Part IV

National, regional, and international efforts to advance health, safety, and the environment

There are several types of environmental problems which have been exacerbated by increased industrial throughput (driven by increased demand) of energy and materials that consume natural and physical resources and energy, and that adversely impact public and worker health and the environment. These problems have already been discussed in prior chapters and include (1) toxic substance exposure that directly affects human health and the environment, (2) global climate change, (3) the compromise of ecosystem integrity and its indirect effects on human health, and (4) the depletion of natural resources and energy.

In the preceding Part III of this work, we explored government intervention designed to enhance economic welfare and the economy. In Part IV of this work, Chapter 9 on "Regulatory Regimes to Protect Health, Safety, and the Environment: The United States Experience" explores one of the earliest and most comprehensive national regulatory systems to address health, safety, and environmental concerns.

Environmental problems are not bounded by geopolitical borders, but rather have international as well as global consequences that must be managed through both domestic and international legal instruments, agreements, and principles. Inherent in the concept of sustainable development is the necessity to have the fundamental tools and instruments to effectively manage environment, health, and safety issues for the well-being of both the present and the future generations.

Chapter 10 on "Regional and International Regimes to Protect Health, Safety, and the Environment" explores the policy tools and instruments to improve health, safety, and the environment that function across, as well as within, national economies. This includes efforts to harmonize national environmental legislation for nations that are members of a federated or politically integrated entity such as the European Union where member-wide regional law is evolving, and for nations operating independently, but often within the context of multilateral environmental, health, and safety agreements.

There are two different policy models for addressing health, safety, and environmental concerns. One approach focuses on *environmental policy* controlling and preventing pollution in various media (air, water, waste, and the workplace), product safety, and industrial chemical production, use, and disposal. An alternative approach focuses on developing an *industrial policy for the environment* which encourages or requires environmentally sustainable production, products, and energy-related activities through the tools of environmental policy and regulation. Both approaches are explored in Part IV. Whether and how technology development might be utilized for improving the environment, employment, and economic welfare is reserved for the concluding Chapter 13.

9 Regulatory regimes to protect health, safety, and the environment

The United States experience

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- 9.1 Introduction 526
- 9.2 The nature of pollution and justification for government intervention 526
- 9.3 Approaches to the pollution problem 527
- 9.4 Choosing the instruments of intervention 528
 - 9.4.1 Direct controls 528
 - 9.4.2 Indirect controls 529
 - 9.4.3 Liability statutes and common law suits 529
 - 9.4.4 Voluntary initiatives 529
 - 9.4.5 Encouraging the adoption of cleaner and inherently safer technology 530

9.5 Principles of environmental, health, and safety law 530

- 9.5.1 The polluter pays principle 530
- 9.5.2 The precautionary principle 531
- 9.5.3 The preference for pollution prevention and inherently safer production 534
- 9.5.4 The principle of extended producer responsibility for products and chemicals, and lifecycle considerations 535
- 9.6 The U.S. regulatory system 536
 - 9.6.1 Introduction to the U.S. system 536
 - 9.6.2 Media-based initiatives 536
 - 9.6.2.1 The workplace: the Occupational Safety and Health Act (1970) 536 9.6.2.1.1 Key osha standards 537
 - 9.6.2.1.2 Regulatory challenges and the role of the federal courts 538
 - 9.6.2.2 The ambient air: the Clean Air Act (1970, 1977, 1990) 539
 - 9.6.2.2.1 National ambient air quality standards for
 - CRITERIA POLLUTANTS 539
 - 9.6.2.2.2 National emission standards for hazardous air pollutants 540
 - 9.6.2.2.3 Prevention of Chemical Accidents 541
 - 9.6.2.2.4 Regulation of greenhouse gases 542
 - 9.6.2.3 Surface waters and drinking water 542
 - 9.6.2.3.1 THE CLEAN WATER ACT (1972, 1977, 1987) 542
 - 9.6.2.3.2 The Safe Drinking Water Act (1974, 1986, 1996) 545
 - 9.6.2.4 The land and subsurface waters 545
 - 9.6.2.4.1 The Resource Conservation and Recovery Act (1976, 1984) 546

9.6.2.4.2 The Comprehensive Environmental Response, Compensation, and Liability Act (1980, 1986) 546

- 9.6.3 Chemical-based statutes 547
 - 9.6.3.1 The Emergency Planning and Community Right to Know Act (1986) 547
 - 9.6.3.2 The Toxic Substances Control Act (1976, 2016) 548
 - 9.6.3.2.1 The first forty years 548
 - 9.6.3.2.2 The 2016 Amendments 550
 - 9.6.3.3 Chemicals in pesticides, food additives, pharmaceuticals, and consumer products 552

526 National, regional, and international efforts

- 9.6.4 Laws integrating pollution reduction into federal decision-making 554
 9.6.4.1 The National Environmental Policy Act (1969) and the Endangered Species Act (1973) 554
 9.6.4.2 The Pollution Prevention Act (1990) 555
- 9.7 Deciding the extent of intervention 556
 - 9.7.1 Trade-off analysis distinguished from cost-benefit analysis 556
 - $9.7.2 \hspace{0.1 cm} \text{Trade-off analysis in the context of sustainability} \hspace{0.1 cm} 565$
 - 9.7.2.1 Operationalizing the social contract 565
- 9.8 Static versus dynamic efficiency and the implications for promoting technological innovation using trade-off analysis 569
- 9.9 References 571

9.1 Introduction

The previous three chapters addressed the two pillars of sustainable development related to economic development: (1) the economic welfare of a nation's population; and (2) that population's earning capacity achieved through employment and ownership of productive capital. This chapter and the next address a third pillar of sustainable development – the environment and public health and safety – which is directly affected by environmental pollution, worker and consumer exposure to toxic substances, global climate disruption from the emissions of greenhouse gases such as CO_2 and methane, and the destruction of the ozone layer that limits the amount of stratospheric high-UV radiation reaching the surface of the earth.

9.2 The nature of pollution and justification for government intervention

It has long been recognized that health, safety, and environmental hazards are byproducts of industrialization, and that they are manifested as exposures leading to harmful effects on workers, consumers, and ordinary citizens, as well as harm ecosystems and the planet. These hazards – which we collectively term "pollution" – represent classic examples of externalities not included in the costs or prices of products, processes, or services. Not accounting for these externalities leads to excess production, geographical and international variations, near-termism in investments, and asymmetric knowledge (about problems and solutions) as between producers/providers and consumers and the general public.

As a result, markets for products and services fail to create sufficient demand on the part of society for pollution control or elimination and create free-rider problems and distance (both in time and in geography) between cause and effect. For all these reasons, unregulated markets are unlikely to deliver adequate pollution control or elimination.

The nature of pollution, externalities, and markets presents a logical opportunity for government intervention, such as the provision of informal guidelines, mandatory standards, and/or economic instruments (such as pollution or energy taxes).

The earliest and most comprehensive national system for controlling pollution was developed in the United States and was later emulated in Europe, where the regulatory stringency now sometimes exceeds that of the U.S. For this reason, we have selected the U.S. system as the baseline example for this chapter, and in the following chapter we compare it to the regional system adopted in the European Union. International environmental law, manifested as multilateral environmental agreements, has been influenced by both the U.S. and the EU regulatory approaches, and is also addressed in the next chapter.

9.3 Approaches to the pollution problem

There are three generic ways for society to address the pollution problem. In increasingly stringent order of market intervention, these are: (1) **provide relevant information** about both hazards and the options for their control to the would-be affected/victims, polluters, and potential developers of substitute technology, resulting in the creation of demand, pressure, and opportunities for pollution reduction or elimination; (2) **control/eliminate the hazard through government regulation and/or government-imposed economic instruments**; or (3) **fashion an industrial policy for the environment and public health** that promotes the development and application of inherently safer and environmentally sounder technologies (substitute products, processes, practices, and systems). National differences in culture and political systems in different countries render these different approaches differentially effective.

The effectiveness of these various approaches can be greatly influenced by whether one has a focus on law or a focus on economics as a lens though which to view the pollution problem. The importance of the differences in focus makes itself known when considering two fundamental decisions: (1) in deciding whether and to what extent to intervene (the decision outcome algorithm - see Section 9.7.1); and (2) if intervention is deemed warranted, in deciding whether to control (or eliminate) the hazard through government regulation or through government-imposed economic incentives/disincentives (the choice of instruments).

In general, society's approach to addressing environmental problems is an evolving one and can be conceptualized as encompassing four stages in the evolution of technological thinking:

- **Pollution control**: the development of end-of-pipe technologies to capture and reduce emissions/waste;
- **Pollution and accident prevention** (otherwise known as **cleaner and inherently safer production**): the creation of better, more environmentally sound products, processes, and services. Gradual pollution, sudden and accidental releases of chemicals, and the production of inherently dangerous products are reduced or eliminated;
- Shifts from products to product-services: the establishment of services to replace the need to purchase products. For example, washing services replace the need to buy a washer and dryer; photocopying services replace the need to buy expensive photocopying machinery; and innovative car-sharing programs in cities replace the need to buy an automobile; and
- System changes: the achievement of broad, systemic innovation, in contrast to the narrow use of innovation in relation to advances in specific products, processes, and services, e.g., transportation systems, agricultural systems, etc. A system innovation changes not only technology but also institutional, organizational, and social structures. Because traditional policies focusing on these different kinds of innovation tend to be somewhat fragmented, there is a need to formally integrate transformative initiatives. This is why, if we are to realize the "natural capitalism" vision espoused by Hawken et al. (2000), government needs to play an active role in encouraging change.^{*} Existing barriers need to be removed, and an integrated systems approach to planning needs to be introduced.

^{*} See Ashford and Caldart (2008) and the discussion in Chapter 13.

9.4 Choosing the instruments of intervention

Government intervention might be classified into five categories: (1) direct controls (often called command-and-control regulation); (2) indirect controls (often called market-based approaches); (3) "cooperative" policy instruments, such as information sharing, technical assistance, and government purchasing practices; (4) statutory and common-law liability for harm; and (5) encouragement of so-called voluntary initiatives. Government programs coming within this last category tend to be premised on either industry's presumed interest in meeting social demands for a cleaner environment, or industry's desire to avoid more stringent regulation. While perhaps not strictly governmental policies, voluntary approaches of this nature often require government acquiescence and encouragement to succeed.

9.4.1 Direct controls

Direct controls are legal commands – or mandated standards – imposed by a government agency, requiring firms to take some action (e.g., reduce emissions to meet environmental objectives, or provide specified information to government, the community, or the public). In the United States, firms usually do not have the choice of not complying with direct controls if they wish to operate within the confines of legal behavior. Noncompliance would be a violation of the law and could subject a firm to legal sanctions, including civil (and possibly criminal) penalties.

Consequently, noncompliance tends to carry with it a stigma of wrongdoing. This form of government intervention is sometimes called command-and-control regulation because it is characterized by legal compulsion. In some European countries, standards may take the form of recommended guidelines – called indicative standards – rather than mandates. In either case, the extent of compliance is dependent on a strong regulatory presence and emphasis.

Standards can be classified in a number of ways. A performance standard is one that specifies a particular outcome, such as a specified emission level above which it is illegal to emit a specified air or water pollutant, or a concentration limit specifying the amount of a particular pollutant allowed to be in a cubic meter of air or liter of water. Performance standards may also be expressed as limits on the degree of lifetime, annual, weekly, daily, or hourly exposure to a harmful substance, or on its flammability or explosive potential. A performance standard does not specify how the required limit is to be achieved.

A design or specification standard, on the other hand, may specify that a particular production or control technology, such as a catalytic converter on an internal combustion automobile engine, must be used to obtain pollution reduction. A ban on the use of a particular chemical in production (or on chemicals that cause a specific kind of damage, such as carcinogens or endocrine disrupters) is a design or specification standard, though it may effectively correspond to an emission standard of zero for that chemical. Similarly, a mandate for the use of cleaner (or inherently safer) technology, or for the reduction of chemical use at the source, is a form of design or specification standard.

In either case, the standard can be based on (1) a desired level of protection for human health or environmental quality, (2) some level of presumed technological feasibility, (3) some level of presumed economic feasibility, or (4) some balancing of social costs and social benefits. Within each of these options, there is a wide spectrum of possible approaches. A human health-based standard, for example, might choose to protect only the average member of the population, or it might choose to protect the most sensitive individual. A technology-based standard might be based on what is deemed feasible for the industry as a whole or alternatively on what is deemed feasible for each firm within the industry. Moreover, some standards might be based on a combination of these factors. Many standards based on technological feasibility, for example, are also based on some concept of economic feasibility.

Beyond standards are a variety of information-based obligations that can also influence industrial behavior, such as (1) the required disclosure of (and provision of public access to) exposure, toxicity, chemical-content, and production data, and (2) requirements to conduct testing or screening of chemical products, and in the case of products (such as pharmaceuticals) to conduct clinical trials for safety and effectiveness.

9.4.2 Indirect controls

Indirect controls provide incentives whose purpose is to induce firms to take some action to improve environmental quality. However, firms are not required by law to take the desired action, and normally no sense of wrongdoing accompanies a failure to do so.

An emissions fee or "tax" that is imposed on firms according to the units of pollution they emit – or units of waste they create – is a type of "negative" indirect control, while tax deductions and credits made available to firms that take pollution reduction measures are types of "positive" indirect controls. Because indirect controls generally take the form of an economic charge or subsidy or some other type of financial incentive, they are often referred to as economic instruments or market-based instruments.

There are other "positive" (or "cooperative") policy instruments that also are designed to indirectly stimulate industry to reduce pollution. Broadly speaking, these programs involve government provision of goods or services that private industry has been unable or unwilling to provide or develop. Examples are the creation of pollution and waste control and prevention information databases and clearinghouses, the establishment of a state office of technical assistance, the sponsoring of technical conferences, the creation of a waste recovery facility to separate out recyclable materials, government projects to demonstrate the feasibility and effectiveness of new pollution-reducing technologies, and the use of government purchasing power to promote cleaner production. Although these programs are conceptually linked to positive market-based incentives such as subsidies and tax credits, they typically involve a greater level of government involvement in the process.

9.4.3 Liability statutes and common law suits

Liability statutes and common law suits that result in damage awards for health or environmental consequences can, under some circumstances, be incentives to reduce pollution and waste. By creating financial liability for future harms that may be caused by pollution or waste, these mechanisms can create an incentive for firms to reduce or eliminate these externalities, and thus to reduce or eliminate the future liability. In the United States, the so-called Superfund statute (CERCLA, the Comprehensive Environmental Response, Compensation, and Liability Act) is perhaps the most prominent of such liability statutes on the federal level. Also included in this category are financial responsibility requirements that mandate firms, or their agents, to provide collateral (such as financial bonds) to guarantee that there will be funds available to pay for future environmental damage resulting from their operations.

9.4.4 Voluntary initiatives

The types of voluntary initiatives that can be encouraged by governmental programs include: so-called industrial ecology practices (involving exchange of wastes and materials among commercial and industrial firms with resulting efficiency gains in collectivizing waste treatment); industry self-enforcement, encouraged by industry codes of practice;

and voluntary programs or covenants between industry and governments to go beyond legally mandated standards. It should be noted that "voluntary" is a relative term in this context, as many of these programs are conducted against the backdrop of an evolving system of mandatory standards. Moreover, the term "voluntary" is a misnomer when it is applied to programs designed to bring firms into compliance with existing standards.

9.4.5 Encouraging the adoption of cleaner and inherently safer technology

If the system of health and environmental protection is to be instrumental in moving society to a more sustainable structure, it should be focused on eliminating pollution (and chemical accidents) at the source, which requires the substitution of inputs and starting materials, changes in the final product, and/or changes in the production process. There are a number of approaches that may help stimulate such changes. For example, adjusting the governmental subsidies associated with industrial production and taxing inputs as well as pollution and waste can be useful in encouraging the development and application of inherently safer and environmentally sound technology. Similarly, enforcement of regulatory standards requiring the adoption of best available technologies, imposition of financial liability for harm to health or the environment, and the implementation of a system of tradable emissions permits subject to an overall "cap" on collective emissions may help the diffusion (and even spark the innovation) of cleaner production technologies and practices.

9.5 Principles of environmental, health, and safety law

As environmental, health, and safety law has evolved, certain policy principles have become established as potential guides to the development of legislation and its implementation through regulation. As explored in this chapter and the next, the degree to which these principles are incorporated into the law varies both among the institutional regimes (i.e., the U.S., the EU, and international law) and, within those regimes, among the various subjects of regulation.

9.5.1 The polluter pays principle

The polluter pays notion holds that polluting enterprises should assume the liability for correcting the harmful consequences of these activities. In other words, this principle aims to compel polluters to be responsible for their externalities. In the United States, the principle has been applied to liability for environmental, but not health, damage in the Superfund legislation, which imposes liability for the remediation of leaking hazardous waste sites on the generators of that waste. Under that statute, the courts have imposed joint, several, and retroactive liability on waste generators, and federal taxes on current chemical, petroleum, and gas industries were levied to pay for abandoned hazardous waste sites. The upstream cost of the minimization and treatment of waste is imposed on polluters by another law, the Resource Conservation and Recovery Act (RCRA). See Section 9.6.2.4.1 for a more detailed discussion of Superfund liability.

In contrast to the polluter pays principle, an alternative perspective, known as the Coasean view, is advocated, especially by neoclassical economists. To use an illustrative example, imagine that industrial producers of a certain product freely use the air or water to dispose of a noxious substance (rather than control or treat it), which imposes costs on individuals who live downstream or downwind from the site at which the noxious substance is produced. The lower cost offered by this method of disposal may benefit consumers through lower prices for the product, may benefit the producers through higher profits, or some combination of the two. In either case, neither the producers nor the consumers have an incentive to account for the externality costs that the production of the product imposes on persons living downstream or downwind from the site of production.

In his Nobel Prize-winning work, *The Theory of Social Cost*, Coase (1960) argues that the problem of environmental externalities can be solved by market-like transactions involving negotiations between polluters and citizens. Coase (1960, p. 2) analyzes the issue as being one in which there is a "reciprocal nature of the problem." Were it not for the polluter, there would be no problem. If the citizens did not live downstream, there would likewise be no problem. Coase argues that, in the absence of transaction costs, it makes no sense for the government to impose a solution. Through negotiation, no matter which group initially has property rights in the air or water, the same outcome would result. The resource (air or water) would be put to its most valued use.

Instead of the government regulating the polluter, those individuals affected by the externalities could band together and pay the producers to use different methods of pollution disposal. Alternatively, the producers could pay the affected individuals for the continued convenience and commercial value to them of polluting the air or water. Depending on which is most valuable, the outcome will be the same. However, in assuming that transaction costs are low, what Coase neglects is that, in reality, coordinating collective action among affected individuals is often fraught with difficulty (transaction costs are high) and would require, among other things, the formation of, and agreement within, community-based organizations (Congleton and Sweetser 1992) and avoidance of the "free rider" phenomenon, in which some individuals choose to avoid contributing to the negotiated cost while still enjoying the fruits of the group efforts. In practice, both affected parties would look to the next most valuable alternative or substitute activity in deciding what the value of using the resource is.

Even if a Coasean negotiation of this nature were successful in achieving an agreement between the polluters and those affected by the pollution, there is the substantial question of who, as a matter of *equity*, should bear the cost of pollution. Alternatively, rather than depending on successful organizing to negotiate with polluters and consumers, those affected could pressure government to regulate or tax the harmful product or activity.*

9.5.2 The precautionary principle

The precautionary principle, which is more subtle and less clearly defined than the polluter pays principle, incorporates the notion that one should err on the side of caution where evidence of harm is not well-characterized. In many cases, the timescales and consequences of the environmental, health, and safety impacts of pollution are unknown and difficult to define in scientific or quantitative terms. Impacts from activities carried out

* It bears noting that prospects for "[Coasean] solutions are also affected by a variety of government policies and may require changing those policies. The initial assignment of rights determine[s] what course of action is necessary. Within governments characterized by an aggressive tort law, those living downstream or downwind could launch a class action suit against the producers for damages imposed by the use of the air or water systems to dispose of waste products. In the absence of such legal remedies, a new organization would have to be created to collect money in order to compensate producers and consumers of X. Such organizations would require some process of collective choice to determine negotiation strategies, assign cost shares to members, and design methods for punishing those who fail to contribute.

In the end, the [Coasean] result reflects a variety of government policies that affect organizational costs, contract enforcement, and liability under tort law. Government policies may affect such internal arrangements of such groups or special service districts insofar as its policies [... discourage] interest group formation (as within dictatorships), is neutral toward them, or actively encourages them" (Congleton 2003, p. 1).

today may not be seen for many generations and certainly may have implications beyond current political terms and agendas. The precautionary principle can be incorporated into legislation and regulation as a means of addressing the various uncertainties regarding the ultimate effects of anthropogenic activities. It is an embodiment of the duty to prevent pollution or harm even if the evidence is weak.

In the United States, a precautionary approach has been applied in various ways in decisions about health, safety, and the environment since at least the 1970s, much longer than more recent commentaries would have us believe, and earlier than the formal appearance of the "precautionary principle" in European law (Ashford 2007). For example, the Clean Air Act of 1970 requires the ambient air (concentration) standards for certain air pollutants to be set at the level that will protect public health with an "adequate margin of safety." In interpreting this provision when reviewing the ambient lead standard issued by the Environmental Protection Agency (EPA), the U.S. Court of Appeals for the District of Columbia noted that

Congress provided that the Administrator is to use his judgment in setting air quality standards precisely to permit him to act in the face of uncertainty. And as we read the statutory provisions and the legislative history, Congress directed the Administrator to err on the side of caution in making the necessary decisions.

(Lead Industries Assoc., Inc. v. EPA, 647 F.2d 1130 (D.C. Cir. 1980))

What this means is that where there are possibilities of large or irreversible serious effects, action must be taken, even if there is considerable scientific uncertainty (Ashford 2007, p. 354). This is an influential and fairly precise formulation of the mandatory version of the precautionary principle. Alternative permissive, rather than mandatory formulations, also exist, allowing, but not requiring, precaution to be exercised (Ashford 2007, pp. 354–355). The U.S. courts authorized the Department of Labor to move forward in the face of sparse data on the toxicity of workplace chemicals when setting worker protection standards under the feasibility-based mandate of the Occupational Safety and Health Act, noting that Congress intended regulatory action even where existing methodology or research is deficient (Ashford 2007, pp. 361–363).

From approximately 1980 onwards, however, with increasingly industry-oriented presidential administrations and/or Congresses, the political appointees in leadership positions in the regulatory agencies became less willing to regulate without clear and unequivocal evidence of environmental or health harm, and the newly appointed federal judges made it increasingly difficult for health, safety, and environmental standards to survive court review/challenge (Ashford and Caldart 2008).

In today's political climate, the burden of scientific proof often poses a difficult barrier to overcome in any effort to protect health, safety, and the environment in the United States. Actions to prevent harm are often taken only after strong scientific proof of harm has been established, at which point it may be too late to prevent significant damage. To see this, one need look no further than the current political debate over global climate change (although that could also be characterized as an unwillingness to accept the proof of harm that has been scientifically established). Moreover, hazards typically are addressed by industry and government agencies one at a time, in terms of a single pesticide or chemical, rather than as broader issues such as the need to promote organic agriculture and nontoxic products or to phase out whole classes of dangerous chemicals.

This is not to say, however, that a precautionary approach is no longer an important part of U.S. health, safety, and environmental law. The judicial precedents established in the 1970s still retain power, especially where, as with the Clean Air Act, the statute itself incorporates strong precautionary language. Further, for certain classes of products, such as pharmaceuticals, food additives, and pesticides, the manufacturer bears the initial statutory burden of proving the safety of its products. Indeed, since 1958 the Delaney Clause of the Federal Food, Drug, and Cosmetic Act has banned food additives found to cause cancer in humans or in animals, thus making the precautionary determination that substances that are carcinogenic in animals are also carcinogenic in humans, and making the further determination that any risk of cancer from food additives should be avoided. Although this provision has been softened somewhat by more recent legislation (it no longer applies to pesticide residues that concentrate in processed foods), it has been upheld by the federal courts. Moreover, arguments over the strength of the scientific data on harm and causation can be avoided (or, at least, minimized) when Congress specifies protective standards be set according to technological and/or economic feasibility – that is, when firms (or industries) are told to reduce pollution to the extent that they can.

Congress took this approach in 1972 and 1977 in specifying national effluent standards for water pollution under the Clean Water Act, and in 1990 in specifying national emission standards for hazardous air pollutants under the Clean Air Act. And the EPA adopted this approach in implementing the 1984 amendments to the Solid Waste Disposal Act (also known as the Resource Conservation and Recovery Act, or RCRA), which specified national standards for the land disposal of hazardous wastes. In each of these instances, Congress specified a large group of chemicals or wastes for which such standards must be set, thus effectively removing from the discussion the question of whether, and to what extent, those substances cause harm to health or the environment when they are discharged to the water, emitted to the air, or disposed in the ground. In other words, Congress itself made the (implicit) determination that these substances are harmful and should be regulated; although, perhaps not a clear articulation of the precautionary principle, this nonetheless is an application of a precautionary approach. Indeed, the Clean Water Act sets as a "national goal" the *elimination* of all discharges of pollutants to the waters of the United States (regardless of whether clear data demonstrates that all such discharges would be harmful), and specifies that discharge standards for most pollutants be set at zero if it is technologically and economically feasible for the regulated industry to meet that standard - see generally, Ashford and Caldart (2008). The country is nowhere near these statutory goals at this point, but the persistence of this language in the statute provides a principled basis for the advocacy of a precautionary approach before both the EPA and the federal courts.

What brings the precautionary principle into sharp political focus in the U.S. today are (1) the fact that the nature of scientific uncertainty is changing, as more and more kinds of damage mechanisms from chemicals are identified and the complexity of the influences on global climate change becomes clearer, (2) the increasing pressure to base governmental action on more "rational" schemes, such as cost–benefit analysis (an embodiment of "rational choice theory" promoted by the Chicago school of law and economics) and/or quantitative risk assessment, and (3) the increasing prominence and importance of the precautionary principle in European and international environmental law.

The precautionary principle has been criticized as being both too vague and too arbitrary to form a basis for rational decision-making. The assumption underlying this criticism is that any scheme not based on cost–benefit analysis and risk assessment is both irrational and without secure foundation in either science or economics. We contest that view and argue that the tenets of the precautionary principle are rational within an analytical framework that is as rigorous as uncertainties permit, and one that mirrors democratic values embodied in statutes (regulatory and compensatory) and common law (see Section 9.6).

On closer examination, the precautionary principle is not in conflict with science, but rather with cost–benefit analysis. What becomes important is not the most likely or best estimate of costs and benefits of interventions, but rather how society considers what kinds of errors a government should make in deciding what, whether, and to what extent to regulate environmental hazards.

Policy-makers must address both uncertainty about the nature and extent of health, safety, or environmental risks, and about the performance of an alternative technology in controlling or eliminating the risk. First, they must choose whether to err on the side of caution or risk. With regard to the first type of uncertainty – scientific uncertainty – two mistakes can be made. A "type I" error is committed if society regulates an activity that appears to be hazardous, but turns out later to be less harmful or even harmless (a "false positive" in the parlance of experimental findings) and resources are needlessly expended. Another error, a "type II" error, is committed if society fails to regulate an activity because the evidence is not initially thought to be strong enough, but that finally turns out to be harmful (a "false negative"). A "type III" error is said to occur when one provides an accurate (or precise) answer to the wrong problem. For example, not taking into account opportunities to change technology restricts the decision-maker to "static solutions" and thus gives rise to the further error of considering options within "bounded rationality."

Where uncertainty exists on the technology side, type I errors can be said to be committed when society mandates the development or adoption of a technology that turns out to be much more expensive or less able to reduce risks than anticipated, and when resources are needlessly or foolishly expended. Type II errors might be said to be committed when, because of insufficient commitment of resources or political will, a significant missed opportunity is created by which society fails to force or stimulate significant risk-reducing technology. An important distinction between a cost–benefit approach and one based on precaution is that the former is "risk neutral" in the balancing of costs and benefits with their attendant uncertainties, and the latter reflects "risk averseness" for some kinds of errors.

Value judgments clearly affect decisions on whether to tolerate type I or type II errors with regard to *both* risk and technology choices. This is because the cost of being wrong in one instance may be vastly different from the cost of being wrong in another. For example, banning a chemical essential to a beneficial activity, such as the use of radio nuclides in medicine, has potentially more drastic consequences than banning a nonessential chemical for which there is a close, cost-comparable substitute. It may be perfectly appropriate to rely on "most likely estimates" of risk in the first case and on "worst-case analysis" in the second.

A type II error on the technology choice side was committed in the case of the Montreal Protocol banning chlorofluorocarbons (CFCs) by creating a scheme through which DuPont and ICI, the producers of CFCs, were allowed to promote the use of their own substitute, hydrochlorofluorocarbons (HCFCs), rather than adopt a more stringent protocol that would have stimulated still better substitutes.

Evaluating errors and deciding which way to lean is not a precise science. However, making those evaluations and valuations explicit within a trade-off analysis that acknowledges distributional effects, accounts for uncertainties in risk assessments, and considers opportunities for technological change will reveal the preferences upon which policies are based and may suggest priorities (see Section 9.7 for a discussion of a trade-off analysis framework).

9.5.3 The preference for pollution prevention and inherently safer production

End-of-pipe pollution control focuses on treating or collecting the harmful emissions, effluents, or waste from industrial processes (or, in the case of workers' exposure, on ventilating the workplace or providing personal protective equipment), usually without altering inputs, feed stocks, processes, or final products. Early preoccupation with minimizing air and water pollution often shifted the problem to the hazardous waste stream and/or increased workplace exposure, resulting in what is popularly known as a "media shift." It also often changed the nature of the hazard by increasing the potential for chemical accidents (sudden and unexpected chemical releases, sometimes with accompanying fires and explosions), thus resulting in what is popularly known as a "problem shift."

Pollution prevention – what the Europeans call "cleaner" production or technology – received its first political push in the United States with the mid-1980s pursuit of "waste minimization," an economically driven movement that grew out of a recognition that the best way to avoid the rising costs of treatment and disposal of hazardous wastes often is simply to generate less waste. Depending on the context and the time period, pollution prevention has also been known as elimination of pollution "at the source," "source reduction," and "toxics use reduction." This approach (whatever its name) entails fundamental changes to the means and/or outputs of production.

Pollution prevention is not a refined version of pollution control. It involves fundamental changes in production technology: substitution of inputs, redesign and reengineering of processes, and/or reformulation of the final product. It may require organizational and institutional changes as well.

"Inherent safety" – also known as "primary" accident prevention – is the analogous concept for the prevention of sudden and accidental chemical releases. Inherent safety is a concept similar to – and often is a natural extension of – pollution prevention. The common thread linking the two concepts is that they both attempt to prevent the possibility of harm, rather than to reduce the probability of harm, by eliminating the problem (chemical accidents and chemical pollution, respectively) at its source. The changes necessary for pollution prevention often are associated with improvements in eco-efficiency and energy efficiency. In the context of chemical production, they often involve the exploration of alternative synthetic pathways and green chemistry initiatives. The search for and identification of alternative production methods may also promote the development and use of inherently safer production technology, although minimizing accident potential may require a somewhat different (though not necessarily inconsistent) set of changes.

9.5.4 The principle of extended producer responsibility for products and chemicals, and lifecycle considerations

In a real sense, developing policies focusing only on the consumer safety aspects of products is out of date. Environmental and safety risks from the extraction of materials, from the transformation of these materials into feed-stocks and starting materials for product manufacturing to the manufacturing, transportation, use, and disposal of the ultimate product, are all part of a product's life cycle. If sustainability is to be achieved, these various health, safety, and environmental concerns need to be taken into account at the design stage, where the choice of materials, manufacturing methods, and safety and disposal consequences may all be considered. The design of sustainable products is a critical part of sustainable development.

While the EU Integrated Product Policy (discussed in Section 10.2.4 in Chapter 10) focuses mostly on environmental impact, it does pay some attention to consumer safety. Partial attempts to integrate various stages of a product's life into product regulation are reflected in the developing European laws implementing extended producer responsibility, whereby producers of industrial chemicals have an obligation to ensure safe use by their industrial customers and/or to buy back products from consumers once the products have reached the end of their useful life (such as the buyback programs for used motor-oil in Germany and for some electronics EU-wide). Such laws establish a more complex system linking producers and users.

Until recently, U.S. regulatory law did not incorporate extended producer responsibility for chemicals. However, the 2016 reform of the Toxic Substances Control Act did articulate the principle that all participants in the supply chain of chemicals (producers, formulators, users, and disposers) have concurrent responsibility for chemical safety (see Section 9.6.3). In addition, some states have take-back laws for certain electronic products (such as flat-screen televisions).

9.6 The U.S. regulatory system

9.6.1 Introduction to the U.S. system

Although federal laws intended to protect the environment and ensure food and pharmaceutical safety had existed in some form earlier in the twentieth century, the start of the "modern" U.S. regulatory system for pollution control came in 1969, with the passage of the National Environmental Policy Act, which was designed to imbue the federal government with an environmental consciousness. This was followed in fairly rapid succession over the next six years by four "media-based" initiatives intended to control the release of pollution into, respectively, the workplace, the air, the surface waters, and the ground and groundwater. Rather than craft these initiatives as a comprehensive and coordinated effort to reduce pollution, however, Congress designed them as largely separate regulatory systems, each with its own standards and permitting requirements. The 1970s also saw the passage of the Toxic Substances Control Act, which gives the EPA the authority and opportunity to adopt a more coordinated approach and to address the pollution problem on a chemical-by-chemical basis. Both by design and because of inertia, however, that law has taken a back seat to the far more prominent media-based statutes.

In the 1980s and 1990s, Congress took steps to strengthen the laws protecting the three environmental media – though it left workplace protections largely unchanged – and passed the Superfund legislation to hasten the remediation of sites contaminated by hazardous substances. Congress also used this period to fashion new legislation designed to reduce the likelihood and severity of chemical accidents, to grant the public access to information regarding the chemicals used and released by industrial facilities, and to encourage the EPA to prioritize pollution prevention in its administration of environmental laws.

Since the mid-1990s, Congress has done little to change this regulatory system, and most major policy changes regarding pollution control have come through the regulatory system, and through federal court decisions interpreting the various statutes, as the EPA and other agencies do battle with industry and environmental groups over the extent of the agency's statutory authority and responsibility. But in two instances during this period, a bipartisan majority in Congress passed fundamental amendments to an existing law. In 2006, the Consumer Product Safety Act was amended to place increased emphasis on removing lead and certain phthalates from consumer products, while in 2016 the Toxic Substances Control Act was amended in ways that are likely to weaken that already peripheral statute.

9.6.2 Media-based initiatives

We address the media-based statutes in rough chronological order. There are a number of similarities among the various statutes, but one key difference is that all of the laws addressing pollution of environmental media give the affected public the right to file suits in federal court to enforce applicable standards when the government does not do so. Workers, however, are not given a comparable right to enforce workplace standards.

9.6.2.1 The workplace: the Occupational Safety and Health Act (1970)

The Occupational Safety and Health Act (OSH Act) of 1970 established the Occupational Safety and Health Administration (OSHA) in the Department of Labor to implement

and enforce compliance with the act, and the National Institute for Occupational Safety and Health (NIOSH) in the Department of Health and Human Services (under the Centers for Disease Control and Prevention) to perform research and conduct health hazard evaluations. The act requires OSHA to (1) encourage employers and employees to reduce hazards in the workplace and to implement new or improved safety and health programs, (2) develop mandatory job safety and health standards and enforce them effectively, (3) establish separate but dependent responsibilities and rights for employers and employees for the achievement of better safety and health conditions, (4) establish reporting and record-keeping procedures to monitor job-related injuries and illnesses, and (5) encourage states to assume the fullest responsibility for establishing and administering their own occupational safety and health programs, which must be at least as effective as the federal program.

9.6.2.1.1 KEY OSHA STANDARDS

The OSH Act provides two general means of protection for workers. First, the act imposes on virtually every employer in the private sector a *general duty* "to furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm" (OSH Act, Section 5(a)(1)). A recognized hazard may, for example, be a workplace chemical which research has indicated is likely to harm humans. The burden of proving that a particular substance is a recognized hazard and that industrial exposure to it results in serious harm is placed on OSHA. Because standard setting is a slow process, protection of workers through the employer's general duty obligation could be especially important for newly discovered harms. Nonetheless, the successful use of the general duty clause depends both on the existence of reliable health effects data and on the willingness of a particular OSHA administration to use it as a vehicle for protection.

The OSH Act's second means of protection is the promulgation of specific standards to which specified categories of employers must adhere, and OSHA is given specific authority to address workplace exposure to toxic substances. OSHA standards for workplace exposures are expressed as permissible exposure levels (PELs). Section 6(b)(5) directs OSHA to set standards for "toxic materials" and "harmful physical agents" that

most adequately assure [...], to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has a regular exposure to the hazard dealt with by such standard for the period of his working life.

With this language, the act indicates that exposures to toxic materials that have long latency periods (such as carcinogens) and exposures to reproductive hazards need to both be specifically addressed. Nonetheless, the burden of proving the hazardous nature of a substance under Section 6(b)(5) is placed on OSHA, as is the burden of proving that the proposed controls are technologically feasible.

In 1971, OSHA invoked Section 6(a) of the act, which allowed for the adoption without critical review of 450 threshold limit values (TLVs) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) as guidelines for protection against the toxic effects of these materials. These TLVs, which had been recommended by ACGIH in 1969, thus became formal OSHA standards. The inadequacy of these 450 TLVs as a means of worker protection has become widely known. They were designed to protect the average worker from either recognized acute effects or easily recognized chronic effects and were based on animal toxicity data or the limited epidemiologic evidence available at the time. They do not address sensitive populations within the workforce or those with prior exposure or existing disease; nor do they address carcinogenicity, mutagenicity, or teratogenicity.

After adopting these TLVs, OSHA began the slow process of setting updated standards under Section 6(b)(5). In the 1970s, OSHA set updated standards for asbestos, vinyl chloride, arsenic, dibromochloropropane, coke oven emissions, acrylonitrile, lead, cotton dust, and a group of fourteen carcinogens. In the 1980s, OSHA set 6(b)(5) standards for benzene, ethylene oxide, and formaldehyde as carcinogens, and strengthened the standard for asbestos (down to 0.2 fibers per cm³) to reflect its carcinogenic properties. In the early 1990s, OSHA regulated cadmium, blood-borne pathogens, glycol ethers, and confined spaces. OSHA also lowered the PEL for formaldehyde from 1 to 0.75 parts per million (ppm; averaged over an 8-hour period). In 2016, after decades of delay, OSHA issued a new PEL of 50 mg per m³ (averaged over an 8-hour period) for silica dust, which replaces the 1971 PEL of 250 mg per m³, and should provide further protection against silicosis, lung cancer, other respiratory diseases, and kidney disease.

9.6.2.1.2 REGULATORY CHALLENGES AND THE ROLE OF THE FEDERAL COURTS

The evolution of case law associated with the handful of standards that OSHA promulgated under Section 6 is worth considering in detail. The courts addressed the difficult issue of what is adequate scientific information necessary to sustain the statutory requirement that the standards be supported by "substantial evidence on the record as a whole." The cases also addressed the extent to which economic factors were permitted or required to be considered in the setting of the standards, the meaning of feasibility, OSHA's technology-forcing authority, the question of whether a cost-benefit analysis was required or permitted, and the extent of OSHA's jurisdiction in addressing different degrees of risk. Although much of this jurisprudence is supportive of a precautionary approach to workplace risk, there are notable exceptions. In its review of OSHA's benzene standard, the U.S. Supreme Court held that a 6(b)(5) standard may be issued only where the exposure in question poses a "significant risk" of harm. The court did not define that term but did note that a lifetime risk of 1 in 1,000 of developing a serious disease (or death) certainly poses a "significant" risk, while 1 in 1 billion did not. This led business-friendly OSHA administrations to invoke 1 in 1,000 as a necessary threshold for regulation.

The necessarily slow and arduous task of setting standards substance by substance makes it impossible for OSHA to deal realistically with the estimated 13,000 toxic substances or approximately 250 suspect carcinogens on NIOSH lists. Efforts were made to streamline the process by (1) proposing generic standards for carcinogens and (2) proposing a generic standard updating the ACGIH PRLs. Neither of these efforts was successful. The generic standards were not adopted, and the attempt to update the ACGIH standards en masse was struck down by the U.S. Court of Appeals for the Eleventh Circuit, which held that OSHA could not take such action unless it first made a credible "significant risk" determination for each of the chemicals under regulation. However, the courts gave their blessing to another of OSHA's generic toxic substance regulations, the Hazard Communication Standard. That standard, promulgated under Section 6(b)(5) in 1983, requires employers to notify their workers about chemical hazards in their workplaces and to supply them with Material Safety Data Sheets on those chemicals if requested. Although this standard does not directly regulate workplace exposures, it supplies workers (and, where applicable, their unions) with information that can be used to press for chemical substitution and other measures to reduce chemical exposures, and it makes it difficult for employers to argue that harmful conditions do not exist.

9.6.2.2 The ambient air: the Clean Air Act (1970, 1977, 1990)

The modern Clean Air Act (CAA) came into being in 1970, and although significant changes were made in 1977 and 1990, the basic structure of the act has remained the same, with the addition of provisions for authority over acid rain, chlorofluorocarbons (CFCs), indoor air, and chemical safety. The CAA regulates both stationary and mobile sources of pollution, taking into account the relative contributions of each to specific air pollution problems, and the relative capacity of different kinds of sources within each category to reduce their emissions. The recognition that sources using newer technology might be able to achieve greater emission reductions than older sources with older technology led to the act's distinction – both in the stationary and mobile source provisions – between new and existing sources. Driven by equity considerations regarding the relative financial and technical burdens of pollution reduction, this approach unwittingly discouraged modernization or replacement of facilities and resulted in the operation of older (especially energy) facilities beyond their expected useful life. For new sources within each industrial sector, there was a general recognition of the need for uniformity and also for encouraging technological innovation through technology-forcing inherent in stringent standards. The court decisions upholding the EPA's technology-forcing authority were influenced by the cases affirming OSHA's early technology-forcing approach to worker protection.

9.6.2.2.1 NATIONAL AMBIENT AIR QUALITY STANDARDS FOR CRITERIA POLLUTANTS

Section 109 of the CAA directs the EPA to establish ambient air quality standards (maximum allowable concentrations in the ambient air) for certain substances designated by the EPA as "criteria" air pollutants. The *primary* standards for these pollutants are to protect public health with "an adequate margin of safety." As interpreted by the courts and supported by congressional history, these standards were to be established without consideration of economic or technological feasibility. In addition, secondary ambient air quality standards for the same pollutants are to be established to protect "the public welfare [...] within a reasonable time." Thus far, these national ambient air quality standards (NAAQS) have been established (and subsequently revised) for eight criteria pollutants: carbon monoxide (CO); sulfur dioxide (SO_{a}) ; oxides of nitrogen (NO_{x}) ; coarse particulate matter (PM_{10}), defined as "inhalable" particulates up to 10 µm in diameter; smaller particulate matter ($PM_{9.5}$), defined as "respirable" particles of less than 2.5 µm in diameter; photochemical oxidants, measured as ground-level ozone; and lead. The NAAQS are expressed as a specified maximum concentration in a specified area over a specified period of time. The 2010 primary standard for SO₉, for example, is no more than 75 parts per billion (75 ppb).

The CAA contemplates a federal/state partnership to achieve and maintain the national primary and secondary ambient standards. On the federal side, Section 111 directs the EPA to set national New Source Performance Standards for new stationary sources of air pollution (those built or substantially modified after the issuance of the standard). These are technology-based emission limits, set on an industry-by-industry basis. (Emission standards, in contrast with ambient concentration standards, are expressed as an emissions rate – milligrams emitted per 100 kg of product, per hour, per day, per week, per quarter, per year, per BTU, per passenger mile, or other unit of measurement.) Further, the act specifies federal tailpipe emission standards for new mobile sources and contains a number of other programs designed to reduce air pollution from motor vehicles. The states' obligation emanates from Section 110 of the act, which directs each state to develop a State Implementation Plan (SIP), subject to approval by the EPA, designed to attain the

NAAQS within that state. These SIPs include state emission limitations placed on existing stationary sources of air pollution, and inspection and maintenance programs designed to ensure that on-the-road vehicles are meeting federal tailpipe emission standards.

9.6.2.2.2 NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

In contrast to its approach to the criteria pollutants, Congress has required uniform national emission standards for hazardous air pollutants. Hazardous air pollutants are those recognized as extraordinarily toxic and eventually regarded as non- or low-threshold pollutants. These pollutants, Congress determined, are sufficiently dangerous to preclude any reliance on atmospheric dispersion and mixing as a means of reducing their ambient concentrations. Because of their extraordinary toxicity, "hot spots" of these pollutants were to be avoided, and because ambient standards were considered impractical and of little relevance for sporadic and idiosyncratic sources, uniform federal emission standards were considered necessary. In specifying compliance with federal emission standards, Congress expressed concern with possible hot spots of localized intense pollution and also with intermittent versus continuous versus sudden and accidental releases of harmful substances.

Initially, Section 112 of the CAA specified that the federal emission standards for hazardous air pollutants were to be established solely with reference to public health and were to assure "an ample margin of safety," without regard to cost or technological feasibility. It is likely that this phraseology reflected an early assumption that, though very dangerous, hazardous pollutants did exhibit a finite threshold (a nonzero level of exposure below which no harm would occur). As the 1970s progressed, however, there was a growing recognition that this assumption might be wrong, and that for many hazardous pollutants there was no level of exposure (at least at levels within the limits of detection) below which one could confidently predict that no harmful or irreversible effects (especially cancer or birth defects) would occur. Seeking to avoid promulgating zero emission standards - which would effectively have banned the use of the regulated chemicals in many industries - the EPA instead set standards for hazardous air pollutants based on technological and economic feasibility. Using this approach, the EPA set finite (nonzero) standards for a handful of substances: arsenic, asbestos, benzene, beryllium, coke oven emissions, mercury, vinyl chloride, and radionuclides. This process was slow, often had to be forced by litigation, and basically came to a halt during the anti-regulatory administration of President Ronald Reagan.

Congress transformed the regulatory process for hazardous air pollutants as part of the 1990 amendments to the CAA. The revised Section 112 lists 189 substances and directs EPA to set national technology-based emission limits for those substances, on an industryby-industry basis, according to a specified timetable. Standards for major sources of these pollutants are to reflect the EPA's assessment of the Maximum Achievable Control Technology (MACT), which is to be based on the emission levels attained by the best-performing facilities within the particular industry (considering cost), with new sources subjected to more stringent limits than existing sources. Standards for small ("area") sources are to be based on Generally Achievable Control Technology (GACT), or specified management practices, and generally are less stringent than the MACT standards. This specific congressional directive effectively jump-started the issuance of scores of national, industry-specific emission standards, based on technological and economic feasibility, for hazardous air pollutants. (See Section 9.7 for a discussion the trade-off (or technology options) analysis framework that could be used as an alternative to MACT.)

For substances with an identifiable nonzero threshold, the EPA may at its discretion instead set a health-based standard that assures an "ample margin of safety." In addition, the EPA is directed to eventually set more stringent health-based standards, as necessary, for other substances; these standards are to ensure no greater than a 1 in 1 million lifetime risk of cancer from the exposure. Finally, EPA is directed, "where appropriate," to add other pollutants to the statutory list

which present or may present [...] a threat of adverse human effects (including, but not limited to, substances which are known to be or may be reasonably anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentration, bioaccumulation, deposition or otherwise. (42 U.S. Code § 7412 (b)(2))

9.6.2.2.3 PREVENTION OF CHEMICAL ACCIDENTS

The 1990 amendments to the CAA also added a lengthy new subsection (r) to section 112 addressing the release of chemicals to the air (and/or workplace) through accidents. Section 112(r) directs EPA to develop regulations regarding the prevention and detection of accidental chemical releases and to publish a list of at least 100 chemical substances (with associated threshold quantities) to be covered by the regulations. The regulations must include requirements for the development of risk-management plans (RMPs) by facilities using any of the regulated substances in amounts above the relevant threshold. These RMPs must include a hazard assessment, an accident prevention program, and an emergency release program. The 1990 amendments also direct OSHA to promulgate a Process Safety Management (PSM) standard under the OSH Act.

The OSHA workplace PSM standard, promulgated in 1992, is designed to protect employees (1) working in facilities that use "highly hazardous chemicals" (a list of acutely toxic, highly flammable, and reactive substances), and/or (2) working in facilities with more than 10,000 pounds of flammable liquids or gases present in one location. The PSM standard requires employers to compile safety information (including process flow information) on chemicals and processes used in the workplace, complete a workplace process hazard analysis every five years, conduct triennial compliance safety audits, develop and implement written operating procedures, conduct extensive worker training, develop and implement plans to maintain the integrity of process equipment, perform pre-startup reviews for new (and significantly modified) facilities, develop and implement written procedures in production methods, establish an emergency action plan, and investigate accidents and near-misses at their facilities.

EPA's RMP rule, promulgated in 1996 and modeled on the OSHA PSM standard, is estimated to affect some 66,000 facilities. The rule requires a hazard assessment (involving an offsite consequence analysis – including worst-case risk scenarios – and compilation of a five-year accident history), a prevention program to address the hazards identified, and an emergency response program. Worst-case chemical accident scenarios – called "onsite consequence analyses" (OCA) – are available for reading, but not for copying, in locally designated reading rooms.

In addition, CAA section 112(r) imposes a "general duty" on all "owners and operators of stationary sources," regardless of the particular identity or quantity of the chemicals used on site, to: (1) identify hazards that may result from (accidental chemical) releases using appropriate hazard assessment techniques; (2) design and maintain a safe facility, taking such steps as are necessary to prevent releases; and (3) minimize the consequences of accidental releases which do occur. The act specifies that this obligation to anticipate, prevent, and mitigate accidental releases is "a general duty in the same manner and to the same extent as" that imposed by the OSH Act. Thus, as under the OSH Act, compliance with other regulatory standards should not relieve a firm of its general duty to ensure chemical safety. Arguably, this imposes a continuing duty on employers to seek

542 National, regional, and international efforts

out technological improvements that would improve safety. Further, the requirement that owners and operators "design and maintain" a safe facility would seem to extend the obligation into the area of primary prevention, rather than merely hazard control. In general, however, this potential for a direct focus on primary accident prevention has yet to be realized by the EPA and OSHA.

9.6.2.2.4 REGULATION OF GREENHOUSE GASES

Perhaps, the most contentious issue to arise under the CAA since the turn of the century has been the regulation of carbon dioxide (CO_{2}) and other "greenhouse gases" (GHGs). After the EPA took the position that CO₂ is not an "air pollutant" within the meaning of the CAA, a coalition of states and environmental groups took to the courts to compel the agency to regulate the chemical. In 2007, a closely divided U.S. Supreme Court ruled that CO₉ meets the CAA's definition of pollutant, and ordered the EPA to determine, under the act's mobile source provisions, whether CO₂ emissions "endanger" public health or welfare. In 2009, the EPA made a formal finding that GHG emissions from motor vehicles pose an endangerment to public health and welfare by contributing to global warming, and the agency subsequently set tailpipe GHG emission standards for cars and light duty trucks. The endangerment finding also triggered a requirement that GHG emissions from major stationary facilities be subject to technology-based limits, and the EPA imposed a set of limits that began to take effect in 2011. These GHG regulations, which thus far have been largely upheld by the courts, extend to six substances, which are measured in carbon dioxide-equivalent (CO_{$_9$} e) units for regulatory purposes. As this book goes to press, however, the administration of President Donald Trump has indicated its intent to weaken or extinguish these regulations, and the issue is once again in the courts.

9.6.2.3 Surface waters and drinking water

The two most important federal statutes regulating water pollution are the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). The CWA regulates the discharge of pollutants into navigable surface waters (and into smaller waterways and wetlands that are hydrologically connected to navigable waters), and the SDWA regulates the level of contaminants in public drinking water.

9.6.2.3.1 THE CLEAN WATER ACT (1972, 1977, 1987)

The modern Clean Water Act has its origins in the Federal Water Pollution Control Act Amendments of 1972. The basic structure of the act was established at that time, although it was refined and refocused by the Clean Water Act Amendments of 1977 (from which it also took its name) and by the Water Quality Act Amendments of 1987. The regulatory focus of the CWA is the discharge of pollutants to surface waters from "point sources," principally industrial facilities and municipal sewage treatment plants (known under the act as publicly owned treatment works, or POTWs). The CWA flatly prohibits any discharge of a pollutant from a point source to surface waters unless it is done in conformance with the requirements of the act, and the statute has since 1972 retained as an explicit "national goal" the elimination of all point-source discharges to surface waters by 1985. Although this goal may never be attainable in practical terms, it has helped focus the act's implementation on gradual – but inexorable – pollution reduction, as discharge limits are made more stringent over time.

The centerpiece of this pollution reduction scheme is the National Pollutant Discharge Elimination System (NPDES) permit. In theory, all point sources must have an NPDES permit before discharging pollutants to surface waters. In practice, however, many dischargers (mostly smaller ones) still do not. The NPDES permit, which is issued after public notice and an opportunity for comment, is to incorporate all of the various requirements of the act – including discharge limits – that are applicable to the point source in question. Point sources are subject both to technology-based and water quality-based limits and to the more stringent of the two when they overlap.

In addition, the act created an oil and hazardous substance spill program that served as a model for the 1980 Superfund hazardous waste remediation statute. Under the CWA program, point sources (including vessels) that spill significant quantities of oil or other hazardous substances onto the surface waters may be held liable for the cost of cleanup and also be subjected to monetary penalties. This application of the polluter pays principle had perhaps its most famous use in compelling British Petroleum to finance a cleanup of the Gulf of Mexico after the 2010 Deepwater Horizon oil spill. In 1990, Congress added a complementary oil spill program under the separate (but related) Oil Pollution Act (OPA), which was enacted in response to the 1989 Exxon Valdez oil spill in Prince William Sound, Alaska. The OPA was intended to streamline federal oil spill response law so as to provide quick and efficient cleanup of oil spills, to compensate victims of such spills, and to internalize the costs of spills within the petroleum industry. The OPA imposes strict liability on parties responsible for the discharge of oil.

National technology-based effluent limitations The technology-based limits are established by the EPA as national standards. To set these standards for industrial dischargers, the EPA first divided industry into various industry categories and then established effluent limits for each category based on its assessment of what was technologically and economically feasible for the point sources within that category. Further, as required by the act, the EPA set different standards within each industrial category for conventional pollutants (biochemical oxygen demand, fecal coliform, oil and grease, pH, and total suspended solids), toxic pollutants (currently a list of 129 designated chemical compounds), and nonconventional pollutants (which simply are other pollutants, such as total phenols, which are listed under neither the conventional nor the toxic designation).

In recognition of the fact that conventional pollutants usually are amenable to treatment by the types of pollution control equipment that have long been in use at conventional sewage treatment facilities, the standards for conventional pollutants are set according to what can be obtained through the use of the Best Conventional Pollution Control Technology (BCT), taking into account the reasonableness of the cost. The standards for toxic and nonconventional pollutants, on the other hand, are set according to the EPA's determination of the level of pollution reduction that can be achieved through the application of the Best Available Technology Economically Achievable (BAT). (See Section 9.7 for a discussion the trade-off (or technology options) analysis framework that could be used as an alternative to BCT and BAT.)

Originally, Congress had directed the EPA to set health-based standards for toxic pollutants, on a pollutant-by-pollutant basis, but this resulted in only a handful of standards (mostly for pesticide chemicals). The political difficulty of establishing national healthbased standards for toxic chemicals led environmental groups, in a suit against the EPA to compel regulation, to agree to a schedule for setting technology-based standards for a list of 129 designated toxic pollutants. Congress formally endorsed this approach in 1977 by amending the act to require the EPA to set BAT standards for all of the toxic pollutants on that list.

Under the CWA, the EPA is to consider both control and process technology in setting BAT standards, which are to "result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants" and are to require "the elimination of discharges of all pollutants [where] such elimination is technologically and economically

544 National, regional, and international efforts

achievable." An individual discharger may obtain a cost waiver from BAT standards for nonconventional pollutants if it cannot afford to comply, but no cost waiver is available from the standards for toxic pollutants. For new industrial sources within an industry category, the EPA is to set standards based on Best Available Demonstrated Technology (BADT), which can be more stringent than BAT or BCT because of the greater technological flexibility inherent in the design and construction of a new facility. Although industry-wide costs are to be considered by the EPA in establishing BADT standards, no waivers are available to individual applicants once the standards are set.

The CWA also imposes technology-based standards on POTWs, based on the limitations that can be met through the application of secondary sewage treatment technology. In essence, this requires an 85 percent reduction in biochemical oxygen demand and total suspended solids. In addition, the act imposes limitations on discharges by industrial sources into POTWs. Such discharges are known under the act as indirect discharges (because the pollutants are not discharged directly to surface waters but rather are discharged indirectly to surface waters through a public sewer system). Limitations on indirect discharges are known under the act as pretreatment standards, because they have the effect of requiring the indirect discharger to treat its wastewater before discharging it to the POTW for further treatment. The EPA has set national technology-based limitations (known as the categorical pretreatment standards) on indirect discharges of toxic pollutants by firms in certain industrial categories. In addition, the act requires the POTW to set such additional pretreatment limits and requirements as is necessary both to ensure the integrity of the sewage treatment process and to prevent the indirectly discharged pollutants from passing through the sewer system and causing a violation of the POTW's discharge permit.

Ambient water quality standards and water quality-based effluent limitations For the first 15–20 years of the act's implementation, the primary focus was the establishment and implementation of the technology-based limits discussed above. More recently, however, considerably more attention has been given to the act's system of water quality-based limits, which is equally applicable to industrial sources and POTWs. Since 1972, the CWA has directed the states to establish, and periodically revise, ambient (in-stream) water quality standards for all of the lakes, rivers, streams, bays, and other waterways within their borders and has required the EPA to set and revise these standards to the extent that a state declines to do so. Further, the act has required since 1977 that NPDES permits include such additional discharge limits – beyond the national technology-based limits – as may be necessary to meet the ambient water quality standards of the waterway in question.

To help call attention to these water quality requirements, Congress in 1987 added what became known as the toxic hot spot provision of the CWA, which directed the EPA and the states to identify those waters that were in violation of ambient water quality standards because of toxic pollution, to identify those point sources whose discharges of toxic pollutants were contributing to those violations, and to develop an "individual control strategy" for that source (which almost always meant a revision of the source's NPDES permit to add or tighten limits on toxic pollutants). Another provision of the act that has prompted the addition or tightening of water quality-based discharge limits has been the requirement that the states (and, if they decline, the EPA) calculate a total maximum daily load (TMDL) for all waters that are in violation of ambient water quality standards. For any particular body of water, the TMDL for a particular pollutant is the total amount of that pollutant that may be discharged to the water body in a day without violating the relevant ambient water quality standard. When a TMDL is set, it often leads inexorably to a tightening of the NPDES permits of those point sources whose discharges are contributing to the particular violation of water quality standards. Although the TMDL requirement has been in the act since 1972, the states and the EPA were slow to implement it. Over the past twenty years or so, however, as a result of several successful suits by environmental groups seeking to compel the EPA to set TMDLs in the face of state inaction, the TMDL requirement has come considerably more to the fore. Consequently, the inclusion of water quality-based limits in NPDES permits has become more commonplace.

9.6.2.3.2 THE SAFE DRINKING WATER ACT (1974, 1986, 1996)

Although many sources of drinking water are regulated as surface waters under the CWA, the legislation specifically designed to protect the safety of the drinking water actually delivered to the public from public water systems is the Safe Drinking Water Act (SDWA). Passed in 1974 after a series of well-publicized stories about the number of potential carcinogens in the Mississippi River water used as drinking water by the City of New Orleans, it contains very little that is designed to address the sources of drinking water pollution. Instead, the SDWA directs the EPA to set national health-based goals – known as maximum contaminant level goals (MCL goals) – for various drinking water contaminants and to set MCLs that are as close to the MCL goals as is technologically and economically feasible. All public water systems, defined as those with at least fifteen service connections or that serve at least twenty-five people, are required to meet the MCLs.

Over the act's first eight years, the EPA set only twenty-three federal drinking water standards. Dissatisfied with the pace of implementation, Congress amended the act in 1986 to spur the agency into action. It directed the EPA to set standards (MCLs and MCL goals) for eighty-three specified contaminants within three years and to set standards for twenty-five additional contaminants every three years thereafter. Ten years later, with scores of MCLs and MCL goals now on the books, Congress scaled back. In a 1996 compromise endorsed by environmental groups and water suppliers alike, Congress eliminated the requirement for twenty-five new standards every three years. At the same time, it added provisions that effectively ensured both that the standards that had been set would largely be allowed to remain in place and that new standards would be far slower in coming (and likely would be relatively weaker because of the addition of a cost-benefit requirement).

Since then, the primary focus of the SDWA program has been bringing public water systems throughout the country into compliance with the existing standards. Although the MCLs are set at a level deemed to be technologically and economically feasible, many water systems have had difficulty affording the cost of meeting, and monitoring compliance with, the MCLs. To attempt to ameliorate the financial burden on municipal water systems, the SDWA has periodically made federal funds available for technology upgrades and infrastructure improvements. The task, however, remains a daunting one. In 2013, the EPA (2013) estimated that approximately \$384.2 billion would be needed over the next twenty years to upgrade the nation's 52,000 community water systems. These water systems serve just under 300 million people (ACSE 2017). Around one-fifth (17 percent) of these systems supply water to 92 percent of the total population, with the remaining population being served by small systems that face technical, managerial, and financial challenges and frequently violate the SWDA (ibid.).

9.6.2.4 The land and subsurface waters

Broadly speaking, the disposal of hazardous wastes on or into the ground, and thus directly or potentially into groundwater, is regulated by the interaction of two federal statutes. The primary federal law regulating the generation, handling, and disposal of hazardous wastes is officially known as the Solid Waste Disposal Act. In 1970, Congress amended that statute with the Resource Conservation and Recovery Act (RCRA), and the law has come to be popularly known by that name. In 1980, Congress added a separate

statute – popularly known as the federal Superfund law – to compel the remediation of sites that have become contaminated with hazardous waste. Together, these statutes have tended to make the generation of hazardous waste increasingly expensive.

9.6.2.4.1 THE RESOURCE CONSERVATION AND RECOVERY ACT (1976, 1984)

RCRA was given regulatory teeth in 1976 with a set of amendments under which the EPA, in 1980, promulgated regulations establishing a cradle-to-grave system for hazardous wastes that tracks the generation, transportation, and disposal of such wastes and establishes standards for their disposal. Initially, however, the EPA's disposal standards were minimal to nonexistent and did little to discourage the landfilling of chemical wastes. This led Congress, in 1984, to pass sweeping amendments to RCRA that (1) established a clear federal policy against the landfilling of hazardous wastes unless they have first been treated to reduce their toxicity, and (2) gave the EPA a specific timetable by which it had to either set treatment standards for various categories of waste or ban the landfilling of such waste altogether. Consequently, the EPA has set treatment standards – which are commonly known as the land disposal restrictions (LDRs) – for hundreds of types of hazardous wastes. These standards are based on the EPA's assessment of the Best Demonstrated Available Technology for treating the waste in question.

Thus, RCRA *directly* regulates the handling and disposal of hazardous wastes. And by establishing a set of requirements that must be followed once hazardous waste is generated, it also *indirectly* regulates the generation of hazardous wastes. RCRA regulations have increased the cost of disposing of most types of waste by two orders of magnitude over the past twenty-five years. In this sense, RCRA operates as a de facto tax on the generation of hazardous waste.

However, RCRA does not extend full regulatory coverage to all harmful industrial wastes. For example, a range of oil and gas exploration and production wastes are exempted from regulation as hazardous waste. This serves to exclude many wastes from hydraulic fracturing (commonly known as fracking) operations seeking to extract underground quantities of natural gas or oil. Such wastes are still subject to RCRA regulation under the less comprehensive provisions applicable to solid wastes, however. Moreover, the disposal of such wastes in subsurface storage wells – as well as the use of diesel in the fracking process – is subject to regulation under an underground injection control program administered by the EPA under the Safe Drinking Water Act.

9.6.2.4.2 THE COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION,

AND LIABILITY ACT (1980, 1986)

Another statute that acts as an indirect check on hazardous waste generation (and that provides additional incentive to ensure that one's waste is safely disposed) is the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as the federal Superfund law). The primary focus of this law is the remediation (cleanup) of hazardous waste contamination resulting from imprudent handling and disposal practices of the past and the recovery of remediation costs from those designated as "responsible parties" under the act. CERCLA imposes liability for the costs of remediating a hazardous waste site both on the owners and operators of the site and on those generators of hazardous waste that sent waste to the site.

Because the owners and operators are often business entities that are no longer financially viable, CERCLA liability often falls most heavily on the hazardous waste generators. CERCLA liability is also strict liability, meaning that the exercise of reasonable care by the generator is not a defense. Further, unless the generator can establish a convincing factual basis for distinguishing its waste from all or part of the contamination being remediated, CERCLA liability is joint and several, meaning that each responsible party is potentially liable for the full cost of remediation. As a practical matter, this means that the cost of remediation will be borne by those among the responsible parties who are financially solvent. The prudent business entity, then, has a strong financial incentive to take such actions as will minimize the likelihood that it will face CERCLA liability in the future. As the only certain way to avoid such liability is to refrain from generating the waste in the first instance, CERCLA does provide a rationale for pollution prevention. Further, it provides firms with an incentive to meet – or perhaps to go beyond – RCRA regulations in dealing with such wastes that they do generate.

This is not to say, of course, that substantial amounts of hazardous waste are no longer generated in the United States, that all hazardous wastes are adequately treated and safely disposed, or that all instances of hazardous waste contamination are being adequately addressed (or addressed at all). RCRA and CERCLA both contain what might reasonably be called loopholes and gaps in coverage, and hazardous waste contamination remains an ongoing issue. Further, the most common treatment methodology incorporated into the EPA's RCRA treatment standards is incineration, which has brought with it a release of airborne contaminants that is only partially addressed by regulation. There is no question, however, that the country has made considerable progress from the late 1970s, when disposal of chemical wastes in unlined landfills – at a cost of roughly \$15 per ton – was the common practice.

9.6.3 Chemical-based statutes

Other federal anti-pollution statutes have been directed at protecting humans and/or the environment from exposure to particular chemicals or to chemicals put to particular uses. We briefly discuss some of the major examples below.

9.6.3.1 The Emergency Planning and Community Right to Know Act (1986)

In 1986, two years after a deadly industrial chemical accident in Bhopal, India, Congress passed the Emergency Planning and Community Right to Know Act (EPCRA), a comprehensive federal community right-to-know program implemented by the states under guidelines promulgated by the EPA. The central feature of this federal program is broad public dissemination of information pertaining to the nature and identity of chemicals used at commercial facilities. In essence, the statute attempts to make far more transparent the use and release of potentially dangerous chemicals by industry, with a primary goal of creating community pressure for reducing the release of these chemicals into each of the media discussed above, and a secondary goal of providing communities with information that should assist them in minimizing harm should a chemical accident occur at a nearby facility.

The implementation of EPCRA began with the creation of state and local bodies to implement this community right-to-know program. The governor of each state was directed to appoint a "state emergency response commission" (SERC), to be staffed by "persons who have technical expertise in the emergency response field." In practice, these state commissions have tended to include representatives from the various environmental and public health and safety agencies in the state. Each state commission in turn was required to divide the state into various "local emergency planning districts" and to appoint a "local emergency planning committee" (LEPC) for each of these districts. These state and local entities are responsible for receiving, coordinating, maintaining, and providing access to the various types of information required to be disclosed under the act.

548 National, regional, and international efforts

EPCRA established four principal chemical reporting requirements. All facilities that manufacture, process, use, or store certain "extremely hazardous substances" in excess of certain quantities are to provide "emergency" notification to the SERC and the LEPC of an unexpected release of one of these substances. Facilities covered by the OSHA Hazard Communication Standard must prepare and submit to the LEPC and the local fire department material safety data sheets for chemicals covered by the OSHA standard. Many of these same firms are required to prepare and submit to the LEPC an "emergency and hazardous substance inventory form" that describes the amount and location of certain hazardous chemicals on their premises. Finally, firms in the manufacturing sector must provide to the EPA an annual reporting of certain routine releases of enumerated hazardous substances. These reports comprise what is known as the Toxics Release Inventory (TRI). In addition, certain commercial facilities are required to cooperate with their respective LEPCs in preparing emergency response plans for dealing with major accidents involving hazardous chemicals. The applicability of these provisions to any particular facility depends on the amount of the designated chemicals that it uses or stores during any given year.

These requirements constitute a broad federal declaration that firms choosing to rely heavily on hazardous chemicals in their production processes may not treat information regarding their use of those chemicals as their private domain. Indeed, except for trade secrecy protections that generally parallel those available under the OSHA Hazard Communication Standard, there are no statutory restrictions on the disclosure of EPCRA information to the general public. The act mandates that most of the information subject to EPCRA reporting requirements "be made available to the general public" upon request and requires each local emergency planning committee to publicize this fact in a local newspaper.

9.6.3.2 The Toxic Substances Control Act (1976, 2016)

9.6.3.2.1 THE FIRST FORTY YEARS

The Toxic Substances Control Act (TSCA), passed in 1976, was envisioned as an omnibus chemical law that would allow the EPA both to obtain information about new and existing chemicals and to regulate the production, use, and/or disposal of those chemicals that pose an "unreasonable risk of injury to health or the environment." The law extends to all "chemical substances" (and "mixtures" of chemical substances), which it defines broadly enough to include almost all substances except those that are explicitly exempted: pesticides, tobacco, radioactive materials, alcohol, foodstuffs, cosmetics, and pharmaceuticals (all of which are regulated under separate authorities). Given the breadth of TSCA's mandate, the EPA has used the statute as a means of regulating bioengineered substances and nanotechnology, as well as more "traditional" chemical substances.

TSCA authorizes the EPA to order the manufacturer to conduct health and safety testing of new or existing chemicals under certain prescribed circumstances and to report the results of such testing to the agency. The act also authorizes the EPA to require industry to provide data on the production, use, and health and environmental effects of chemicals. TSCA contains a pre-market notification – but not pre-market screening – process for new chemicals and for existing chemicals put to a significant new use. Manufacturers of such chemicals must file a premarket notification (PMN) with EPA. Clearance of a chemical for commercial use proceeds automatically if the EPA does not take regulatory action to limit production, use, or exposure within 90 days (or 180 days if the EPA chooses to extend the period) or to require more information before introduction of the chemical into commerce. The EPA may also order a specific change in chemical process technology. In addition, TSCA gives aggrieved parties, including consumers and workers, specific rights to sue to enforce the act, and to petition the EPA for regulatory action.

The EPA's authority to regulate chemicals under the 1976 act was theoretically broad – including the power to impose a ban on production and use – but was dependent on the EPA's first determining that the chemical "presents or will present" an unreasonable risk. Although "unreasonable risk" was undefined in the statute, TSCA did specify that the EPA "shall consider the environmental, economic, and social impact of any action" taken under the statute, which suggested an obligation to evaluate the costs and benefits of a proposed regulation. Congress also made what was essentially a statutory finding that polychlorinated biphenyls (PCBs) pose an unreasonable risk, as TSCA specifically directed the EPA to regulate, and phase out, PCBs. Of the EPA's twenty-two regulatory actions under TSCA directed at existing chemicals between 1977 and 1990, fifteen addressed PCBs.

Moreover, the potentially powerful role of TSCA regulation was dealt a serious blow in 1991, when the U.S. Court of Appeals for the Fifth Circuit overturned an asbestos phaseout rule issued by the EPA under TSCA. Citing language in TSCA that required the EPA to use "the least burdensome requirements" necessary to protect against unreasonable risks, the court held that the EPA erred in issuing a ban on asbestos without having first considered the costs and benefits of each regulatory alternative that would have been less burdensome to industry.^{*} This arguably would require the agency to perform a comprehensive, detailed, and resource-intensive alternatives analysis prior to regulating chemicals under TSCA, something which the plain text of TSCA did not require. As noted by Harvard's Cass Sunstein (2017, p. 19), who is in general a strong advocate of using costbenefit analysis in deciding whether and to what extent to regulate chemicals,

it is not at all obvious that the court was right. An agency's obligation to use the least burdensome alternative does not, by itself, require a quantitative analysis of the costs and benefits of that alternative, even under a statute that requires cost–benefit analysis of the ultimate policy choice.

Nonetheless, the EPA viewed this case (which was not appealed to the U.S. Supreme Court) as a prohibitive obstacle to future TSCA regulations, and the agency generally thereafter regarded standard-setting for chemicals other than PCBs to be a nearly impossible task.

While some may not agree, a more determined EPA might have avoided this result. The EPA's reluctance to go back to the Fifth Circuit with an extensive analysis of the costs and benefits of each alternative to an asbestos ban is understandable in terms of the agency resources needed to do so. But allowing twenty-five years to pass without a single attempt at challenging the Fifth Circuit's rationale in another circuit court – in another case, involving another chemical – is not. Indeed, the Fifth Circuit itself stressed that TSCA did not require "an exhaustive, full-scale cost–benefit analysis," which arguably left the door open for a favorable review of new TSCA regulation even in that court.

TSCA's testing authority was also compromised by the EPA's reluctance to establish testing rules, and its tendency to instead negotiate testing agreements with industry which avoided statutory deadlines. To date only five chemicals have been banned under TSCA (Ashford 2017) and 600 await the completion of risk evaluations (Erickson 2017).

Indeed, perhaps the most significant regulatory advance under TSCA during this period came at the specific direction of Congress. Although the EPA had declared formaldehyde a probable carcinogen and the International Agency for Research on Cancer classified it as a confirmed human carcinogen, the EPA initially chose not to address the substance

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

550 National, regional, and international efforts

under TSCA, opting instead to defer to OSHA workplace regulations. However, Congress ultimately intervened in 2010, probably influenced by the government's reluctance to house Hurricane Katrina refugees in trailers containing formaldehyde particle-board, and added a new Title VI to TSCA establishing national limits for formaldehyde emissions from composite wood products, mirroring standards previously established by the California Air Resources Board for products sold, used, or manufactured for sale in California.

9.6.3.2.2 THE 2016 AMENDMENTS

A more ambitious congressional "fix" of TSCA came in 2016 (the fortieth anniversary of the original act), when the chemical industry teamed with a portion of the environmental community to persuade a bipartisan congressional majority to make sweeping changes to the core of the act. The revised TSCA makes a clear demarcation between risk assessment and risk management – prohibiting the consideration of costs and benefits at the risk assessment stage but requiring consideration of those factors during the risk management stage – and also seeks to focus the EPA's attention on the most serious risks. The EPA is directed to establish "a risk-based screening process, including criteria for designating chemical substances as high-priority substances for [subsequent] risk evaluations or low-priority substances for which risk evaluations are not warranted at the time." The amended statute defines as "high-priority" chemicals those that the EPA

concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant.

The agency is then required, according to a specified timeframe, to perform a risk evaluation for each chemical designated as a high-priority substance, to determine whether the chemical actually poses an unreasonable risk.

As before, "unreasonable risk" is not defined. Rather, the EPA is directed to determine whether, "under the conditions of use," the chemical substance "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." In eschewing consideration of "nonrisk factors," the amendments essentially transform the "unreasonable risk" determination into a "significant," "substantial," or "serious" risk determination. While this allows the agency to focus on the degree of potential harm, it may also mask the opportunity to strengthen the market for safer chemicals. For example, if a chemical is found to pose a moderate risk, the EPA might decide to declare a "reasonable" risk based solely on the chemical's projected level of harm. However, if the agency took into account the wide availability of a safer substitute chemical, the chemical under review might very well be deemed to pose an unreasonable risk (because the risk could be reduced by substituting the safer chemical). For this reason, it is hoped that the EPA does not characterize the availability of substitutes as a "nonrisk factor."

Moreover, in limiting the determination to whether the chemical "presents" an unreasonable risk and removing the original statutory requirement that the EPA also regulate chemicals that "will present" an unreasonable risk, the amended statute arguably restricts the EPA's ability – and obligation – to be proactive and to look beyond current uses of a chemical. This concern may be offset by the revised statute's directive to the EPA to consider "the circumstances [...] under which [...] a chemical [...] is [...] reasonably foreseen to be [...] used." As this book goes to press, however, the Trump administration has indicated that the EPA's review will not even consider all *current* uses of a chemical. Finally, if the agency reads its mandate to conduct a risk evaluation as requiring a full, formal, science-based risk *assessment* before a chemical can be deemed to pose an unreasonable risk, it may limit its unreasonable risk findings to chemicals for which full testing has already been done, meaning that fewer chemicals are likely to cross the threshold for mandatory risk reduction. The lack of explicit reference to the precautionary principle in the revised statute may also encourage the agency to insist on stringent criteria for determining unreasonable risk. This concern could be moderated if the EPA makes use of its authority to issue testing rules (with incorporated timelines) for high-priority chemicals, but this depends on the willingness of the agency to take this step.

If the EPA makes the determination that a chemical does present an unreasonable risk, the agency is required to regulate that chemical, according to a specified timeframe, "to the extent necessary so that [sic] the chemical substance or mixture no longer presents such risk." The afore-mentioned requirement that the EPA select "the least burdensome requirements" to accomplish that goal has been deleted. However, the EPA is required to consider, "to the extent practicable," (1) the benefits of the substance, (2) reasonably ascertainable economic consequences of the rule, (3) the costs, benefits, and costeffectiveness of the proposed action as weighed against at least one regulatory alternative, and (4) in the case of a ban or phase-out, whether "technical or economically feasible alternatives" will be available as a substitute. While these considerations do not override the primary requirement to eliminate the unreasonable risk (defined without respect to costs and nonrisk factors), they do add time-consuming complexity to the EPA's analysis, thus raising the specter of the regulatory inertia that has plagued TSCA in the past. Further, simply shifting economic concerns to the risk management stage does nothing to address the practical reality that economic considerations will often trump public health and environmental protection.

Chemicals subject to the PMN process – new chemicals or existing chemicals put to a significant new use – are targeted for an expedited review process. The EPA is required to review such chemicals as part of the PMN process and determine whether they pose an unreasonable risk. If the agency determines that such a chemical (1) presents an unreasonable risk, (2) may present an unreasonable risk, or (3) will be produced in large amounts and will result in large releases or exposures, or if the agency determines that it lacks sufficient information to make a reasoned evaluation as to the extent of the chemical's risk, the EPA must impose restrictions to the extent necessary to protect against any such risk. This gives the agency a stronger obligation to regulate (and/or require testing of) new chemicals, but a timid or business-friendly EPA could avoid this obligation simply by concluding that there is no unreasonable risk to reduce.

In summary, it is unclear whether the 2016 TSCA will advance the protection of consumers, workers, or the general public. Ashford (2016) warned that serious flaws existed in the proposed reforms, and these flaws largely persist in the version ultimately passed by Congress (Ashford 2017). In addition, the revised TSCA preempts more stringent state regulation of chemicals, which threatens to weaken protection in some states (Polsky 2016).

It is certainly conceivable that an administration dedicated to implementing environmental laws and willing to exercise its discretion towards the protection of public health could use the revised act to make some real progress on chemical safety. For example, if the EPA were to aggressively promote safer substitutes for chemicals found to pose an unreasonable risk, a greater number and variety of environmentally superior chemicals might emerge. Further, TSCA and the OSH Act, used together, could still provide potentially comprehensive and effective information-generation and standard-setting authority to protect workers. In particular, the information-generation activities under TSCA could provide the necessary data to have a substance qualify as a "recognized hazard" under the OSH Act that, even in the absence of specific OSHA standards, must be controlled in some way by the employer to meet the general duty obligation under the OSH Act's requirement that the employer provide a safe and healthful workplace.

9.6.3.3 Chemicals in pesticides, food additives, pharmaceuticals, and consumer products

It has long been recognized that pesticides – which are valued precisely *because* they can kill certain species of animals or plants – pose a potential risk to human health and the environment. Similarly, food additives and pharmaceuticals (therapeutic drugs) have long been of public health interest because they are directly ingested by humans. Federal statutes addressing all three date far back into the twentieth century, and have gradually evolved to a similar approach: the pre-market screening of new products, with the burden of establishing the requisite margin of safety placed on the manufacturer.

Pesticides: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which has been substantially amended a number of times, most recently in 1988, began as a law designed to ensure the efficacy of pesticide products. As concern over the environmental effects of pesticides grew – spurred by Rachel Carson's influential book *Silent Spring* (1962; see Chapter 2) – Congress moved to recraft the statute as a means of protection from, as well as promotion of, pesticides. FIFRA regulates the production and use of pesticides, requires manufacturers to meet certain standards for safety and efficacy before marketing new pesticides, and allows the EPA to remove existing pesticides from the market under certain circumstances. Throughout, the burden is on the manufacturer or commercial supplier to establish that the pesticide does not generally cause "any unreasonable risk to [humans] or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide." The EPA's often relaxed administration of FIFRA has been widely criticized by environmental and public health groups, and the act contains several provisions that allow unsafe pesticides to remain in use. Pesticide manufacturers, on the other hand, complain that the tests that the EPA requires them to conduct before they are allowed to broadly market new products can cost in excess of \$20 million per pesticide. From a long-term societal perspective, however, the most telling criticism of FIFRA may be that - at least as presently administered - it does little to promote a transition to a more sustainable form of agriculture. The act's risk-benefit approach would appear to provide an *opportunity* for such promotion, as the relative benefit of a dangerous chemical pesticide diminishes when safer substitutes, such as integrated pest management approaches, are available to farmers. Thus far, however, the EPA has not used FIFRA in this manner.

Feed additives and drugs: Food additives (e.g., chemicals added to foods as preservatives, stabilizers, or to enhance flavor) and pharmaceuticals are both regulated by the Food, Drug, and Cosmetic Act (FDCA), which is administered by the Food and Drug Administration (FDA). Like FIFRA, the FDCA incorporates a pre-market screening process for new products. The system for pharmaceuticals, like FIFRA's for pesticides, employs a risk-benefit approach and requires manufacturers to compile data on both safety and efficacy. In general, then, new drugs are allowed onto the market if their value to the people who will take them is adjudged to be greater than the risk to those persons (and to the population as a whole). The FDCA's regulation of food additives, however, is based on safety alone. The manufacturer of a new food additive is required to bring forth data demonstrating that the additive is "safe" under its conditions of use, which has generally been interpreted as requiring a showing of a "reasonable certainty" of no harm. Further, the act specifically provides that no additive can been deemed "safe" if it has been shown to cause cancer in humans or animals. This latter provision, placed into the law in 1958, was an early - if somewhat modest – application of the precautionary principle. Sweeping aside arguments that certain cancers have a nonzero safety threshold, that cancer causation in an animal test may not presage cancer causation in humans, or that cancer causation through a different route of exposure may not indicate cancer causation through human ingestion, Congress declared a strong preference for being risk averse in the face of uncertain data. Despite this safety-based approach, however, the FDCA has allowed food additives on the market, such as aspartame, whose long-term effects, especially over a large population of consumers, are controversial. Indeed, many have criticized the FDCA's approach to food additives precisely because it is based on safety alone, with no requirement to demonstrate either that the additive does what it is purported to do or that its purported function is something that is *needed*. If the manufacturer were required both to demonstrate the benefit of the additive and to show that this benefit outweighs the potential risks, the law might actually do more to promote safe and healthful foods.

Consumer products: Toxic materials in consumer products in general are regulated by the Consumer Products Safety Act (CPSA) and the Federal Hazardous Substances Act. The CPSA was enacted with considerable fanfare in 1972, with the common expectation that it would do for consumer protection what the various environmental protection statutes were doing for human health and the environment. The reality has been far different. The act created the Consumer Products Safety Commission (CPSC) and charged it with a broad mandate to ensure the safety of consumer products, but the impact of the CPSC has been far less pronounced than that of the EPA, OSHA, or the FDA.

Like the program for pesticides and pharmaceuticals, the CPSA relies on risk-benefit (or risk-utility) analysis to trigger regulation. If the CPSC finds that a product poses "an unreasonable risk of injury" – that is, if the risk of a consumer product outweighs its utility – the commission is empowered to issue a consumer product safety standard either imposing conditions for the product's safe use or, if no such conditions can be found, banning the product. Unlike the provisions for pesticides and pharmaceuticals, however, the CPSA does not require pre-market screening. Perhaps because this same risk-utility standard is already employed in the common law tort system for products liability that has long been the primary driver of product safety in the U.S., and certainly because CPSC has never found a champion among the many presidential administrations it has served, the CPSA has been far more useful as a generator of information on consumer product safety than as a regulator of consumer products.

This has been especially true with regard to products that pose potential toxic chemical hazards. While the courts have made clear that a small individual risk of a great harm (such as cancer) can be an "unreasonable" risk, they have also emphasized that the burden is on the CPSC to establish that risk with substantial evidence. This was made clear to the CPSC in the early 1980s, after it issued a standard banning the use of urea-formaldehyde foam insulation in new construction. The CPSC took this action after an industry-funded research lab conducted a long-term study indicating that formaldehyde causes cancer in rats (the test animals used in the study). The International Agency for Research on Cancer subsequently confirmed that the study was performed in accordance with accepted protocols, and issued its own finding that formaldehyde is a probable human carcinogen. Nonetheless, the Fifth Circuit Court of Appeals struck down the CPSC's formaldehyde standard, ruling that reliance on a single study was not "good science." The court also cited a provision in the CPSA stating that the CPSC must use the Federal Hazardous Substances Act (FHSA) unless it can make a showing that regulation under that statute would be inadequate. The federal government – then administered by the popular and avowedly anti-regulatory President Ronald Reagan - chose not to appeal that decision, and thereafter the CPSC generally confined its regulation of toxic chemical hazards to the FHSA, which operates largely through mandated product labeling and warnings (but not safety standards).

The 2006 amendments to the CPSA, however, signaled something of a change of course. The amendments repealed the direct statutory preference for the use of the FHSA for toxic products and sought to bring renewed attention to the use of the CPSA to address

554 National, regional, and international efforts

those hazards. Also, by directing the CPSC to take specific actions with regard to products containing lead and certain phthalates, Congress both spurred the commission to action with regard to those products and made it easier for its regulation of those products to withstand court challenge. As with TSCA and its mandate to regulate PCBs, a specific congressional mandate to take particular actions with regard to particular hazards is perhaps the most reliable way to prompt agency action. It remains to be seen if the CPSC will build upon this mandate to promulgate regulations that more broadly encourage the substitution of known and suspected toxicants in consumer products with safer substitutes.

9.6.4 Laws integrating pollution reduction into federal decision-making

Recognizing that the policies and programs of the federal government often set the tone both for private industries and for state governments, and that the activities of the federal government can themselves have profound effects on environment and human health, Congress has endeavored, with varying degrees of success, to orient government programs toward measures that will reduce, rather than increase, pollution. We address the three most important of these below.

9.6.4.1 The National Environmental Policy Act (1969) and the Endangered Species Act (1973)

The first of such statutes, and the first of the major modern environmental initiatives passed by Congress, was the National Environmental Policy Act (NEPA), which was joined four years later by a revitalized Endangered Species Act (ESA). Although both have had significant implications for private industry, each has as its primary focus the policies and programs of the federal government, and each seeks to instill federal agencies and instrumentalities with an appreciation for environmental amenities.

The National Environmental Policy Act acknowledges "the critical importance of restoring and maintaining environmental quality to the overall welfare and development" of society and imposes on federal agencies a general obligation to develop and operate their programs so as to attain a number of broadly phrased goals, including fulfillment of "the responsibilities of each generation as trustee of the environment for future generations." NEPA also declares it an overall national policy "to create and maintain conditions under which [humans] and nature can live in productive harmony." Arguably, this presupposes a gradual evolution toward a more sustainable economy, when trade-offs between human advancement and the environment will be far less necessary.

While these declarations of policy are of strong thematic importance, their implementation is both difficult to measure and difficult to enforce. To help with these issues, NEPA created the federal Council on Environmental Quality (CEQ), which is charged with advising the president on matters of the environment and gathering and publishing data on the quality of the environment. Annual CEQ reports received considerable attention during the 1970s, but with the increasing importance of the EPA and the burgeoning public and private sources of information on the environment, CEQ's influence has waned over the years. And, not surprisingly, the relevance and importance of NEPA's goals and principles to overall federal policy has tended to wax and wane with the respective viewpoints of the various presidential administrations.

One aspect of NEPA that has retained considerable vitality and influence though the years, however, is the requirement that federal agencies and instrumentalities conduct an environmental review before embarking on programs or projects likely to have an environmental impact, and that they prepare a formal, detailed environmental impact statement (EIS) before undertaking a major federal project that is likely to have a

significant impact on the environment. Except where exempted by other statutes, this requirement applies broadly to prospective federal regulations and projects, including private projects that require a federal license to proceed. As a practical matter, this often means that the EIS, when required, is prepared by private consultants hired by the private party seeking the federal license. While the Supreme Court has held that NEPA imposes no substantive obligation to take any particular action in response to the findings of an EIS, the court has also made clear that the requirement to perform a meaningful EIS must be followed, and that the EIS must consider a reasonable array of alternatives to the proposed federal action if they would reduce the overall environmental impact. Thus, the EIS process – while by no means a guarantee of an environmentally protective outcome – provides an opportunity for those favoring interests to make their case known to the government.

One of the reviews typically conducted during a NEPA environmental evaluation is a consideration of how the contemplated project may affect imperiled animal or plant species. This is driven by the Endangered Species Act, which requires federal agencies and instrumentalities to consult with the National Marine Fisheries Service (NMFS) and/ or the U.S. Fish and Wildlife Service (USFWS) to determine whether the contemplated action is "likely to jeopardize the continued existence of any threatened or endangered species," and to take action to protect those species.

The ESA declares that the natural diversity of animal and plant species is "of aesthetic, ecological, educational, historical, recreational, and scientific value to the Nation and its people," and establishes as "the policy of Congress" that "all federal departments and agencies seek to preserve" that diversity. To this end, the ESA charges NMFS and USFWS (commonly collectively referenced as "the Services") with the duty to "list" (as "threatened" or "endangered") animal and plant species that face potential extinction. The ESA imposes a duty on all federal agencies and instrumentalities to refrain from harming these species, and potential harm to these species triggers consultation with the Services. Moreover, the act prohibits *all* persons, including industrial actors, from committing a "take" of a member of an endangered species (e.g., by causing "harm"), and this prohibition is often extended to threatened species as well. There are provisions in the act that allow "incidental takes" to occur – such as where harm to a species is "incidental" to the operation of a factory – such authority commonly is conditioned on the taking of certain actions to protect and preserve the species in question.

The Services' determination of what is, and what is not, "jeopardy" is often controversial (sometimes on both sides of the issue), but there is no doubt that the ESA provides a layer of environmental protection beyond that provided by NEPA and the various mediabased statutes. And the reach of the ESA clearly extends to pollution-caused harm that may be enabled by federal decision-making. When various species of Pacific Salmon were listed under the ESA, for example, Clean Water Act ambient water quality criteria were scrutinized to determine whether the permissible pollutant concentrations posed harm to salmonid species.

9.6.4.2 The Pollution Prevention Act (1990)

The Pollution Prevention Act (PPA) endeavors to imbue the EPA and other federal agencies with a preference for pollution prevention and inherent safety and directs them to encourage both. The PPA declares it the "national policy" that pollution be addressed in a hierarchical fashion. First, "pollution should be prevented or reduced at the source whenever feasible." Second, "pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible." Third, "disposal or other release into the environment should be employed only as a last resort." The PPA uses the rubric of "source reduction," which it defines as

any practice that (1) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and (2) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants.

Explicitly included within the statutory definition are "equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control," while explicitly *excluded* is any practice that

alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to and necessary for the production of a product or the providing of a service.

Thus, pollution prevention and primary accident prevention both come within the PPA's definition of "source reduction." On the other hand, recycling or reuse does not meet this definition unless it is done as part of a closed-loop production process (as is often done within the metal finishing industry, when metals are recovered at the end of the process and immediately returned to the beginning of the process).

Like NEPA, the PPA relies on mostly "soft" directives that rely on the willingness of the federal government to take them seriously and are more difficult to enforce through the courts. The act directs the EPA to evaluate its existing and proposed regulations to ensure their consistency with source reduction, to coordinate among its various offices and with other agencies to research and promote source reduction, and to establish a separate office to carry out these policies. The EPA did establish an Office of Pollution Prevention, but the tremendous potential of the PPA has yet to be realized. The EPA's overall commitment to implementing the PPA has waned considerably since the early 1990s, as no presidential administration has wholeheartedly embraced the potential opportunities for fundamental change that the PPA represents. And now, and as this book goes to press, President Trump has announced plans to eliminate the Office of Pollution Prevention altogether.

Nonetheless, many industrial firms have found it in their economic interest to adopt pollution-prevention approaches because they can eliminate the need for waste handling, disposal, and treatment and can reduce pollution-control and abatement costs. However, these incentives are often absent with regard to the prevention of chemical accidents; because these events are both rare and not statistically predictable, the potential for rational behavioral changes premised on cost avoidance is much smaller.

Finally, the PPA amended EPCRA to require firms subject to TRI reporting to also report their "source reduction" (pollution prevention) and waste management practices on an annual basis.

9.7 Deciding the extent of intervention

9.7.1 Trade-off analysis distinguished from cost-benefit analysis

Those decision-makers who are influenced by neoclassical economics often rely on the use of cost–benefit analysis (CBA) as a decision outcome algorithm or rationale to decide whether and to what extent to exercise control over environmental, health, and safety

hazards (Ashford and Caldart 2008, Chapter 3). The problems with cost-benefit analysis are widely acknowledged and include:

- 1 The difficulty of monetizing health, safety, and environmental benefits based on inherently uncertain risk assessment and epidemiological data and on monetary values that are not well-established or agreed-upon (e.g., what is a human life or case of disease prevented worth?)
- 2 Using a discount rate to address far-future benefits (and deciding what rate to use);
- 3 Using costs of compliance generated by the regulated industry;
- 4 Failure to take learning and economies of scale into account (which tends to inflate costs);
- 5 Failure to take technological innovation (which changes, and can often reduce, costs) into account; and
- 6 Failure to delineate and distinguish who benefits and who bears the costs of a proposed regulation, i.e., failure to take distributional effects into account.

In contrast, trade-off analysis requires decision-makers to explore the trade-offs that are often obscured in tools such as cost–benefit analysis. Instead of aggregating a wide range of heterogeneous factors into a single monetary value, trade-off analysis keeps each factor in its natural units. The trade-off analysis approach can be characterized by a series of six steps outlined below (Ashford 1978, 2007; Hall et al. 2008).

- **Step 1 Define the problem**: Describe the societal or technical problem in need of attention (for example, unmet needs or technical/institutional failure). Describe why the problem arose. Clarify the problem type (see Table 9.1) and describe why an intervention is required. Identify the key stakeholders.
- **Step 2 Describe previous efforts to address the problem**: Describe any prior attempts to resolve/improve the problem, and discuss their inadequacy/failures in terms of:
 - Economics and markets
 - inadequate and/or perverse incentives, prices, markets, institutional/organizational structure and behavior, free-rider problems, and unrecognized/ unmet needs and demands
 - Legislation and political process
 - inadequacy of existing legislation/regulations, lack of knowledge/enforcement thereof, and inadequate stakeholder involvement
 - Public/private sector management
 - lack of adequate incentives or perverse incentives for, or commitment to, management of the problem
 - Technical system capabilities
 - inadequacy of existing technology to address the problem or a lack of any suitable technological solution
- **Step 3 Identify instruments to promote change**: Identify the tools, models, techniques, and approaches that could affect the willingness, opportunity/motivation, and capacity of the stakeholders (that is, industry, consumers, workers, citizens, government at all levels) to change (see Section 7.6 in Chapter 7).

Willingness

- towards change in general (rigidity)
- influenced by an understanding of the problem
- influenced by knowledge of options or solutions
- influenced by the ability to evaluate alternative courses of action

Opportunity/motivation

- presented by gaps in technological/scientific capacity
- possibility of economic cost savings or new/expanded market potential (competitiveness)
- consumer/worker/societal demands
- regulatory/legal requirements

Capacity

- influenced by an understanding of the problem
- influenced by knowledge of options or solutions
- influenced by the ability to evaluate alternative courses of action
- resident/available skills and capabilities
- **Step 4 Develop alternatives**: Make a creative effort to formulate several alternative futures to address the problem, paying special attention to distributional inequalities. The alternatives should be developed in consultation with the stakeholder groups.^{*} Formulate specific strategies (economic, legal, institutional, firm-based, societal-based, etc.) for each alternative to affect the willingness, opportunity/motivation, and capacity for change. If technology is an important part of the problem, consider ways to address the problem through technological advancement. The alternatives should consider the following:
 - Economics and markets
 - changes in prices, markets, and industry structure
 - changes in demand
 - Legislation and the political process
 - changes in law and political process (legislation, regulation, negotiation, and stakeholder participation)
 - Public/private sector management
 - system changes related to organizational/institutional structure
 - · changes in public and private sector activity
 - The technical system
 - technological/scientific changes (options for R&D, innovation, and diffusion)

^{*} A complementary step here is not only to consult with stakeholders to identify future positions/states of the world that represent solutions to the current problem, but also to use a participatory backcasting approach (see Section 8.4 in Chapter 8) and work backwards from these positions/states to identify a series of policies/choices to achieve this future. Adopting a participatory backcasting approach is recommended if a decision-maker/agency/community is confident of the desirability of future positions or states that are to be achieved (the targets of backcasting). However, if a single desired future is difficult to choose, a portfolio approach may be better since a variety of alternative futures can be investigated.

Problem types	Examples
Informational: Problems relating to contradictory or uncertain scientific and technological information	Breast implants; missile defense systems
Technology : Problems relating to the adverse effects of technology on humans and the environment	Climate change; toxic chemicals
Technology development : Problems relating to the creation of technology in a socially beneficial way/direction	Genetically engineered crops
Undeveloped technology : Problems relating to the lack of technology available to meet unmet human needs	Rapid rail/transport systems; new cancer therapies
Accountability: Responsibility of scientists and engineers in industry and government	Challenger (space shuttle) accident; FDA clearance of questionable pharmaceuticals
Distributional : Uneven distributions of the benefits and costs of a technology or policy	Access to health care technology

Table 9.1 Examples of problem types that can be addressed using trade-off analysis

- **Step 5 Analyze alternatives:** Use the trade-off matrix (represented in its generic form in Table 9.2) to qualitatively and quantitatively assess (in a *comparative* manner) the likely outcomes from each alternative against a "do nothing" scenario. Evaluate the likelihood that an alternative will solve the problem under different future scenarios.* Particular attention should be paid to whether distributional inequalities are adequately addressed.
- **Step 6 Overcoming Barriers to Change**:[†] Identify potential barriers (economic, legal, institutional, firm-based, technology-based, societal-based, value-based,[‡] etc.) to change and identify strategies to overcome them, recognizing that political coalition-building is likely to play an important role.

Step 1 of trade-off analysis is to describe the societal or technical problem in need of attention. To provide a context to the problem, it is often helpful to document a brief history of why the problem arose and why specific action needs to be taken. Many sociotechnical problems form/develop over time until they reach a point where action becomes necessary. It is also useful to characterize the type problem since this can inform the development of alternatives – for example, is the problem relating to a lack of information or undeveloped/missing technology (see Table 9.1)? Finally, the primary stakeholders impacted by the problem should be identified.

Step 2 should be undertaken in parallel with Step 1. In this step, any prior attempts to address the problem should be identified and documented. To ensure the problem is

- † Step 6 is to be undertaken by the politician/decision-maker and not the analyst. The role of the analyst is to develop and present (in Steps 1 through 5) objective information and to avoid promoting one alternative over another.
- ‡ Value-based conflicts may be characterized as: (1) conflicts arising from differences in legitimate interests of different actors/institutions; (2) conflicts in moral and legal duties of each actor/institution; and (3) conflicts among actors/institutions arising from different perceptions of what is right or wrong, fair, or unfair (Ashford 1994, p. 1427).

^{*} Since the future is uncertain, creating several scenarios against which a policy alternative can be assessed is likely to provide an indication of the robustness of the alternative.

Group	Effects		
	Monetary/financial	Health/safety	Environmental
Group/region A Group/region B Group/region C 	$\begin{array}{c} C_{\$}, B_{\$} \\ C_{\$}, B_{\$} \\ C_{\$}, B_{\$} \\ \cdots \end{array}$	$\begin{array}{c} C_{\rm H/S}, B_{\rm H/S} \\ C_{\rm H/S}, B_{\rm H/S} \\ C_{\rm H/S}, B_{\rm H/S} \\ \cdots \end{array}$	$\begin{array}{c} C_{\text{Env}}, B_{\text{Env}}\\ C_{\text{Env}}, B_{\text{Env}}\\ C_{\text{Env}}, B_{\text{Env}}\\ \end{array}$

Table 9.2 Generic matrix of policy consequences for different groups/regions

considered from multiple perspectives, the analyst should be guided by four broad lenses of inquiry. Each lens focuses on a particular system - that is, economics and markets, legislation and the political process, public/private sector management, and the technical system. For example, if we consider the poor fuel efficiency of the U.S. vehicle fleet, it is possible to characterize the problem as (1) a failure to price fuel correctly, (2) a failure to develop sufficiently stringent corporate average fuel economy (CAFE) standards, (3) a failure of the private sector to invest sufficient R&D funds into the development of more fuel efficient vehicles/technology, and (4) a lack of readily available technology – such as a hydrogen fuel cell or electric vehicle – to address the problem. In reality, many sociotechnical problems, such as the one described, will be the result of a combination of economic, political, management, and technology failures. If an analyst were to use only an economic lens to view the problem, the alternatives/solutions created might address economic concerns to the exclusion of others. The root cause(s) of the problem may continue to persist in the other systems that were not considered. Thus, adopting an approach that seeks to uncover the full complexion of a problem – rather than focusing only on those aspects of a problem that relate to one's area of responsibility/expertise – is essential if society is to make progress on problems relating to sustainable development, which often pervade disciplinary boundaries. In this regard, sins of omission are just as important as sins of commission that occur when an alternative is influenced/captured by special interests.

Once any previous attempts to address the problem have been identified, Step 3 considers ways to affect the willingness, opportunity/motivation, and capacity of the stakeholders associated with the problem to change (see Section 7.6 in Chapter 7, for a detailed discussion of these factors). While many stakeholders might have the willingness to act, they may not have the opportunity or capacity to do so. Therefore, developing creative ways to support these elements of change is a valuable starting point from which to create alternatives (Step 4) for addressing the problem.

When developing the alternatives in Step 4, it is important to return to the four system lenses (introduced in Step 2) to ensure that all the dimensions of the problem are addressed. The task of developing the alternatives should be considered as a creative process, which draws upon the rich information and knowledge developed in Steps 2 to 4.

Step 5 of trade-off analysis is to analyze the alternatives using a trade-off matrix (represented previously in its generic form in Table 9.2). An important task when creating the matrix is to determine which indicators to use to evaluate each alternative. Ideally, these indicators should be developed in cooperation with stakeholders and should provide clear information on the state of the system over time. To make the analysis manageable, it is recommended that a small number of important environmental, health/safety, and monetary/financial indicators are used. The indicators can be of a quantitative or qualitative form.

The structure of the trade-off matrix keeps the environmental, health/safety, and monetary/financial impacts in their natural units for each stakeholder group. By keeping

Group	Effects at time $T_1 / T_2 / \dots$			
	Monetary/financial	Health/safety	Environmental	
Group/region A Group/region B Group/region C	$\begin{array}{c} \Delta C_{s}, \Delta B_{s} \\ \Delta C_{s}, \Delta B_{s} \\ \Delta C_{s}, \Delta B_{s} \end{array}$	$\begin{array}{c} \Delta C_{H/S^{\prime}} \; \Delta B_{H/S} \\ \Delta C_{H/S^{\prime}} \; \Delta B_{H/S} \\ \Delta C_{H/S^{\prime}} \; \Delta B_{H/S} \end{array}$	$\begin{array}{c} \Delta C_{Env}, \Delta B_{Env} \\ \Delta C_{Env}, \Delta B_{Env} \\ \Delta C_{Env}, \Delta B_{Env} \end{array}$	
• • •			• • •	

Table 9.3 Using the trade-off matrix for a comparative analysis of policy alternatives

these factors separate, it is possible to assess who benefits and whose condition is made worse as the result of a proposed alternative when compared to the "do nothing" scenario.* Further, the trade-off between the costs of environmental or health improvements are made explicit, if they occur. While it has been argued that the informational burden of such an approach to decision-making "tends to reduce the efficacy of political institutions" and leads to stakeholder conflict and delay (Congleton and Sweetser 1992, p. 16), hiding such information would surely be inappropriate in a democratic process. Hence, one benefit of using a trade-off matrix is that stakeholders have the option to become involved in the process of deciding the trade-offs. In this regard, decision-making becomes more open and transparent and is "based on accountability rather than accounting" (Ashford 2005, p. 5; Ashford 2007).

An additional benefit of non-aggregation is that the time period in which each effect is experienced can be revealed and future non-monetary benefits/costs need not be discounted to a present value. The impact of time can be considered using a *time series* of trade-off matrices. These matrices would capture the changing dynamics of the system under analysis and facilitate a *comparative analysis* of alternatives over time. Table 9.3 shows how the generic trade-off matrix shown previously can be used in a *comparative* sense to present the changes in each indicator between time periods. This "back of the envelope" approach to the analysis of alternatives can be relatively straightforward. It is also of particular value to decision-makers, who will be able to see the likely implications of changing an existing alternative to overcome any problems that have been identified.

One challenge facing decision-makers/analysts is often described narrowly as how to create an alternative that arrives at an appropriate trade-off or balance between economic efficiency and equity. Given that decision-making is political, not formulaic (Swartzman 1982; Sagoff 1988), arriving at a single or "right" answer is unlikely. The fact that there are likely to be multiple solutions increases the importance of transparent decision-making, which makes decision-makers more accountable for their actions.

In a situation where potential solutions raise unacceptable compromises in economic efficiency or equity, trade-off analysis enables the decision-maker to explore more effective alternatives. In this regard, trade-off analysis resists simplistic thinking and allows decision-makers to deal with those difficult questions involving (1) economic efficiency/ equity trade-offs, and (2) alternatives analysis. In effect, uncertainties and distributive inequalities are accepted as part of the normal (real world) decision-making process. A critical point is that trade-off analysis holds the potential for environmental, social, and

^{*} The idea of using a form of trade-off analysis that considers utilitarian and non-utilitarian factors, as well as the consequences of alternative courses of action, was endorsed by the Millennium Ecosystem Assessment. See the Millennium Ecosystem Assessment report, Ecosystems and Human Well-being (pp. 19–21), available at http://pdf.wri.org/ecosystems_human_wellbeing.pdf (accessed June 5, 2018).

562 National, regional, and international efforts

	Ideologically closed	Ideologically open
Highly aggregated	I	II
0,00,0	[CBA]	
Highly disaggregated	III	IV
		[Trade-off analysis]

Table 9.4 A classification of approaches to decision-making and evaluation

Source: Adapted from Söderbaum (2000, p. 80).

monetary/financial factors to be considered on a more equal footing and provides a setting where *alternatives* can be considered that do not raise Hobson's choices.

The final step of trade-off analysis (Step 6) is to identify any potential barriers to the chosen alternative and create strategies to circumvent them. One objective of trade-off analysis is to minimize stakeholder conflict by adjusting alternatives as potential conflicts arise. However, it is recognized that it may not be possible to address all stakeholder concerns and that disagreements occur as a normal part of the democratic process. It is the decision-maker's responsibility to address any conflicts in a fair manner, recognizing that political coalition-building is likely to play an important role in overcoming any barriers to change.^{*}

Trade-off analysis has two main differences from a tool such as CBA. Whereas CBA is an aggregated and ideologically closed framework (quadrant I, Table 9.4), trade-off analysis is disaggregated and ideologically open (quadrant IV, Table 9.4). CBA is aggregated in that all factors are translated into a single monetary value, and ideologically closed in that neoclassical economics (or economic rationality) is the decision-making lens. Trade-off analysis is disaggregated in that environmental, social, and monetary/financial factors/ indicators are kept in their natural units, and ideologically open in that it permits alternatives to be evaluated through any lens (for example, from the perspective of deep ecology, social welfare, economic rationality, etc.).

It is helpful to consider some examples of how a trade-off matrix can be used to inform decisions. The first example explores the type of trade-offs that face the EPA when it is formulating air and water pollution regulations. Figure 9.1 shows how the costs of more stringent regulation are borne by all stakeholder groups (to varying degrees) and how the benefits are received primarily by customers and others (that is, society). If the EPA were to promulgate more rigorous air quality standards aimed at electricity utilities, for instance, much of the compliance costs would likely fall upon consumers (assuming the producers pass on the costs). This example demonstrates a classic externality problem where the health risks are unknowingly and involuntarily assumed by society (Ashford 1978). Thus, a critical question is how much pollution abatement are we willing to pay for?

The trade-off matrix enables a range of solutions to be explored. If we adopt a polluter pays approach, the regulation will focus on making utilities take the necessary steps for compliance.⁺ Thus, the key trade-off is between monetary costs to the producer/consumer

^{*} Former President Obama's struggle to provide an expanded health care system for the U.S. provides a vivid example of how difficult it can be to satisfy all the stakeholders in transforming a system. The new administration is having an even more difficult time at restructuring his effort. For that reason, asking "who is standing in the way of needed progress" in examining attractive alternatives is essential.

[†] In this situation, a utility might decide to buy the right to pollute, adopt a more efficient technology, or search for alternative fuels or methods for producing electricity. If the focus is placed on the availability and price of electricity, the method by which it is generated becomes less of a concern to the consumer. Therefore, adopting a polluter pays approach might raise the price of electricity (e.g., through the



Figure 9.1 Trade-offs of EPA air- and water-pollution regulations Source: Adapted from Ashford (1978, p. 166).

and environmental and health benefits to society. (Note: Society is considered here to receive the utility for improvements in the well-being of affected species or the natural environment. An alternative approach would be to create a fifth group for species and/ or the natural environment.) A different policy approach, however, would be for government to subsidize the costs of compliance, thereby passing the costs onto society. Under each regulatory scenario, a *comparative analysis* of the benefits, costs, and distributional effects over time can be undertaken using a trade-off matrix (Table 9.3). In addition, consideration needs to be given to the likely effects of technological change (see the discussion in the next section of technological options analysis (TOA)), the proper treatment of uncertainty, and potential future changes to the legal environment (Ashford 1978; Driesen 2003, 2004). Each of these factors can change the outcomes in a trade-off matrix and therefore should not be excluded from the decision-making process.

A second example is the controversy over the continued use of the organophosphate insecticide Chlorpyrifos in the United States. The pesticide has been correlated with neurodevelopmental problems in children and adults who consume it in food, and in farmworkers who are exposed during their work (Figure 9.2). It is widely criticized by environmental scientists worldwide and is subject to greater restriction and scrutiny in

introduction of a carbon tax) to a point where new ways of generating electricity that were previously too expensive become feasible. For example, households may find it is more cost-effective to buy an array of photovoltaic cells and produce their own electricity than pay the higher price for electricity generated by coal or gas. Interestingly, the term polluter pays can be confusing since it is the customer – not the producer – who will ultimately pay for the internalization of negative externalities. However, if an increase in the price of electricity results in a change in consumer behavior, the producer might "pay" in the long-term if its business is disrupted by a more effective way of producing electricity.





Europe. If banned, the likely loser of a market is Dow-DuPont, while the economic winners are likely to be the industrial promoters of a safer substitute, and children, adults, and farmworkers who would benefit from better neurological health. Its continued use is undoubtedly motivated by benefits it bestows on the producer, whose chief administrative officer is, as this book goes to press, heading a U.S. manufacturing initiative by the Trump administration. This demonstrates the importance of asking whose health and whose economic benefits are served by its continued use.

In summary, trade-off analysis requires decision-makers to make the difficult trade-offs among *effects*, among *actors*, and across *time periods*^{*} that tend to be obscured by techniques such as CBA. As a decision-support tool, it (1) allows decision-makers to avoid monetizing and aggregating non-monetary factors over time; (2) invites the involvement of stakeholders into policy debates since there is greater transparency as to who benefits

^{*} The Stern (2007) report on global climate change came under severe attack for using too small a discount rate for the benefits of preventing global warming that would accrue to some in the future. It might have been better for the effects to have simply been presented in the time period over which they occurred – with no discounting – rather than for the analysts to choose a discount rate which would engender criticism no matter what the value.

and who is harmed by a particular policy; (3) enables analysts to undertake a comparative analysis of alternatives over time; (4) takes into account the important role of technological change in shaping the state and performance of a system, and (5) requires decision-makers to be accountable for their actions. Finally, since the approach encourages the development *and* redesign of alternatives during the analysis to overcome difficult trade-offs, perhaps a more appropriate name for the tool might be *Alternatives Analysis*, although one must be vigilant to ensure that alternatives analysis is not reduced to alternative *cost–benefit* analysis.

9.7.2 Trade-off analysis in the context of sustainability

If achieving sustainable development is the desired objective, it is important to consider the likelihood of arriving at a more sustainable outcome when one uses trade-off analysis. Because the ideological orientations (or value systems) of decision-makers and stakeholders can vary significantly, there is no guarantee that this approach will promote sustainable development. At best, keeping the environmental, social, and monetary/financial indicators in their natural units can promote a more transparent approach to considering non-monetary indicators. But such indicators and their relative impacts can be undervalued if those engaged in the decision-making process favor (or promote) monetary/ financial measures. Further, the type of indicators used in the analysis will also play a critical role. Ideally, the indicators should capture changes in the state of the system, as well as the intensity of the flows (or pressures) that change the system's state between time periods. If sustainable development is a primary concern, these indicators need to set parameters that can monitor and guide future development away from critical environmental thresholds and unsustainable activities. Again, the ideological orientations of the decision-makers and stakeholders will play an important role in framing the problem and determining what is measured. Thus, if sustainability is not a leading priority, it may not be adequately reflected by the indicators or the decision situation.

Therefore, there is an opportunity to consider ways to integrate a *sustainability ideology* into trade-off analysis. Because *equity* and *environmental protection* lie at the heart of sustainable development,^{*} one way to guide decision-making toward sustainability is to adopt a decision-making philosophy that is grounded on these objectives. The following section outlines a revised Rawlsian decision-making philosophy (see Section 1.2.1 in Chapter 1 for a discussion of Rawl's *Theory of Justice*), which can be applied when using trade-off analysis to combine equity considerations and environmental protection in the decision-making process.

A second issue that is often left out of many analysis tools/frameworks and has a direct impact on sustainability is technological innovation. Technological change should be a central consideration in trade-off analysis. Section 9.7 takes a closer look at how the trade-off analysis framework can be used to consider or promote innovation.

9.7.2.1 Operationalizing the social contract

Given the preceding discussion, a critical question remains: how should we operationalize the social contract in environmental decision-making? Further, if government is to act as a trustee, how should it interact with the public? One of the authors of this text has

^{*} In the broader context of this book, which identifies competitiveness, the environment, and employment as the three main pillars of sustainability, equity must include both environmental justice and economic equity involving goods, services, and employment. The original formulation of trade-off analysis considers equity in this manner.

previously proposed an answer to these questions. Ashford and Rest (2001) argue that the perceived and actual role of government in public participation is crucial, as is the role adopted by the stakeholders:

In order for the government to act in a trusteeship capacity, it must be committed to justice and fairness in the Rawlsian sense – i.e., it must first and foremost encourage or allow those activities that provide relatively greater advantage to those individual members or groups who are relatively worse off to begin with. [...] In a political climate where stakeholder involvement is encouraged to legitimize conflict resolution or the parceling out of scarce agency resources, government can easily abdicate its trusteeship role in favor of a more utilitarian approach to problem solving. The result is often a continued polarization of various community groups and members.

(Ashford and Rest 2001, pp. VII-9).

The research underlying this observation (Ashford and Rest 2001) indicates that the outcome of discourse between government agencies and the public depends on the roles adopted by each. To help visualize the interactions between government and society, they developed a matrix that presents the likely outcomes under the different government/ stakeholder positions (Table 9.5).

In the left column of Table 9.5, the two roles of government are indicated: (1) the government acts as a *trustee* of stakeholder interests, and (2) the government acts as a *mediator* of conflicting interests between or among stakeholders. For the stakeholders, two (somewhat idealized) positions are presented: (1) *utilitarianism*, in which stakeholders seek to maximize their own utility; and (2) *communitarianism*, in which stakeholders act for what they perceive as the greater social good. Further, a distinction is made between the *participating* stakeholders – that is, those actively involved in public participation efforts – and the nonparticipating public who are also stakeholders.

Government's role	Stakeholder posture		
	Utilitarian (Maximizing individual/social benefit)	Communitarian (Promoting the greater social good)	
As a trustee for the affected stakeholders	1 Decision is made by government in a trusteeship role on behalf of all the <i>participating stakeholders</i> .	2 Decision is made by government in a trusteeship role on behalf of the stakeholders (mirroring a <i>normative</i> consensus, possibly expanding to benefit the larger nonparticipating public as well).	
As a facilitator of utilitarian or majoritarian consensus, or alternative dispute resolution among the stakeholders	3 Stakeholder involvement processes reach a <i>consensus</i> or <i>compromise</i> among the <i>participating</i> stakeholders.	4 Îdealized stakeholder involvement processes reach <i>normative</i> consensus, possibly expanding to benefit the larger nonparticipating public as well.	

Table 9.5 Types and outcomes of interactions between the government and stakeholders

Source: Adapted from Ashford and Rest (2001, pp. VII-14).

If we consider the first row in Table 9.5 where the government adopts the role of *trustee*, two situations can arise (Ashford and Rest 2001, pp. VII–13). First, government acts on behalf of the participating stakeholders to promote utilitarian solutions (cell 1). Second, government acts on behalf of all stakeholders, including those who are not present, to promote communitarian solutions (cell 2). Likewise, if we consider the second row in Table 9.5 where the government adopts the role of *facilitator* of compromise or consensus, we see two different situations (ibid.). First, government acts to implement the compromise or consensus reached by the participating stakeholders (cell 3). Second, government acts to implement the normative consensus achieved by stakeholders on behalf of the larger nonparticipating public (cell 4). As before, the former promotes utilitarian solutions and the latter communitarian ones.

A *Rawlsian outcome* is where new legislation, policies, or programs support initiatives that offer greater advantage to individuals or groups who are relatively worse off to begin with. A *Rawlsian government* refers to a government that is willing and has the capacity to either impose or endorse Rawlsian outcomes.

It follows that a *non-Rawlsian government* is either unwilling or does not have the capacity to impose Rawlsian outcomes on the stakeholders. Instead, it adopts the position of mediator of stakeholder interests. Under this arrangement, the responsibility for achieving a just and fair society is left to the stakeholders. A non-Rawlsian government does not mean that a Rawlsian outcome cannot be achieved; it simply means that the government does not act as a trustee for stakeholder interests, and it would take a strong communitarian group of stakeholders to press for a Rawlsian outcome.

The Rawlsian approach should be seen as a movement (a process) and not a final state, but it is nonetheless possible to operationalize Rawls's theory of justice by "bounding" the acceptable moves and rejecting the clearly utilitarian moves that are not Rawlsian.

If we consider the concept of sustainable development, an important question is whether Rawls's theory of justice can ensure that human activity does not degrade the environment to a state where it is unable to recover. The reason for asking this question is simple. It stems from the belief that the ultimate rationale of governance is to support and encourage a way of life that recognizes and values human needs (economic and social) and the natural environment, is just and fair, and continually strives to achieve an acceptable balance between civil liberty and regulation. Hence the philosophy of government and the stakeholder posture adopted by society will have a significant influence on whether it is able to move toward sustainability.

We have argued that the four major environmental factors that underlie the concern for sustainable development are the following:

- 1 The disruption of ecosystems and loss of biological diversity and the indirect effects these have on human health and well-being;
- 2 The rapid use of finite resources and energy supplies;
- 3 The direct impacts of toxic pollution on human health and the health of other species; and
- 4 The disruption of the global climate.

All four of these factors occur as a result of *human action* and the *technology* we have at our disposal. Therefore, it will be possible to address these problems only if there are social arrangements that enable us to do so in an effective manner. The growing interest in *environmental justice* provides some evidence that society is willing to ensure that development does not adversely affect the disadvantaged by protecting the environment in which they live. However, as a practical matter, environmental justice is primarily concerned with the protection of people. Hence, in addition to searching for Rawlsian solutions to

social problems (which include economic and indirect environmental considerations), government and stakeholders also need to search for solutions that take environmental protection into consideration.

In *A Theory of Justice*, Rawls provides little discussion of the environment. In many ways, his decision not to extend his theory from the social to natural worlds represents a missed opportunity. Because protecting and preserving the environment are essential for the longevity of the human race, we propose the following principle of justice that could be considered in the original position:

Third Principle. Social arrangements are to be organized so that they (a) protect and improve the environment, especially for those individuals and species most heavily affected by environmental degradation or pollution, and (b) do not result in activities that exceed ecological carrying capacity.

The intent of the third principle – the environmental principle – is (1) to ensure that society continually strives to protect and improve the environment and the lives of people negatively affected by pollution (broadly defined), and (2) to keep human activity within ecological limits.^{*} The basic premise of this principle is twofold. First, protecting human health is believed to be of paramount importance. Second, the natural environment is believed to be good in and of itself and should be protected and regenerated if it is being degraded by human activity. In reality, part (a) of this principle is likely to be the most useful because defining and agreeing on the ecological carrying capacity of the environment to implement part (b) is still a major work in progress. In addition, part (a) of the principle aligns well with the idea of movement toward justice (or fairness) and does not attempt to define an end state or goal.

The addition of the environmental principle to Rawls's framework directly links the social and natural worlds and holds the potential to promote sustainable development in decision-making. First and foremost, it places social equity at the center of decision-making. Second, it supports the notion of economic growth so long as the benefits from this growth are distributed fairly among society. Social and economic inequalities are tolerated only if the most disadvantaged members of society are made better off under new arrangements. Finally, it makes movement toward a better environment a critical component of any new social arrangements. The combination of the proposed addition to the Rawlsian/utilitarian decision-making philosophy (presented above) with the trade-off analysis framework (in Section 9.7.1), creates a valuable approach to decision-making for sustainable development. More specifically, the approach can reveal the equity/ distributional consequences and impacts of environmental, health, and safety regulation or the likely impacts of regulatory inaction.

A second issue, in addition to the fairness of a regulatory decision, that is often left out of many analysis tools/frameworks and has a direct impact on sustainability is the importance of technological innovation. Technological change must be a central consideration in trade-off analysis, and, as discussed in Chapter 8, this brings a dynamic element into what might otherwise be a static assessment of the effects of regulation.

^{*} A significant work that focuses on the links between environmental quality and human equality and those between sustainability and environmental justice more generally is Agyeman et al.'s (2003) *Just Sustainabilities: Development in an Unequal World.* This publication, which consists of a selection of essays, focuses specifically on the linkages between the political and policy processes surrounding environmental justice and sustainability. *Just Sustainabilities* highlights "an important and emerging realization that a sustainable society must also be a just society, locally, nationally and internationally, both within and between generations and species" (ibid., p. 3).

9.8 Static versus dynamic efficiency and the implications for promoting technological innovation using trade-off analysis

Before considering how trade-off analysis can be used to promote technological innovation, this section begins with a brief discussion of the important difference between static and dynamic efficiency (as a focus of environmental policy) and how these views can affect the analysis of technology.

It is important to emphasize the difference between achieving *static* and *dynamic* efficiency in applying technological solutions to societal problems. Having static efficiency as the mainstay of neoclassical environmental economics ignores the important role of innovation in achieving better environmental outcomes (Ashford and Hall 2011; Ashford and Caldart 2008; Driesen 2003, 2004; Jänicke et al. 2000, 2005, 2010). It assumes that the objective of decision-makers is to reach an efficient state where social welfare is maximized. If the prevailing state of the world is suboptimal, a more efficient state is identified, and changes are made to move the system toward that state. In general, neoclassical economists define this efficient state by matching supply and demand in a competitive market, with the assumption that technology remains constant. In contrast, dynamic efficiency places considerable attention on instruments that will encourage transformations. Driesen observes: "Economic dynamic analysis emphasizes change over time, systematic change, and precise analysis of how incentives affect individuals and institutions" (Driesen 2004, p. 515).

The roots of dynamic efficiency must be understood in the context of institutional economics and organizational theory (Driesen 2003),^{*} where it is important to appreciate the difficulty that a new incentive has in capturing the attention of institutions and individuals, given that their decisions are influenced by path dependency or lock-in (that is, past actions/decisions might constrain future actions/decisions) and bounded rationality (that is, purposes, knowledge, and habits combine to constrain the choices an institution/ individual makes) (Driesen 2003, 2004).

Dynamic efficiency views technological change (with accompanying institutional, organizational, and social changes) as a central variable in the analysis of environmental policy, increasing the importance of understanding the direction of change and how technology might alter benefits/costs over an appropriate time horizon (Ashford 2002). Given that changing a sociotechnical system is likely to require a long timeframe, the role of government in setting technology and environmental policy to guide innovation increases in importance. Further, whereas static efficiency focuses on the efficient state that appropriately balances competing goals, dynamic efficiency emphasizes win-win outcomes that are achieved through the co-optimization of multiple societal goals. Thus, achieving dynamic efficiency focuses on the process of a sustainable transformation, while achieving static efficiency focuses on a sustainable, or more optimal, state. This observation highlights the implicit bias embedded in traditional analytic tools. Tools such as cost benefit analysis, which are based on static efficiency (or optimality), move considerations of the process of transformations outside the analytical framework. In contrast, Driesen's (2003) focus on the economic dynamics of environmental law places the process of transformation at the center of the analysis. In trade-off analysis, in contrast with traditional cost-benefit analysis, the process of technological change and innovation is an explicit consideration in the analysis (Hall 2006; Hall et al. 2008). In addition to evaluating the multivariate impacts of different alternatives, a trade-off matrix can be used to assess the impacts of different technology options (Ashford 2000; Ashford et al. 1980). The strength of combining both kinds of impacts in a trade-off matrix is that it can be used to compare multivariate criteria – such as environmental, health/safety, and economic factors – to determine how

^{*} See Chapter 7 on organizational innovation and learning.

570 National, regional, and international efforts

new technology options compare with each other and with the do-nothing scenario. Further, the impacts of each technology option on different stakeholders are made explicit. The comparative analysis of different technology options in a trade-off matrix constitutes what is known as technology options analysis (TOA) (Ashford 2000; O'Brien 2000).

The idea of TOA was first applied to the chemical industry to facilitate the consideration of technology options that could make production processes inherently safer for workers and the surrounding community. Either new technologies could be added to existing systems to mitigate risks, or a production process could be designed to remove the risk altogether. The purpose of a TOA is to inform the firm, the regulating agency, and stakeholders of the full range of technological options that can be used or developed to address a problem or achieve a desired objective.

The benefit of using TOA is that analyzing comparable factors among the technology options is easier than using techniques such as CBA that usually require monetary quantification, aggregation of variables, and discounting to present value. Keeping the variables in their natural units within a trade-off matrix avoids unnecessary assumptions about how to translate environmental or health and safety impacts, for instance, into a monetary value. The result is a more believable, disaggregated analysis of options where the impacts of technologies are made explicit and win-win solutions can be more easily identified. TOA can be used in both a static and a dynamic sense. When used in a static sense, TOA simply compares available (or existing) technology to decide which option should be selected. This is the approach adopted by neoclassical environmental economics (as currently practiced), which searches for optimal outcomes using static efficiency. A failure by environmental economists to take technological innovation into account means that their analysis is likely to overestimate the cost of compliance with new, more stringent environmental regulation. Setting regulation on the basis of existing technology, or what is deemed feasible from a static efficiency perspective, is not likely to produce the kinds of systemic transformations that could lead to sustainable development.

When used in a dynamic sense, TOA is able to compare available technology with technology that could be developed.^{*} Using the trade-off matrix in this manner leads to a form of dynamic environmental economics that includes the consideration of technological change over time (Ashford and Hall 2011; Driesen 2003, 2004).

Achieving dynamic efficiency requires the analyst or decision-maker to focus on the transformation process, paying special attention to path dependency and bounded rationality of institutions and stakeholders.[†] Given that changing a sociotechnical system is likely to require a long time frame, the role of government in setting technology and (stringent) environmental policy to guide innovation is of particular importance (see Section 8.3.5 in Chapter 8 for a discussion of the weak vs. strong form of the regulation-induced innovation

- * One benefit that traditional cost-benefit analysis has in considering only existing technologies for the purposes of assessment is that these technologies are easy to identify and cost; although, the latter usually leads to large cost overestimates, especially if provided by a regulated industry. By explicitly considering technological options that include innovation not yet undertaken, the assessment becomes open ended. What will the performance and cost of new technology be? Regulatory history has confirmed impressive positive results in general, justifying stringent regulatory requirements, but there will be uncertainties in any particular case. Analysts do not like open-ended assessment. Politicians may be reluctant to bank on future innovation, but that is precisely what government investments in new technologies count on and what government incentives for innovation are provided for.
- † The trade-off matrix enables decision-makers to ask what could be done to improve the prevailing situation. Because the trade-off matrix for each technology option (existing and undeveloped) presents information in a disaggregated form, the potential political implications of setting more stringent regulation or investing in a certain type of technology become apparent. Once these factors are identified, steps can be taken to address the problems of path dependency and bounded rationality.

hypothesis). Adopting an approach that guides technological change means that decision-makers are not relying on serendipitous technological development. Instead, they are pursuing an approach where the development of technology is more likely to progress along a desired pathway. Therefore, it is the dynamic use of TOA that is likely to lead to system transformations toward sustainable development.

Using trade-off analysis, it is possible to consider the dynamics of the impacts associated with more stringent regulation over a number of time periods (Ashford 1978; Hall 2006; Hall et al. 2008). Developing a series of trade-off matrices that capture how the distributed impacts adjust with improving technology might be a useful way to explain to stakeholders how their situations are likely to improve, even if at first they worsen. This approach to analysis also supports Driesen's (2003) description of the economic dynamics of environmental law. Further, the revised Rawlsian/utilitarian decision-making philosophy (discussed in Section 9.7.2.1) provides the philosophical basis upon which decisions for sustainable development can be made within the trade-off matrix.

Using trade-off analysis to assess the stringency and distributed impacts of regulation over time, along with careful consideration of the path dependency and bounded rationality of institutions and stakeholders/players, it may be possible to formulate regulatory initiatives to nurture sustainable transformations. For further reading on stimulating dynamic transformations for environmental improvements, see Ashford and Hall (2011).

In this chapter, we have outlined the U.S. environmental and occupational health and safety regulations and developed a decision-support framework to assess policies and regulations intended to advance sustainable development. In the next chapter, we turn to regional-level approaches that focus on protecting the natural and working environment.

9.9 References

- Agyeman, J., R. D. Bullard, and B. Evans, Eds. (2003). Just Sustainabilities: Development in an Unequal World. Cambridge, MA, MIT Press.
- America Society of Civil Engineers (ASCE) (2017). 2017 Infrastructure Report Card. Drinking Water. ASCE, Washington, DC Available at www.infrastructurereportcard.org/wp-content/ uploads/2017/01/Drinking-Water-Final.pdf (accessed May 1, 2018).
- Ashford, N. A. (1978). *The Role of Risk Assessment and Cost–benefit Analysis in Decisions Concerning Safety and the Environment.* FDA Symposium on Risk/Benefit Decisions and the Public Health, Colorado Springs, February 17. Washington, DC, Government Printing Office.
- Ashford, N. A. (1994). "Monitoring the Worker and the Community for Chemical Exposure and Disease: Legal and Ethical Considerations in the U.S." *Clinical Chemistry* 40/7B Supplement: 1426–1437, July. Available at http://hdl.handle.net/1721.1/1580 (accessed January 22, 2011).
- Ashford, N. A. (2000). "An Innovation-Based Strategy for a Sustainable Environment." Innovation-Oriented Environmental Regulation: Theoretical Approach and Empirical Analysis. J. Hemmelskamp, K. Rennings, and F. Leone. New York, Physica-Verlag Heidelberg: 67–107.
- Ashford, N. A. (2002). "Government and Environmental Innovation in Europe and North America." *American Behavioral Scientist* 45(9): 1417–1434.
- Ashford, N. A. (2005). "Implementing the Precautionary Principle: Incorporating Science, Technology, Fairness, and Accountability in Environmental, Health, and Safety Decisions." *International Journal of Risk Assessment and Management* 5(2/3/4): 112–124.
- Ashford, N. A. (2007). "The Legacy of The Precautionary Principle in U.S. Law: The Rise of Cost-benefit Analysis and Risk Assessment as Undermining Factors in Health, Safety and Environmental Protection." *Implementation the Precautionary Principle: Approaches From the Nordic Countries. the EU and the United States.* N. de Sadeleer. London, Earthscan. Available at http://hdl.handle.net/1721.1/38470 (accessed May 1, 2018).

572 National, regional, and international efforts

- Ashford, N. A. (2016). "The Flaws in the Emerging Toxics Reform Legislation and How They Can Be Fixed." *The Huffington Post*, April 4. Available at www.huffingtonpost.com/nicholas-ashford/the-flaws-in-the-emerging_b_9675374.html (accessed May 1, 2018).
- Ashford, N. A. (2017). "'The New TSCA; Challenges Remain." Global Business Briefing, *ChemicalWatch*, May, pp. 19-20. Available at www.chemicalwatch.com by subscription. For free access, see https://chemicalwatch.com/register?o=56110&productID=1&layout=main (accessed May 3, 2018).
- Ashford, N. A., and C. C. Caldart (2008). Environmental Law, Policy, and Economics: Reclaiming the Environmental Agenda. Cambridge, MA, MIT Press.
- Ashford, N. A., and R. P. Hall (2011). "The Importance of Regulation-Induced Innovation for Sustainable Development." *Sustainability* 3(1): 270–292. Available at http://www.mdpi. com/2071-1050/3/1/270 (accessed May 1, 2018).
- Ashford, N. A., D. Hattis, et al. (1980). Evaluating Chemical Regulations: Trade-Off Analysis and Impact Assessment for Environmental Decision-Making. Washington, DC, NTIS.
- Ashford, N. A., and K. M. Rest (2001). *Public Participation in Contaminated Communities*. Cambridge, Center for Technology, Policy, and Industrial Development, MIT Press.
- Coase, R. H. 1960. "The Problem of Social Cost." Journal of Law and Economics 3: 1-44.
- Congleton, R. D. (2003). "Constitutional Design and Public Policy." Lecture 9: Treaties as Contracts Between Governments, Universiteit Leiden, Fall 2003, Footnote 1. Available at http:// rdc1.net/class/constitutionaldesignclass/CONSDES9.PDF (accessed January 25, 2009).
- Congleton, R. D., and W. Sweetser (1992). "Political Deadlocks and Distributional Information: The Value of the Veil." *Public Choice* 73: 1–19.
- Driesen, D. M. (2003). The Economic Dynamics of Environmental Law. Cambridge, MA, MIT Press.
- Driesen, D. M. (2004). "The Economic Dynamics of Environmental Law: Cost-benefit Analysis, Emissions Trading, and Priority-Setting." *Boston College Environmental Affairs Law Review* 31(3): 501–528.
- U.S. Environmental Protection Agency (EPA) (2013). Drinking Water Infrastructure Needs Survey and Assessment Fifth Report to Congress. Washington, DC, Office of Ground Water and Drinking Water Drinking Water Protection Division.
- Erickson, B. (2017). "Tensions Build as U.S. Chemical Law Turns One." C&Penews, June 25, 25.
- Hall, R. P. (2006). "Understanding and Applying the Concept of Sustainable Development to Transportation Planning and Decision-Making in the U.S." PhD dissertation, Engineering Systems Division. Cambridge, MA, MIT Press.
- Hall, R. P., N. A. Ashford, et al. (2008). "Trade-Off Analysis (with a Revised Rawlsian Decision-Making Philosophy) as an Alternative to Cost–Benefit Analysis (CBA) in Socio-Technical Decisions." Paper presented at the COST 356 Seminar, Towards the Definition of a Measurable Environmentally Sustainable Transport, TOI, Oslo, Norway, February 20.
- Hawken, P, A. Lovins, and L. H. Lovins (2000). *Natural Capitalism: Creating the Next Industrial Revolution*. Boston, Back Bay Books. 416 pages.
- Jänicke, M., J. Blazejczak, et al. (2000). Environmental Policy. Innovation-Oriented Environmental Regulation: Theoretical Approach and Empirical Analysis. J. Hemmelskamp, K. Rennings, and F. Leone. New York, Physica-Verlag Heidelberg: 125–152.
- Jänicke, M., and K. Jacob (2005). Ecological Modernisation and the Creation of Lead Markets. Towards Environmental Innovation Systems. M. Weber and J. Hemmelskamp. Heidelberg, Springer: 175–193.
- Jänicke, M., and S. Lindemann (2010). "Governing Environmental Innovations." *Environmental Politics* 19(1): 127–141.
- O'Brien, M. (2000). Making Better Environmental Decisions: An Alternative to Risk Assessment. Cambridge, MA, MIT Press.
- Polsky, P. (2016). "California Chemicals Regulation After TSCA Reform." Environmental Law News 25(2): 22–30.
- Sagoff, M. (1988). The Economy of the Earth. Cambridge, Cambridge University Press.

- Snyder, A., and A. Gullén (2017). "EPA Memo Reveals Staff Concern about Chemical Safety Rules." Manuscript circulated June 21.
- Stern, N. (2007). *The Economics of Climate Change: The Stern Review*. Cambridge, Cambridge University Press.
- Sunstein, C. (2017). "Cost–Benefit Analysis and Arbitrariness Review." Harvard Law Environmental Review 41: 1.
- Swartzman, D. (1982). "Cost–Benefit Analysis in Environmental Regulation: Sources of the Controversy." *Cost–Benefit Analysis and Environmental Regulations: Politics, Ethics, and Methods.* D. Swartzman, R. A. Liroff, and K. G. Croke. Washington, DC, Conservation Foundation: 53–85.