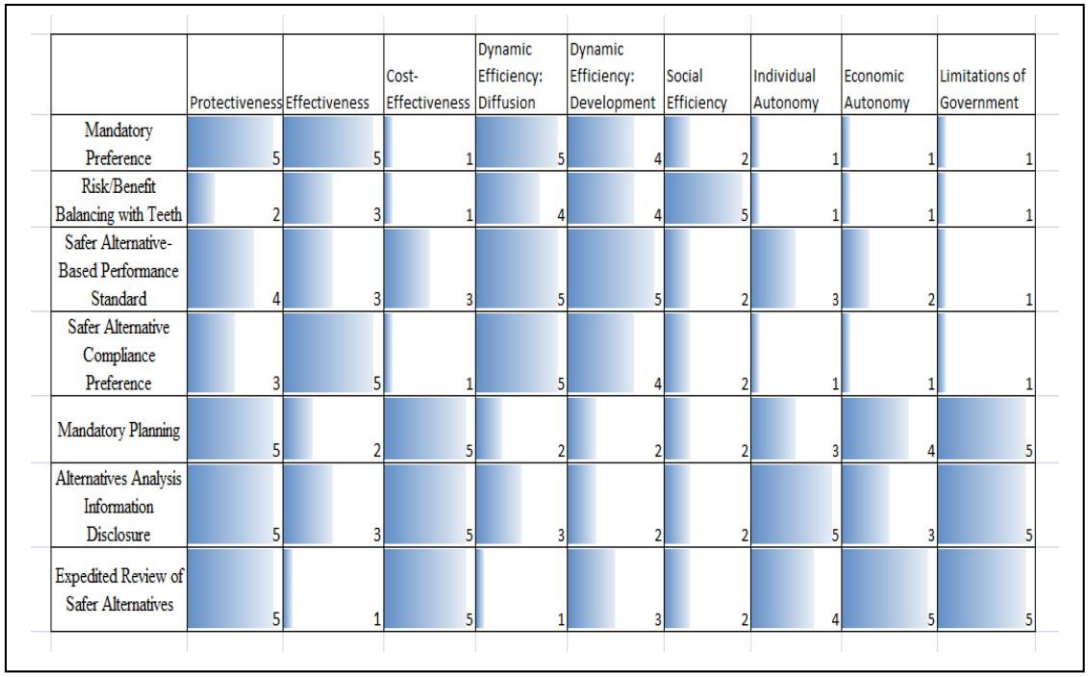
In this case, the *mandatory preference*, *risk/benefit balancing (with teeth)*, *safer alternative-based performance standard*, and *safer alternative compliance preference* are very low performers. Each calls for an agency determination regarding technical feasibility. The remaining approaches are very high performers because, in each, judgments regarding technical feasibility rest solely with the firm.

CONCLUSION

This article began by asking what a mainstream prevention-based regulatory system would look like. Of course there is no single answer to that question. As we have seen, prevention-based regulation could take a variety of forms. The first column of Figure 11 sets out the seven general approaches discussed in this article. The remaining columns summarize how each of the approaches performed across the range of design principles. (The cells display the score from 1 to 5, as well as a solid bar reflecting the score. The bar fills the cell to indicate a score of 5, and decreases proportionately as the score drops.) As Figure 11 illustrates, each prevention-based approach presents a different performance profile, which

raises yet another question: given this differential performance, how should policymakers choose among the potential prevention-based approaches?

Figure 11
Performance Summary



	Protectiveness	Effectiveness	Cost-Effectiveness	Dynamic Efficiency: Diffusion	Dynamic Efficiency: Development	Social Efficiency	Individual Autonomy	Economic Autonomy	Limitations of Government
Mandatory Preference	5	5	1	5	4	2	1	1	1
Risk/Benefit Balancing with Teeth	2	3	1	4	4	5	1	1	1
Safer Alternative-Based Performance Standard	4	3	3	5	5	2	3	2	1
Safer Alternative Compliance Preference	3	5	1	5	4	2	1	1	1
Mandatory Planning	5	2	5	2	2	2	3	4	5
Alternatives Analysis Information Disclosure	5	3	5	3	2	2	5	3	5
Expedited Review of Safer Alternatives	5	1	5	1	3	2	4	5	5

No doubt the ultimate structure of prevention-based regulation will be shaped to a large extent by political compromise and institutional imperatives.[314] Even so, the underlying design principles and the likely performance of the various approaches remain important. They provide the intellectual framework for policymakers engaged in formulating prevention-based regulation, and the metric for measuring what is being gained and lost in negotiations. So, as I explained at the start, for the purposes of this article I put aside the push and pull of politics and compromise, and focus instead on principles.

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314. *See* Alastair Iles, *Greening Chemistry: Emerging Epistemic Political Tensions in California and the United States*, 21 PUB. UNDERSTANDING SCI. 1 (2011) (detailing the political history of California's Safer Consumer Products regulations); Andrew Fasey, *REACH is Here: The Politics are Over, Now the Hard Work Starts* (Lowell Center for Sustainable Production, undated) (describing "8 years of discussions, deliberations, negotiations and often fierce arguments" leading to passage of REACH).

Yet the question of how to choose among the potential prevention-based approaches still remains unanswered. And so it will stay, at least for now. In part that is because of the level of generality at which the analysis has necessarily operated. My goal was to map the broad landscape of prevention-based regulation, bringing some order to an emerging area of regulation. Prevention-based regulation can be used in a variety of settings, and take many forms even within the seven general types discussed in this article. But more importantly, the outcome of principled choice depends on *which* principles the decision-maker values most. Assume that all stakeholders agree on how well each approach performs across the eight design principles, undoubtedly an optimistic supposition. Even in that case, a stakeholder who held protectiveness and effectiveness to be most important would choose a different prevention-based approach than a stakeholder who placed most weight on individual autonomy and cost-effectiveness. Which is the best choice? It depends.

By articulating the design principles and assessing relative performance, however, stakeholders in the policy formulation process may find some common ground despite differing values. Two routes to principled prevention seem particularly promising. First, stakeholders may seek the "second best" compromise choice which performs well, if not the best, on the principles of most importance to the relevant parties. Second, and related, the stakeholders could modify a standard prevention-based approach or devise combinations of prevention-based approaches that optimize each of the important principles.