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The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms

JOHN S. APPLGATE*

INTRODUCTION

For many thousands of years, human beings have selectively bred plants and animals better to serve their needs and wants. Over time, the process of choosing and propagating the most desirable traits of an organism became more deliberate and systematic. Since the work of Gregor Mendel¹ and Charles Darwin,² humans have had a pretty clear idea of the mechanics of selective breeding. Since the discovery of DNA by Watson and Crick,³ we have known the mechanism. Still more recently, scientists have learned how to manipulate the genetic mechanism at the molecular level. This has pushed the long history of selective breeding into a new phase, in which neither the ability of the subject plants or animals to mate, nor the randomness of the results in the offspring, is an obstacle to the creation of new breeds with potentially enormous utility to humans. Drought-resistant crops, pest-resistant crops, and foods with heightened nutritional content are among the many advances within sight.

Genetic modification (GM) is powerful because it manipulates the fundamental workings of the world around us. Like atomic energy, which was first put to use less than eight years before Watson and Crick discovered DNA, the great power of genetic modification may have a dark side. Whatever benefits atomic energy may have conferred on humans, it has also left us with a legacy of

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1. Gregor Mendel, 1822-1884, was an Austrian monk. His work on plant genetics was published in the 1860s, but not widely accepted or acknowledged until after his death. See GREGOR MENDEL, GREGOR MENDEL'S EXPERIMENTS ON PLANT HYBRIDS: A GUIDED STUDY (Alain F. Corcos & Floyd V. Monaghan eds., 1993).

2. CHARLES DARWIN, ORIGIN OF SPECIES (1859). Darwin, of course, wrote about *natural* selection, of which human selection is but a subset. Human selection is a process in which humans create an environment that favors certain traits.

3. James D. Watson and Francis Crick discovered the structure of DNA, and by implication its copying mechanism, at Cambridge University in 1953. See generally JAMES D. WATSON, THE DOUBLE HELIX: A PERSONAL ACCOUNT OF THE DISCOVERY OF THE STRUCTURE OF DNA (1969).

environmental degradation and a continuing threat of annihilation. Genetic modification manipulates not just the building blocks of inanimate elements like uranium and plutonium, but of life itself. Genetic modification poses real dangers, if not of a biological holocaust, then of weeds, pests, and diseases that are aggressively invasive and resist chemical control; of further erosion of the genetic diversity upon which the quality of our lives depends; and of novel toxins and serious food allergies. And if western culture teaches nothing else, it is that playing God like this exacts a terrible vengeance.

The two stories, of astonishing benefits and of fearsome dangers, dominate perceptions of genetically modified organisms (GMOs) and consequently dominate their regulation. The first point of view regards genetic technology as having enormous potential benefits and relatively minor, or at most manageable, risks. Accordingly, regulation should encourage the development of this technology, and new organisms and their derivatives should be regulated on a case-by-case, product-by-product basis. The second point of view focuses on the potential dangers common to GMO technology, and hence to its products. This view counsels regulation that forbids GMOs or at least applies strict screening tests and other controls to all GM products. The United States, a strong supporter of GMO technology, has taken the first approach; the European Union, whose population is strongly opposed to GMOs, has taken the second. This has become a source of considerable tension in trade and environmental relations between these economic superpowers.

In this article, I seek, first, to clarify the difference in the two approaches and the extent to which they rest on two fundamentally different conceptions of GM technology, I will call these conceptions the Frankenstein and the Better Living through Chemistry narratives. Little progress will be made in harmonizing the regulation of GMOs by merely adopting and adapting of one or the other of these widely divergent accounts of GM technology.⁴ Second, I will describe the existing efforts to bridge the gap between the two regulatory systems through the use of prior informed consent, sustainable development, and the precautionary

4. See Sheila Jasanoff, *Commentary: Between Risk and Precaution—Reassessing the Future of GM Crops*, 3 J. RISK RES. 277, 277 (2000).

The trans-Atlantic controversy that erupted in 1999 between proponents and opponents of genetically modified (GM) crops has been framed in sharply dualistic terms more appropriate to a Manichean than a modernist worldview: as a conflict between enlightenment and reaction, rationality and superstition, science and ignorance, trust and skepticism, free trade and protectionism.

Id.

principle.⁵ Third, I will argue that, of these, the precautionary principle is the only workable candidate for a harmonizing role. The precautionary principle is an approach to regulation under uncertainty, and it has been adopted in many international and domestic environmental settings. Probably its most authoritative statement appears in Principle 15 of the 1992 Rio Declaration on Environment and Development: “Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”⁶ Properly construed, this principle defines a process for taking environment- and health-protective actions while the dangers of not taking such protective action remain uncertain. Finally, I will propose a supporting narrative for the precautionary principle, based on the Prometheus legend, which acknowledges the dangers of technology and the need for foresight to discern and address them, but also recognizes that technology dangers can be addressed without abjuring all of its benefits.

I. TWO NARRATIVES

Observers have long been puzzled by the widespread, visceral opposition to GMOs in the absence of actual instances of human or environmental catastrophe, or indeed of any serious injury at all. Nuclear energy has its Three Mile Island and Chernobyl, toxic chemicals have their Bhopal and Woburn and DES, and yet they continue to be used in a broad range of industrial and developing societies. GMOs, on the other hand, are thriving in a few countries, but the subject of sustained attack in many.

These differences are typically put down to an irrational and anti-scientific popular discontent with technology. However, the way that people construct reality—and especially normative reality—is not limited to scientific and other quantitative analyses. For two decades, legal scholars, following the lead of the humanities, have recognized the critical importance of narratives—stories—to the way that humans perceive their world and construct law to give the world

5. My focus is environmental, health, and safety regulation. GMOs implicate a remarkable range of important regulatory interests, including free trade, intellectual property, and global economic equity, which I will address only in passing. Likewise, in keeping with the topic of the symposium, I will limit my purview to agricultural crops and food, even though GMOs find many other uses, for example, in agricultural animals and in pharmaceuticals. See John S. Applegate & Alfred C. Aman, Jr., *Introduction: Syncopated Sustainable Development*, 9 *IND. J. GLOBAL LEGAL STUD.* 1 (2001).

6. Rio Declaration of the United Nations Conference on Environment and Development (UNCED), June 14, 1992, 31 *I.L.M.* 874 [hereinafter Rio Declaration].

normative structure. The *locus classicus* of narrative in the legal academy is Robert Cover's celebrated *Nomos and Narrative* essay. Cover introduced his subject as follows:

No set of legal institutions or prescriptions exists apart from the narratives that locate it and give it meaning. For every constitution there is an epic, for each decalogue a scripture. Once understood in the context of the narratives that give it meaning, law becomes not merely a system of rules to be observed, but a world in which we live.

In this normative world, law and narrative are inseparably related. Every prescription is insistent in its demand to be located in discourse—to be supplied with history and destiny, beginning and end, explanation and purpose. And every narrative is insistent in its demand for its prescriptive point, its moral. History and literature cannot escape their location in a normative universe, nor can prescription, even when embodied in a legal text, escape its origin and its end in experience, in the narratives that are the trajectories plotted upon material reality by our imaginations.⁷

Two very different narratives dominate the contentious debate over GMOs. The Frankenstein narrative takes its name from a now familiar epithet for agricultural GMOs, "Frankenfoods." The other narrative, Better Living Through Chemistry, takes its name from a DuPont advertising campaign of 1930s, and it reflects GMO proponents' confidence in new technologies. Unless we understand these narratives, there is little hope of reconciling the resulting legal systems.

7. Robert M. Cover, *The Supreme Court 1982 Term, Foreword: Nomos and Narrative*, 97 HARV.L.REV.4 (1983).

*A. Frankenstein**1. Playing God*

In outline at least, Mary Shelley's *Frankenstein*⁸ is familiar to most. ("Frankenstein," of course, is the name of the creator of the monster; the monster himself is not given a name.) The novel was originally conceived and written in the summer of 1817 while Mary Shelley was vacationing in the Alps with her husband, Percy Bysshe Shelley, and their friend, Lord Byron. It recounts the story of a young Swiss man, Victor Frankenstein, who at university is enthralled by the possibilities of "natural philosophy, and particularly chemistry, in the most comprehensive sense of the term."⁹ After nearly two years of study, "on a dreary night of November" he creates a living thing, but is so shocked by his creation that he flees his laboratory.¹⁰ When he returns, the monster has disappeared. About two years later, however, the monster kills Frankenstein's younger brother, and their devoted servant is wrongly executed for the murder. Frankenstein then meets the monster and learns from him how he suffered abandonment at his creation, learned language and skills from observing humans, read *Plutarch's Lives* and *Paradise Lost*, and is now rejected, pursued, and tormented. Finding no comfort from humans, the monster demands that Frankenstein create a wife as a companion for him. When Frankenstein ultimately refuses, the monster vows vengeance. The monster kills Frankenstein's best friend and, with cruel irony, Frankenstein's own bride. Frankenstein's father dies of shock from the last deaths. Finally, Frankenstein himself dies in his attempt to track the monster to the Arctic, and the monster disappears for good.

Looking to Shelley's *Frankenstein* as a narrative for GMOs appears all the more promising when one reads the introduction to the 1831 edition of the novel.

In it, Shelley explains that her idea for the story came out of conversations between Byron and Percy Shelley concerning "the principle of life, and whether there was any probability of its ever being discovered and communicated." This already sounds a bit like GMOs, but the next sentence seems even closer to the mark: "They talked of the experiments of Dr. Darwin

8. See generally, MARY SHELLEY, *FRANKENSTEIN, OR, THE MODERN PROMETHEUS* (Airmont Publishing Co. 1963) (1817).

9. *Id.* at 53.

10. *Id.* at 60-61.

. . . who [was supposed to have] preserved a piece of vermicelli in a glass case, till by some extraordinary means it began to move with voluntary motion."¹¹ No, it wasn't quite *the* Darwin. In 1831, Charles Darwin was just setting off on the *Beagle* for the Galapagos Islands; *Origin of Species* was not published until 1859. Shelley was referring to *Erasmus* Darwin, Charles' grandfather, and Shelley was confused about precisely what the elder Darwin did. He did not bring pasta to life; rather, he wrote about an insect, *vorticellae*, that appears to be dead and then revivifies when water is added. He also wrote about a paste (not pasta) of water and flour that, when left for some days, would be teeming with "animacules" that were previously invisible.¹² Even though a different Darwin was referred to, however, it should be clear that he and Frankenstein were both engaged in what can fairly be characterized, like GMOs, as biological innovation.

The Frankenstein analogy is used by opponents of GM technology merely as an epithet to suggest in a superficial way the unnaturalness of the enterprise.¹³ I would like to show that the analogy actually works at a serious level, too.¹⁴ The Frankenstein narrative relates the dangers of tinkering with the secrets of life itself. Like genetic modifiers, Frankenstein's aspiration was grandiose but well meaning—to create a "new species [that] would bless me as its creator and source."¹⁵ But the horror that flows from Frankenstein's ambition provides a straightforward moral: "Learn from me, if not by my precepts, at least by my example, how dangerous is the acquirement of knowledge, and how much happier that man is who believes his native town to be the world, than he who aspires to become greater than his nature will allow."¹⁶ He counsels the explorer who finds him to "[s]eek happiness in tranquility and avoid ambition, even if it be only the apparently innocent one of distinguishing yourself in science and

11. *Id.* at 16-17.

12. LEONARD WOLF, *THE ANNOTATED FRANKENSTEIN* 4 (1977); see also Ashton Nichols, *The Anxiety of Species: A Romantic Natural History*, 28 *THE WORDSWORTH CIRCLE* 130-36 (1997), available at <http://www.dickinson.edu/~nicholsa/Romnat/> (providing links to websites on Erasmus Darwin, Charles Darwin, Mary Wollstonecraft Shelley, Erasmus Darwin and the "Frankenstein Mistake").

13. For example, Germany's Green Party minister for food and agriculture wants to move agriculture "back to nature." Julia A. Moore, *More than a Food Fight*, 17 *ISSUES IN SCI. & TECH.* 31, 31 (2001).

14. For serious and very interesting explorations of *Frankenstein* as it relates to genetic engineering of animals and of human cloning, see Dena S. Davis, *Religious Attitudes toward Cloning: A Tale of Two Creatures*, 27 *HOFSTRA L. REV.* 509 (1999). See also BERNARD E. ROLLIN, *THE FRANKENSTEIN SYNDROME: ETHICAL AND SOCIAL ISSUES IN THE GENETIC ENGINEERING OF ANIMALS* (1995).

15. SHELLEY, *supra* note 8, at 57.

16. *Id.* at 56. Adopting a more explicitly religious tone, Frankenstein later says, "like the archangel who aspired to omnipotence, I am chained in an eternal hell." *Id.* at 211.

discoveries.”¹⁷ This, then, is the philosophical objection to GMOs: it is hubris to advance science beyond that which “nature will allow,” damning “any human endeavor to mock the stupendous mechanism of the Creator of the world.”¹⁸

Further, ventures “in science and discoveries” necessarily take one into unknown realms where the dangers may be great. If Frankenstein did not initially appreciate the potential for harm from his creative enterprise, he understood it all too well when it came to making a partner for his monster. He tells us: “I was now about to form another being, of whose dispositions I was alike ignorant.” She “might become ten thousand times more malignant than her mate, and delight, for its own sake, in murder and wretchedness.” Ultimately, “a race of devils would be propagated upon the earth who might make the very existence of the species of man a condition precarious and full of terror.”¹⁹ These three fears—of the unknown, of the individual dangers of the new species, and of social instability—led Frankenstein to refuse to create the monster’s bride, despite the monster’s threats of retribution. Again, the lesson for GM technology is clear: genetic engineering is an ambitious voyage into the unknown—perhaps into the forbidden—and the individual and social consequences are sure to be horrifying. Far better to deny ourselves the new knowledge than to suffer the hideous consequences of playing God.²⁰

That Shelley would draw this lesson from her tale, and that we would be so receptive to it, is almost inevitable in western culture. In the classical tradition, the gods’ wrath at human hubris is a continuing theme of Greek myth and literature. We see it, for example, in Oedipus’ reckless pursuit of the knowledge of his birth.²¹ In the Judeo-Christian tradition, Adam and Eve’s experience with the fruit of the Tree of Knowledge was negative, to say the least. It is not coincidental that *Paradise Lost* was one of the three books that the monster reported reading, and references to it appear throughout the novel. GMOs have also been portrayed as “tak[ing] mankind into realms that belong to God and God

17. *Id.* at 218.

18. *Id.* at 56, 17.

19. *Id.* at 167.

20. Rollin identifies three similar versions of “the Frankenstein thing;” genetic engineering is inherently wrong because it is playing God; it is wrong because it has unknowable dangers; and it is wrong because it harms the altered creature.” ROLLIN, *supra* note 14, at 21-22, 68, 71-77, 138. Rollin’s third version is not particularly relevant to crops.

21. Rejecting the entreaties of his queen, Jocaste, he declares he has nothing to fear from this knowledge. “However base my birth, I must know about it. . . . I am a child of Luck; I cannot be dishonored.” Sophocles, *Oedipus Rex*, in *THE OEDIPUS CYCLE: AN ENGLISH VERSION* sc. 3, 56 (Dudley Fitts & Robert Fitzgerald, trans. (1977)).

alone,²² or, less theistically, “fundamentally, genetically engineered crops substitute human wisdom for the wisdom of nature.”²³

Modern technology has provided us with fertile soil for technological pessimism.²⁴ Atomic energy, which also manipulates the basic building blocks of the physical world, is an obvious example. The assumption of god-like powers²⁵ has brought with it a great deal of harm, both realized in accidents and environmental degradation, and as yet unrealized in the form of nuclear holocaust.

Nuclear weapons are not just more powerful than dynamite, in the way that dynamite was more powerful than black powder; they are *vastly* more powerful. Moreover, explosive yield is just one dimension of their many deleterious effects.

Radiation poisoning, epidemics, uninhabitable lands, electromagnetic pulses, vast economic dislocation, winter-inducing dust clouds, and widespread starvation are all probable sequelae of a serious nuclear exchange.²⁶ Rachel Carson’s classic *Silent Spring* cast chemical pesticides in a similar light:

This industry is a child of the Second World War. In the course of developing agents of chemical warfare, some of the chemicals created in the laboratory were found to be lethal to insects. The discovery did not come by chance: insects were widely used to test chemicals as agents of death for man.

The result has been a seemingly endless stream of synthetic insecticides. In being man-made—by ingenious laboratory manipulation of the molecules, substituting atoms, altering their

22. Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL’Y & L. 257, 258 (2000) (quoting the Prince of Wales).

It might also be argued that “playing God” (“mocking the stupendous creation”) is in itself a kind of moral or ethical harm to the practitioner of that art or to society as a whole, but I will not consider that set of objections in this discussion of agricultural crops. A related new biological technology, cloning, especially of human beings, poses a far clearer case for ethical wrongs. The ethics of animal engineering are the subject of ROLLIN, *supra* note 14.

23. *Against the Grain: Part 2*, RACHEL’S ENVTL. & HEALTH WKLY., (Envtl. Res. Found.), Feb. 18, 1999, at 22, at <http://www.rachel.org/bulletin/bulletin.cfm?issue>, quoted in Jonathan H. Adler, *More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 25 TEX. INT’L L.J. 173, 178 (2000) [hereinafter Adler, *More Sorry*].

24. See generally EDWARD TENNER, *WHY THINGS BITE BACK: TECHNOLOGY AND THE REVENGE OF UNINTENDED CONSEQUENCES* (1996) (offering numerous examples).

25. The Trinity test moved Robert Oppenheimer to think of a passage from the Hindu scripture in which the god Vishnu says, “Now I am become Death, the destroyer of worlds.” RICHARD RHODES, *THE MAKING OF THE ATOMIC BOMB* 676 (1986).

26. For a dramatic and highly pessimistic description of the consequences of nuclear war, see JONATHAN SCHELL, *THE FATE OF THE EARTH* (1982).

arrangement—they differ sharply from the simpler inorganic insecticides of prewar days.²⁷

Carson referred to these synthetic pesticides as “Elixirs of Death,” because they “have immense power not only to poison, but to enter into the most vital processes of the body and change them in sinister and often deadly ways.” This too is the Frankenstein narrative. Applied to GMOs, GM agriculture holds hugely negative potential for human health and the non-human environment.²⁸ It also poses social risks such as economic dislocation, extinction of the family farm, and political risks like depriving citizens of “meaningful control over technologies that could transform their lives.”²⁹

2. *Fear of the Unknown*

A fundamental concern of GMO opponents is the unknown as such—fears of wholly unanticipated effects, large and small, on humans, the environment, or human society. Such fears are by no means irrational. Theo Colborn, in her indictment of hormone-disrupting chemicals, explains:

This caution does not arise from any propensity for pessimism or dislike of technology. It arises from the very nature of our global experiment and from our inescapable ignorance, which

27. RACHEL CARSON, *SILENT SPRING* 16 (1962).

28. Many of the articles on GMOs begin with overviews of the science of genetic engineering and its potential benefits and risks. A particularly succinct overview can be found in Holly Saigo, Note, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 *GEO INT'L ENVTL. L. REV.* 779, 782-98 (2000). See also Jeffrey K. Francer, *supra* note 22; Sophia Kolehmainen, *Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 *VA. ENVTL. L.J.* 267, 275-87 (2001); Julie Teel, Note, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 *NYU ENVTL. L.J.* 649 (2000).

A good scientific summary can be found in L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 *SCIENCE* 2088 (2000), and Richard Lewontin, *Genes in the Food!*, N.Y. *REV. OF BOOKS*, June 21, 2001, at 81. A comprehensive, detailed treatment of the risks is Royal Soc'y of Can., *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada: An Expert Panel Report on the Future of Biotechnology*, 64 *J. TOXICOLOGY & ENVTL. HEALTH* 1 (2001), available at <http://www.rsc.ca/foodbiotechnology/indexEN.html>. The Canadian government was originally dismissive of the Royal Society of Canada's (RSC) report and produced a strongly pro-GMO response. See CANADIAN BIOTECH. ADVISORY COMM., *IMPROVING THE REGULATION OF GENETICALLY MODIFIED FOODS AND OTHER NOVEL FOODS IN CANADA* (2001), at <http://www.cbac-ccc.ca/documents/GMenglish.pdf>. More recently, however, the government has begun to modify its approach to GMOs to respond to some of the RSC recommendations. See Peter Calamai, *Ottawa Changes Mind on GM Food Report Findings*, *TORONTO STAR*, Aug. 23, 2001, at A16.

29. Shelia Jasanoff, *Product, Process or Programme: Three Cultures and the Regulation of Biotechnology*, in *RESISTANCE TO NEW TECHNOLOGY: NUCLEAR POWER, INFORMATION TECHNOLOGY, AND BIOTECHNOLOGY* 311, 313 (Martin Bauer ed., 1995).

makes it impossible to foresee consequences or guarantee safety. The dilemma is simply stated: the Earth did not come with a blueprint or an instruction book. When we conduct experiments on a global scale by releasing billions of pounds of synthetic chemicals, we are tinkering with immensely complex systems that we will never fully comprehend. If there is a lesson in the ozone hole and our experience with hormone-disrupting chemicals, it is this: as we speed toward the future, we are flying blind.³⁰

While GM technology is often touted as precision breeding, in fact, it is not. While genetic manipulation is precise as to the genetic material (and its trait) that is being removed from one organism and placed in another, it is not precise in determining the full consequences for the host organism. Genes do not generally act alone; they work in tandem, interacting with each other to create the phenotype.³¹ Stephen Palumbi vividly (if hyperbolically) describes “brute-force genetic engineering” (itself a Frankensteinian allusion) as lacking the whole suite of genes that in ordinary natural or artificial selection regulate each other:

Suppose your town wanted a practice area for the Girl Scout rifle team. One option would be to develop a rifle range, complete with professional operators, ear protectors, training classes, and unimpeded targets. Different sites could be compared, evaluated, and tested. Regulations could be developed to fit your community’s priorities and altered as needed to fit emerging needs. That’s one way of proceeding. Another way involves dropping the guns on Main Street and hoping that everything sorts itself out.³²

Moreover, many genes control aspects of an organism—metabolism, aging, reproduction, etc.—that are not immediately apparent. (This, of course, is the source of all the trouble in *Jurassic Park*, Michael Crichton’s novel about genetic engineering.)³³ We simply cannot predict with accuracy all of the effects of a

30. THEO COLBORN *ET AL.*, *OUR STOLEN FUTURE* 242-43 (1997).

31. See Lewontin, *supra* note 28, at 82.

32. Stephen R. Palumbi, *The High-Stakes Battle over Brute-Force Genetic Engineering*, *CHRON. OF HIGHER EDUC.*, Apr. 13, 2001, at B8.

33. MICHAEL CRICHTON, *JURASSIC PARK* (1990).

genetic transfer. The Royal Society of Canada dismisses the idea of “precise” (their quotation marks) genetic modification and warns that “empirical evidence suggests that linear models are not good predictors of complex biological systems.”³⁴

Not only are individual genes being introduced into highly complex genetic structures, but the resultant organisms are being propagated in complex ecosystems.³⁵ This uncertainty, which Shelley powerfully captured in Frankenstein’s refusal to create a bride for his monster,³⁶ gives rise to the concern about superweeds or superpests, that is, genetically modified plants or insects whose traits allow them to invade and dominate ecosystems and to resist control measures. Even if a GMO has been tested and found safe in the ecosystem where it is manufactured, it may have unintended consequences in the many different ecosystems where it is used.³⁷ The experience with exotic species like zebra mussels in the Great Lakes is sobering. They have had profoundly negative effects on their new ecosystems and have proven difficult or impossible to eradicate.³⁸ GMOs could be worse, because of the unlimited potential of genetic design.

At the field level, another major concern, genetic “pollution” of non-GMO species or strains with genetically modified ones, is highly likely, if not inevitable.

Once GM salmon, for example, are introduced into the wild (which has already happened accidentally),³⁹ or GMO crops are grown in the field (100 million acres in 2000),⁴⁰ it is simply impossible to keep the salmon or the pollen entirely confined. To the extent that the genetic modification confers advantages for survival, the new variety could take over existing genotypes, either by themselves or by hybridization with neighboring species. Even if GMOs do not become superweeds and superpests, this pollution will limit the biodiversity that is essential to healthy ecosystems and sustainable agriculture.

34. Royal Soc’y of Can., *supra* note 28, at 184-85.

35. Monocultural agriculture is not all that complex—indeed, the goal is to simplify and so control the ecosystem—but some of the genetic material will almost inevitably leak into the surrounding, uncontrolled environment.

36. “I was now about to form another being, of whose dispositions I was alike ignorant; she might become ten thousand times more malignant than her mate. . . .” SHELLEY, *supra* note 8, at 167.

37. Gareth W. Schweizer, Note, *The Negotiation of the Cartagena Protocol on Biosafety*, 6 ENVTL. LAWYER 577, 584 (2000).

38. See Jonathan H. Adler, *The Cartagena Protocol and Biological Diversity: Biosafe or Bio-Sorry?*, 12 GEO. INT’L ENVTL. L. REV. 761, 774-75 (2000) (arguing that xenobiotics are a serious threat to biodiversity but that the Cartagena Protocol does not regulate them) [hereinafter Adler, *Biosafe*].

39. Royal Soc’y of Can., *supra* note 28, at 150-52.

40. Moore, *supra* note 13, at 31.

The problem of unintended consequences also appears with GMOs that make their own pesticides. A now-famous Cornell study showed that monarch butterflies could be harmed by the pollen of maize plants that had been modified to express Bt toxin.⁴¹ (Further studies, conducted at more environmentally likely levels of pollen, seemed to confirm this result,⁴² though a more recent group of studies commissioned by the U.S. Department of Agriculture suggests that the threat to monarchs is quite limited.⁴³) This raises the possibility that plant-produced pesticides, even if they reduce the use of traditional pesticides,⁴⁴ still harm non-target species. Similarly, the destruction of soil microbes could significantly alter the quality of soils, with severe effects.⁴⁵

Opponents of GMOs further contend that new crops could contain toxicants that are either entirely novel or which do not appear (or not in dangerous quantities) in the non-GM version of the food. There have not as yet been injuries to humans in this way, but the power of the new technology and the impossibility of predicting the interactions of many genes suggest the possibility. What has appeared is the transfer of allergens from one food to a very different one through the use of genetic material from the allergen. Food allergies, especially extremely severe ones, are on the rise,⁴⁶ and it is difficult to know what will trigger an allergic reaction. Serious harm was averted when the genes of a Brazil nut were placed in soybeans, and it was discovered in the pre-market phase that the gene

41. See John E. Losey et al., *Transgene Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999).

42. Royal Soc'y of Can., *supra* note 28, at 144.

43. See Richard L. Hellmich et al., *Monarch Larvae Sensitivity to Bacillus Thuringiensis-purified Proteins and Pollen*, 98 PROC. NAT'L ACAD. SCI. U.S. AM. 11925-11930 (2001), available at <http://www.pnas.org/cgi/content/full/98/21/11925>; Karen S. Oberhauser et al., *Temporal and Spatial Overlap between Monarch Larvae and Corn Pollen*, 98 PROC. NAT'L ACAD. SCI. U.S. AM. 11913-11918 (2001), available at <http://www.pnas.org/cgi/content/full/98/21/11913>; John M. Pleasants et al., *Corn Pollen Deposition on Milkweeds in and Near Cornfields*, 98 PROC. NAT'L ACAD. SCI. U.S. AM. 11919-11924 (2001) available at <http://www.pnas.org/cgi/content/full/98/21/11919>; Mark K. Sears et al., *Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment*, 98 PROC. NAT'L ACAD. SCI. U.S. AM. 11937-11942 (2001), available at <http://www.pnas.org/cgi/content/full/98/21/11937>; Diane E. Stanley-Horn et al., *Assessing the Impact of CryIAb-expressing Corn Pollen on Monarch Butterfly Larvae in Field Studies*, 98 PROC. NAT'L ACAD. SCI. U.S. AM. 11931-11936 (2001), available at <http://www.pnas.org/cgi/content/full/98/21/11931>.

One of the studies demonstrated, however, that a particular variety of GMO maize, Novartis Cry 176, produces Bt pesticide at much higher concentrations and has proven quite harmful to non-target butterflies. See A. R. Zangerl et al., *Effects of Exposure to Event 176 BacillusThuringiensis Corn Pollen on Monarch and Black Swallowtail Caterpillars under Field Conditions*, 98 PROC. NAT'L ACAD. SCI. U.S. AM. 11908-11912 (2001), available at <http://www.pnas.org/cgi/content/full/98/21/11908>.

44. See generally Kathryn Brown, *Seeds of Concern*, SCI. AM., Apr. 2001, at 52, 52-53 (reporting that pesticide use drops with some crops but not with others).

45. Royal Soc'y of Can., *supra* note 28, at 107-15.

46. Susan Dominus, *The Allergy Prison*, N.Y. TIMES MAG., June 10, 2001, at 62, 64.

transmitted a common and severe allergy to Brazil nuts. Allergies are probably the most widely acknowledged concern with GMO foods.

The astonishing rate at which GMO acreage has grown in the United States creates additional unknowns. As we now know, ecosystems are dynamic, so it is no criticism of GMOs that they upset the “balance” of nature. However, when the changes are massive and quick—the extreme example is the dinosaur-killing asteroid—the change outpaces the natural ability to adjust. An editorial in the *Toronto Star* summed up this concern with a rhetorical question: “[I]f you are driving down a steep winding road in the dark and your lights go out, do you drive faster or pull over and reconsider your options?”⁴⁷ The speed of introduction also means that we have no long-term experience with these organisms. Current screening mechanisms can reassure us about short-term issues (allergies, for example), but cannot predict the consequences of long-term presence in the environment.⁴⁸ The changes wrought by new creations, furthermore, may be irreversible. As Stephen Tromans describes it: “[The] behavior and characteristics [of GMOs] in the environment, once released, cannot readily be known. As living entities, they will multiply, adapt, evolve, and interact in ways that traditional inanimate pollutants cannot. Once released, they cannot be recalled, retrieved or neutralized.”⁴⁹ Dr. Frankenstein worried about precisely this problem: female monster might engender a “race of devils [that] would be propagated upon the earth.” GMOs, in sum, provide ample material for fear of the unknown.

The related fear of catastrophe, on the other hand, arises mainly with regard to the potential effects of so-called superweeds and superpests on the non-human environment.⁵⁰ If genetic technology can create new species, it seems entirely plausible that one of them could be adapted to varying conditions, propagate itself readily, and crowd out other species. Such organisms are called “weedy” (this can apply to animals like rats and pigeons, as well as to plants) and examples of

47. Ann Clark, *Contradictory Reports Baffle Public*, TORONTO STAR, Aug. 29, 2001, at A22.

48. Julian Kinderlerer, *Genetically Modified Organisms: A European Scientist's View*, 8 N.Y.U. ENVTL. LJ. 556, 558 (2000).

49. Stephen Tromans, *Promise, Peril, Precaution: The Environmental Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 187, 188.

50. See Kate Graziano, Note, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 179, 188 (1996) (arguing that “agriculture worldwide is at risk”). Jonathan Adler, a supporter of GMO technology, quotes several of the more hyperbolic claims for the dangers of GMOs. Adler, *More Sorry*, *supra* note 23, at 173-75.

naturally occurring xenobiotics abound.⁵¹ Increasing weediness is a concern of ecologists even in the absence of GMOs,⁵² genetic modification intensifies the concern. Superpests are organisms, for example, insects, that are not themselves created by genetic engineering, but that evolve into extremely resistant varieties in response to GM plant pesticides. The phenomenon already occurs with conventional pesticides—it is known as the pesticide treadmill—and the concern is that GM technology would greatly accelerate the process.

A different kind of catastrophe could befall agriculture in the developing world due to social and economic dislocation. While GM technology is often justified in terms of improving the yields of Third World agriculture, GMOs so far have been designed to facilitate large-scale, “industrial” agriculture which is monocultural (hence ecologically fragile) and relies heavily on inputs of pesticides and fertilizers. Expansion of American-style agriculture means sales of American seeds, fertilizers, and pesticides, reinforcing the economic dominance of North over South. These changes could undermine the small-scale, adaptable

51. See David Quammen, *Planet of Weeds: Tallying the Losses of Earth's Animals and Plants*, HARPERS, Oct. 1998, at 67. Quammen defines “weediness” as:

a constellation of characteristics: They reproduce quickly, disperse widely when given a chance, tolerate a fairly broad range of habitat conditions, take hold in strange places, succeed especially in disturbed ecosystems, and resist eradication once they're established.

They are scrappers, generalists, opportunists. They tend to thrive in human-dominated terrain because in crucial ways they resemble *Homo sapiens*: aggressive, versatile, prolific, and ready to travel.

Id.

52. Quammen writes:

Wildlife will consist of the pigeons and the coyotes and the white-tails, the black rats (*Rattus rattus*) and the brown rats (*Rattus norvegicus*) and a few other species of worldly rodent, the crab-eating macaques and the cockroaches (though, as with the rats, not every species—some are narrowly endemic, like the giant Madagascar hissing cockroach) and the mongooses, the house sparrows and the house geckos and the houseflies and the barn cats and the skinny brown feral dogs and a short list of additional species that play by our rules. Forests will be tiny insular patches existing on bare sufferance, much of their biological diversity (the big predators, the migratory birds, the shy creatures that can't tolerate edges, and many other species linked inextricably with those) long since decayed away. They'll essentially be tall woody gardens, not forests in the richer sense. Elsewhere the landscape will have its strips and swatches of green, but except on much-poisoned lawns and golf courses the foliage will be infested with cheatgrass and European buckthorn and spotted knapweed and Russian thistle and leafy spurge and salt meadow cordgrass and Bruce Babbitt's purple loosestrife. Having recently passed the great age of biogeography, we will have entered the age *after* biogeography, in that virtually everything will live virtually everywhere, though the list of species that constitute “everything” will be small. . . . My label for that place, that time, that apparently unavoidable prospect, is the Planet of Weeds. Its main consoling felicity, as far as I can imagine, is that there will be no shortage of crows.

Id. at 67-68.

agricultural practices of developing economies, with disastrous results. So far, it is fair to say that biotechnology has “not yet delivered” on its promises of great benefits for the poor of the world, as opposed to great benefits for the multinationals that provide the bio-engineered products.⁵³

3. *GMOs as Doppelgangers*

GMOs raise fears of the unknown, but they also, paradoxically, raise fears of the familiar. They represent the special dread of the seemingly innocent and familiar that harbor in which great danger. Frankenstein’s monster in some ways seems an odd symbol for this particular fear; the monster is hideous, and much of the pathos of the story derives from people’s hostile reaction to his appearance. At the same time, however, Frankenstein’s monster is human—almost. Much of the horror of the tale comes from the monster’s closeness to humans. Frankenstein gets his materials from “the dissecting room and the slaughterhouse,”⁵⁴ and when he destroys the not-yet-animated bride he says, “I almost felt as if I had mangled the living flesh of a human being.”⁵⁵ Rachel Carson tapped into the same fear in describing “sinister” chemicals that mimic and then pervert normal metabolic functions.⁵⁶ The growing concern with endocrine-disrupting chemicals is based on their ability to mimic naturally occurring hormones sufficiently to deceive and alter the processes that the hormones control.

Many commentators have puzzled over the vociferousness of the public reaction to GMOs in Europe, when so many other forms of modern technology are readily accepted and relied upon. While there are undoubtedly many factors at work (Moore points to a fundamental loss of faith in European government institutions in the wake of Mad Cow disease and Furans in Belgian chicken feed⁵⁷), the Frankenstein narrative suggests this underlying reason. Allergies are a good example. People with severe allergies need to be very watchful of the

53. Kinderlerer, *supra* note 48, at 557. From this perspective, the use of the needs of developing countries as a justification for expanded use of GMOs seems hollow, if not disingenuous. See, e.g., Adler, *Biosafe*, *supra* note 38, at 772-74; INDUR M. GOKLANY, APPLYING THE PRECAUTIONARY PRINCIPLE TO GENETICALLY MODIFIED CROPS (Wash. U. Center for the Study Am. Bus., Policy Study No. 157, 2000).

54. SHELLEY, *supra* note 8, at 58.

55. *Id.* at 172 (emphasis added). Rollin notes that mixing animal and human traits is often viewed as a particular wrong. ROLLIN, *supra*, note 14, at 63-66.

56. This concern has come to fruition in the work of Theo Colborn and her colleagues, who found that many synthetic pesticides mimic and pervert the function of hormones. See COLBORN, *supra* note 30.

57. Moore, *supra* note 13, at 33.

ingredients in their foods—nuts, and especially peanuts, to which many people are severely allergic, tend to appear in unlikely places—and they need to be able to rely on “safe” foods that they know from experience have no allergenicity for them. Genetic engineering could contribute to the spread of modified crops into the pool of unmodified crops. If widely grown, the pollen of an allergenic variety could rapidly invade non-allergenic varieties, and it would become impossible to find a variety without the allergy-causing gene.⁵⁸ Similarly, GM technology could reduce the nutritional content of food (a concern more relevant to the developing than the developed world), but would give no notice of the change. In both cases, the deceptive familiarity of GMOs causes the concern.

B. Better Living Through Chemistry

1. The Progress Narrative

Against the technological pessimism reflected in the Frankenstein narrative must be set the grand tradition in western culture of scientific inquiry and technological achievement. While admiration for science may be on the wane in popular culture, citizens of industrialized nations owe virtually every aspect of the previously unimaginable opulence of their lives to triumphs of science and technology. Say what we will about the fruit of the Tree of Knowledge, every time we turn on a computer or drive a car or watch television or speak on the telephone—the list is really endless—we are taking advantage of a host of technologies that were hardly even dreamt of two hundred years ago.

The narrative of progress, and specifically of scientific and technological progress, is exemplified by the title and subject of a mural by John W. McCoy II, a Brandywine School painter, called *Better Things for Better Living Through Chemistry*.⁵⁹ McCoy painted it for “Wonder World of Chemistry,” the DuPont exhibit for the 1939 World’s Fair. The mural depicts, on the left, a dark and forbidding picture of American frontier life, complete with log cabin and dirt path. The characters are a worried mother, clinging children, and a father bent nearly

58. The problem with Starlink maize illustrates the problem. Starlink was approved for animals, not humans, but somehow it was mixed with maize intended for humans—there is no obvious difference in appearance, and no cheap test for the difference. While the distributors and buyers of the maize made every effort to recall the food products made with Starlink, it keeps turning up in unexpected places.

59. The mural was donated in 1999 to the Hagley Museum and Library in Wilmington, Delaware. Dupont Newsroom, *Dupont Donates Historic Worlds’ Fair Mural to Hagley Museum and Library* (July 7, 1999), available at <http://dupont.com/corp/whats-new/releases/99/990707a.html>.

double with a heavy burden of sticks on his back. On the right, symmetrically arranged to heighten the contrast, we find a happy modern family at play. The daughter no longer clings, but looks out from her picnic-basket-carrying mother's side with anticipation. The father's only burden is a smiling, healthy little boy who waves cheerily to the viewer. A shining city (the Wilmington of Tomorrow?) lies in the background. Separating Before and After, like a bolt of lightning, is a muscular, laurel-wreathed man, labeled "Chemistry," with a beaker in one hand and a tome in the other. The mural is striking on a number of cultural points—especially its negative portrayal of frontier life—but it powerfully conveys a firm confidence in the ability of science and technology to transform our world for the better.⁶⁰ There is no hint of social complication from these wonders of chemistry.

Technological optimism has a historical tradition of its own. The highly successful tradition of systematic scientific inquiry in public health, for example, has yielded longer life expectancies and lower infant and maternal mortality than has ever been enjoyed by anyone on the planet. (Which is not, of course, to say that the benefits are evenly distributed; manifestly, they are not.) Great discoveries like vaccines and antibiotics have saved or improved the lives of millions and millions. And importantly, many of these improvements have been industrial, as the McCoy mural suggests. Penicillin was of little consequence until the industrial capacity and technological know-how of the American chemical industry was put to work to culture, refine, and package the antibiotic on a massive scale.

There is also a strong cultural tradition of faith in Progress, which Christopher Lasch traced over time and cultural milieux in *The True and Only Heaven*. This tradition (of which Lasch was a critic) promised "a steady improvement with no foreseeable ending at all" of the quality and comfort of human life.⁶¹ As James Krier and Clayton Gillette put it, "[t]he [technological] optimists believe in unending human ingenuity, or at least human ingenuity with

60. It is extremely difficult to capture this confidence today without inviting irony, not to say sarcasm. The enormous technological advances of the second half of the twentieth century have been irretrievably tarnished by their hazards, so their images tend to have baggage attached. The phrase, "Our Friend the Atom," (from HEINZ HABER, *THE WALT DISNEY STORY OF OUR FRIEND THE ATOM* (1956). For all its shameless boosterism, it is actually quite informative.) as another example, is universally accompanied by a sneer. This underscores the visceral power of the Frankenstein narrative: we are virtually programmed to regard new technologies as disasters waiting to happen.

61. See CHRISTOPHER LASCH, *THE TRUE AND ONLY HEAVEN: PROGRESS AND ITS CRITICS* 39, 48-9 (1991).

no foreseeable limit.”⁶² The driver for the application of this ingenuity is the “uniform, constant, and uninterrupted effort of every man to better his condition,” in the words of Adam Smith.⁶³ If there is something unsettling about this constant movement from one state to another—

impermanence appears to assure a certain continuity in its own right when conceived as an extension of the self-correcting procedures of scientific discovery, which allow the scientific enterprise as a whole to flourish in spite of the constant revision of particular findings. A social order founded on science, with its unnerving but exhilarating expansion of our intellectual horizons, seems to have achieved a kind of immortality undreamed of by earlier civilizations.⁶⁴

Technology, in this view, may offer new and even frightening prospects, but it is part of a far larger—and to some extent inexorable—project of improvement. Moreover, to the extent that scientific and technical process has in fact paralleled increased material abundance, freedom, and human happiness, there is little reason to question faith in it.⁶⁵

2. *The Continuation of Breeding by Other Means*

In the Better Living Through Chemistry narrative, genetic modification is a technology of enormous power and promise.⁶⁶ Even limiting our consideration to agriculture, the range of plausible applications is impressive: GM technology can improve yield, provide protection against pests with fewer pesticides, conversely resist pesticides and herbicides, increase nutritional value, decrease susceptibility to drought, and permit cultivation of saline soils. Further, supporters of GMOs

62. James E. Krier & Clayton P. Gillette, *The Un-Easy Case for Technological Optimism*, 84 MICH. L. REV. 405, 409 (1985).

63. LASCH, *supra* note 61, at 53.

64. *Id.* at 48.

65. Alain Touraine, *The Crisis of Progress*, in RESISTANCE TO NEW TECHNOLOGY: NUCLEAR POWER, INFORMATION TECHNOLOGY, AND BIOTECHNOLOGY 45, 47 (1995). Touraine argues that the current crisis in belief in progress occurred when scientific progress seemed to drift away from these benefits, and also seemed to take control from individuals and give it to large institutions, governments, or international organizations. *See id.* at 48-51.

66. For fairly typical encomiums to the promise of biotechnology, see Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 719 (2000); Adler, *Biosafe*, *supra* note 38; Adler, *More Sorry*, *supra* note 23, at 175-80.

like to point out that GM technology is central to the achievement of several important and widely shared goals, such as sustainable agriculture, a nutritionally adequate food supply for the developing world, and the reduction of expensive and destructive pesticide use. For example, it is argued that as a secondary effect GMOs will help to *protect* biodiversity. The greatest threat to biodiversity is habitat loss; therefore, by increasing the agricultural (and nutritional) productivity of existing farmland, GMOs can reduce the pressure to use more and increasingly marginal non-farm habitat.⁶⁷ While it may be debated whether GMOs in fact will play a major role in achieving these goals and whether there are other ways to achieve them—new conventional agricultural techniques, better distribution of existing food supplies, etc.—the potential, at the very least, is there.

In short, “the promising future of Bt-corn and GM-crops in general appears endless.”⁶⁸ It is true that many of these benefits have yet to be realized in practice. Almost all of the advances in GMOs have so far been directed to agricultural profitability (a predictable result, in view of the commercial funding of the research)⁶⁹ and only a small number of crops have yet been planted in significant acreage.⁷⁰ Nevertheless, the technological optimists believe that significant benefits are just around the corner. Given the extraordinarily rapid progress of the technology to date, this is not an unreasonable expectation.

Despite the great possibilities of GM technology, the Better Living Through Chemistry narrative also emphasizes that, fundamentally, it is but the continuation of breeding by other means, an incremental refinement of existing practices. “Genetic modification appears to be part of the normal and well-established

67. Adler, *Biosafe*, *supra* note 38, at 766-68, 771-74; INDUR M. GOKLANY, CTR. STUDY AM. BUS., POLICY STUDY NO. 157, APPLYING THE PRECAUTIONARY PRINCIPLE TO GENETICALLY MODIFIED CROPS 4 (Aug. 2000). The seeming logic of this claim is undercut by two facts: first, there has yet to be any significant deployment of GM crops in areas of the world that are not already awash in surplus agricultural production, so it is strictly hypothetical; and second, no matter how good they are, genetically modified crops are unlikely to be able to relieve the extreme poverty of the developing world so much that third world farmers would no longer have any incentive to seek out new farmland.

68. Kurt Buechle, *The Great Global Promise of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety*, 9 IND. J. GLOBAL LEGAL STUD. 283, 288 (2001).

69. Ellen Messer, *Food Systems and Dietary Perspective: Are Genetically Modified Organisms the Best Way to Ensure Nutritionally Adequate Food?*, 9 IND. J. GLOBAL LEGAL STUD. 65 (2001). Arguably, this is the financially necessary precursor to innovation for the public good. See Buechle, *supra* note 68.

70. According to Hagen & Weiner, “Soybean, corn/maize, cotton, and canola/rapeseed accounted for most of the transgenic crop plantings in 1999. Transgenic potato, squash, and papaya also were commercially planted in 1999 but represented less than one percent of the global area planted in GMO crops.” Paul E. Hagen & John Barlow Weiner, *The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms*, 12 GEO. INT’L ENVTL. L. REV. 697, 699 (2001). The world total area of GMO crop plantings was 39.9 million hectares in 1999, of which 72% was in the United States. *Id.* at 698.

trajectory of gaining control over and manipulating biological processes to achieve greater productivity.⁷¹ Thus, it “makes [no] sense to talk about ‘natural’ food crops that are the result of thousands of years of human husbandry.”⁷² Genetic modification is just faster, more precise, and can draw on a greater range of genetic material.⁷³ As Richard Lewontin puts it, while genetic modification is “a radically new way to manipulate heredity,” even the old way created “organisms that are not only very different from their wild ancestors, but are in many characteristics the very opposite of the organisms from which they were derived.”⁷⁴ The entities resulting from genetic modification are thus within the range of normal manipulation—a GM soybean is still recognizably a soybean, even if a fish gene has been added. While the Frankenstein narrative emphasizes unknown and catastrophic effects, the Better Living Through Chemistry narrative places GMOs in the far more comforting context of incremental change in existing breeding practices.

If GM technology is not entirely new and unknown, its risks are not, either. The risks of genetic pollution, creation of exceptionally aggressive weedy species, and unrecognized allergens are not only small but, more importantly, *manageable* with proper care.⁷⁵ The direct, demonstrated harms from GMOs are, at worst, few and far between, and there is no real evidence of catastrophe on the horizon.⁷⁶ Pest resistance can be handled by creating refuges that will reduce the incentive for new, super strains of insect pests to multiply, by maintaining the selective advantage of existing strains in certain areas. The spread of superweeds can be avoided by buffer zones, which can also act as refuges. Moreover, superweeds are a self-limiting problem, since crop species are highly fragile and occupy an extremely specialized ecological niche (i.e., farms) that must be maintained by extensive human intervention.⁷⁷ Wheat, to put in another way, does not stand a chance in the real world; it can only survive when carefully

71. Stephen B. Brush, *Genetically Modified Organisms in Peasant Farming: Social Impact and Equity*, 9 *IND. J. GLOBAL LEGAL STUD.* 135, 137 (2001).

72. Kevin Finneran, *What's Food Got to Do With It?*, 17 *ISSUES SCI. & TECH.* 24, 25 (2001).

73. Conventional breeding is not limited to species (e.g., horse + donkey = mule), but the species must be closely related; fish cannot mate with strawberries except through genetic engineering.

74. Lewontin, *supra* note 28, at 81.

75. See Deborah Katz, *The Mismatch Between the Biosafety Protocol and the Precautionary Principle*, 13 *GEO. INT'L ENVTL. L. REV.* 949, 967-75 (2001).

76. See Lewontin, *supra* note 28, at 83; see also Brown, *supra* note 44, at 55 (reviewing the evidence for superweeds).

77. Lewontin, *supra* note 28, at 82-83 (citing JANE RISSLER & MARGARET MELTON, *THE ECOLOGICAL RISKS OF ENGINEERED CROPS* (1996)).

nourished and protected. As a result, GM crops have not in actuality lead to the loss of natural habitats. In any event, exotic species (kudzu, zebra mussels) already pose the superweed problem, and, while annoying, they have not seriously threatened human health or civilization. Finally, allergies—the most credible problem—can be predicted to some degree (e.g., using nut genes in non-nut products) and can be screened in advance.⁷⁸

The problem of harm to non-target species is a case in point. Whether or not extrapolation of the Cornell study of monarch butterflies is justified (a hotly debated subject),⁷⁹ GMO proponents note that effects on non-target organisms are a familiar and indeed inherent problem with *all* pesticides. Rachel Carson's plea to end the indiscriminate use of DDT and other synthetic pesticides was based largely on non-target effects to humans and other animals. Federal law requires the analysis and consideration of non-target effects in the registration of a pesticide.⁸⁰ It is not a new problem at all, and it can be controlled (if not entirely avoided) by good pesticide application practices. Such practices can, with some ingenuity, be translated to the use of GM pesticide plants.

Many of the criticisms of GMOs are in fact retooled critiques of monoculture generally and industrial agriculture specifically (which, from the Better Living Through Chemistry point of view, makes perfect sense, since GMOs are but an extension of modern agricultural practices).⁸¹ A good example is the experience in the Philippines with a whole series of conventional rice hybrids, each of which seemed better than the traditional varieties but each of which succumbed to some aspect of the Philippine environment. When the inventors gave up and tried to return to the original varieties, they had been "all but eliminated" when farmers switched to the first hybrid.⁸² This misadventure, like the risk of a general blight

78. Proponents of GMOs like to use the analogy of fire. It certainly poses serious dangers, ranging from severe burns on an individual to conflagrations encompassing human or natural communities, but it is also eminently controllable. And when its benefits are measured against these risks, there is simply no question of its net desirability. At a minimum, we can and should draw distinctions among uses of GMOs in terms of their risks, ability to control, and benefits. The RSC report, for example, convincingly demonstrates that the risks of genetic pollution by transgenic animals, specifically fish, are more serious, because of their much greater ability to mix with other populations. Similarly, to continue the fire analogy, the use of controlled burns is appropriate for some objects, in some places, and in some conditions, but not in others.

79. See *infra* text accompanying notes 39-41.

80. See 7 U.S.C. § 136a(5) (2000).

81. See generally David Pimentel, *Overview of the Use of Genetically Modified Organisms and Pesticides in Agriculture*, 9 IND. J. GLOBAL LEGAL STUD. 51 (2001) (evaluating GM plant pesticides as substitutes for conventional pesticides).

82. Saigo, *supra* note 28, at 794-95.

affecting an entire genetically identical crop,⁸³ has everything to do with monoculture and little to do with source of the monocultured crop. Likewise, the pesticide treadmill may well be replicated by pesticide-producing GM crops, but that is all—there is no *special* treadmill effect.⁸⁴ Resistance to the Bt pesticide in GM maize is the same problem as resistance to Bt that is sprayed on maize (used by organic farmers), because the same chemical is involved. A joint study by several national academies of sciences emphasizes, in addition, that “[m]odern agriculture is intrinsically destructive of the environment” and so “the environmental risks of new GM technologies need to be considered in the light of the risks of continuing to use conventional technologies.”⁸⁵

Surprisingly, in view of the European Union’s general anti-GMO stance, a new report by the European Commission takes essentially the same position. It concludes that its biosafety research to date “has not shown any new risks to human health or the environment, beyond the usual uncertainties of conventional plant breeding.” Moreover, “if there are unforeseen environmental effects—none have appeared as yet—these should be rapidly detected by [EU] monitoring requirements.”⁸⁶ Even though the Commission takes GMO risks seriously (which many GMO proponents do not), it also regards them as manageable with existing safeguards, like other agricultural risks.

II. TWO REGULATORY APPROACHES

The Frankenstein and Better Living Through Chemistry narratives have become the templates for the two dominant regulatory approaches to GM technology. Regulators in Europe and United States approach GMOs in dramatically different ways. The fundamental technical difference is well known:

83. *Id.* at 795-96.

84. With respect to a single pesticide, the widespread use of the GM crop may hasten the resistance effect. This is the concern of many organic farmers who use the Bt toxin as an external pesticide for their crops; if this pesticide is used by nonorganic farmers as well—thus increasing the amount of use enormously—then the process of resistant varieties of insects may be sped up. On the other hand, the same would be true if nonorganic farms simply decided to use Bt as an external pesticide, avoiding any GM involvement at all.

85. ROYAL SOC’Y OF LONDON et al., *TRANSGENIC PLANTS AND WORLD AGRICULTURE* 19 (2000), available at <http://www.nap.edu/html/transgenic>. The report was written by a working group comprised of members from the United Kingdom, United States, Brazil, China, India, Mexico, and the Third World Academy of Sciences. See also Pimentel, *supra* note 81 (making this point about pesticides).

86. Press Release, European Commission, *GMOs: Are There Any Risks? Launch of a European Round Table on GMO Safety* (Oct. 8, 2001), <http://europa.eu.int/comm/research/press/2001/pr0810en.html>; see also EUROPEAN COMM’N, *EC-SPONSORED RESEARCH ON SAFETY OF GENETICALLY MODIFIED ORGANISMS: A REVIEW OF RESULTS*, <http://europa.eu.int/comm/research/quality-of-life/gmo> (last visited Nov. 18, 2001).

opponents of GMOs would regulate any item derived through the GM *process*, while proponents would regulate only the characteristics of the finished *product*. I will show in this section that the product-versus-product difference is one of several important ways in which European and American regulatory structures diverge to a degree that severely challenges the ability of international environmental and trade law to harmonize them.

A. Process-Based Regulation

The principal concerns raised by the Frankenstein narrative are the unknown and unintended consequences of the technology, the potential for catastrophic and irreversible invasions of alien species, and familiar products that hide malign characteristics. These concerns cannot be expiated by identifying individual products as safe or unsafe by conventional measures, because the products have not been created in conventional ways and their dangers are as yet unknown. The danger is not the apparent characteristics of the product, but genetic modification *as such*, and a process-based regulatory regime is designed to anticipate and prevent these harms.

The European Union's regulation of GMOs is built on this model.⁸⁷ Agricultural GMOs are regulated by two major legal structures: Directive 2001/18⁸⁸ (which replaced Directive 90/220⁸⁹) on the marketing and release of GMOs into the environment, and Regulation 248/97⁹⁰ concerning novel foods, which will probably be replaced in the near future.⁹¹ The recitals preceding 2001/18 emphasize the Bride-of-Frankenstein fears of reproduction in the environment and irreversibility. In addition, the EU has imposed a *de facto*

87. See generally Tromans, *supra* note 49. For useful overviews of the EU regulatory scheme, see also A. Bryan Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union," 22 LOY. L.A. INT'L & COMP. L. REV. 453 (2000); Jeffrey K. Francer, *supra* note 22; Les Levidow et al., *Genetically Modified Crops in the European Union: Regulatory Conflicts as Precautionary Opportunities*, 3 J. RISK RESEARCH 189 (2000); Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243 (1999).

88. Council Directive 2001/18/EC, 2001 O.J. (L 106) 1.

89. Council Directive 90/220/EEC, 1990 O.J. (L 117) 15.

90. Council Regulation 258/97, 1997 O.J. (L 043) 1.

91. See Commission Proposal for Regulation on Genetically Modified Food and Feed, COM (2001) 425 final [hereinafter Labeling Proposal].

moratorium on new approvals of GM products until the Commission finalizes new rules for labeling and traceability.⁹²

The requirements of the EU regulatory scheme—notification, proof of safety, labeling, and so on—apply to all GMOs regardless of their individual characteristics (though Directive 2001/18 provides a “differentiated” (i.e., streamlined) procedure for well-known GMOs⁹³). Under the existing novel foods regulation, a GM food that is substantially equivalent to its conventional counterpart is exempt from pre-market approval, but not from labeling.⁹⁴ The proposed new version goes further and abandons even the special approval procedure for substantially equivalent products.⁹⁵ It is the process, and not the final product, that matters.

Both pieces of legislation centralize and politicize⁹⁶ regulation of GMOs. Under Directive 2001/18, initial notification of the proposed release or marketing of a GMO is made to the member state where it will occur, and the member state’s eventual consent to release or marketing is, as usual in a common market system, binding on the other member states. Here, however, devolution ends. The initial notification, including a rather vast amount of information supporting the application, is communicated, through the Commission, to all of the other member states. They may comment or object, and the handling of objections is not symmetrical. If there are no objections (and that has never happened⁹⁷), the notification state may approve or not, as its own judgment dictates. However, under the new GMO directive, if there are objections that are not resolved or agreed to by the notification state, then the matter must be resolved by the Commission, advised by a special committee of all members voting by qualified majority, with disagreements resolved at the Council and Parliament level.⁹⁸ (The old directive also elevated such disputes to the Council for resolution; consent could only be granted if the Council agreed to it.) The proposal for novel foods goes even further in centralizing and politicizing these decisions by vesting an

92. Patrice Laget & Mark Cantley, *European Response to Biotechnology: Research, Regulation, and Dialogue*, 17 ISSUES IN SCI. & TECH. 37, Summer 2001, at 37, 40.

93. Council Directive 2001/18/EC, art. 7, Annex V, 2001 O.J. (L 106) 1.

94. Council Regulation 258/97, art. 8, 1997 O.J. (L 043) 1.

95. Labeling Proposal, *supra* note 91, recital (6).

96. I do not use “politicize” pejoratively. To the extent that the process broadens the debate beyond narrow quantitative measures, it is a good thing.

97. Endres, *supra* note 87, at 468.

98. Council Directive 2001/18, arts. 13, 18, 30(2), referencing Council Decision 1999/468/EC arts. 5, 7.

initial opinion in the new European Food Authority. The final decision is taken by the Commission, but it can be appealed to the Council by any member state.⁹⁹

The EU legislation does not directly address the question of burden of proof in these proceedings, but it quite plainly lies with the proponent of the GMO. Structurally, the legislation establishes a baseline of no releases, no marketing, and no use as or in food; prior consent is required.¹⁰⁰ Before release, marketing, or food use, the applicant must submit a comprehensive battery of scientific information, set out in detail in the legislation, demonstrating human and environmental safety. Similar provisions for pesticide regulation in the United States are read by U.S. courts to place the burden of proof on the registrant of the pesticide,¹⁰¹ and there seems no reason that the same logic should not apply here.

Finally, the EU directives and regulations offer member states a great deal of flexibility in responding to GMOs by permitting objections by any member state—as noted above, at least one state has objected to every application to date—by setting no limitations on the conditions of consent, and by permitting the later withdrawal of consent.¹⁰² A flexible response to GMOs is a hallmark of the anti-GMO position,¹⁰³ and it responds directly to the fear of the unknown in the Frankenstein narrative. This flexibility has been curtailed somewhat by a recent decision of the European Court of Justice, which insisted that only *new* information can serve as the basis for withdrawing consent.¹⁰⁴ Similarly, one can read the Commission's narrow interpretation of the precautionary principle—insisting, among other things, on detailed scientific and economic investigation in advance of invoking the principle, on a “proportionate response,” and on further research when it is invoked—as an effort to rein in this flexibility.¹⁰⁵ Nevertheless, six member states have stated that they will suspend new authorizations for GMOs pending adoption of new legislation on tracing, labeling, and environmental liability.¹⁰⁶ On the whole, then, the European system is dominated by the concerns of the Frankenstein narrative.

99. Labeling Proposal, *supra* note 91, arts. 7, 8, 36.

100. Council Directive 2001/18, art. 19 is absolutely explicit about this.

101. *See* *Env'tl. Def. Fund v. EPA*, 548 F.2d 998 (D.C. Cir. 1976) (use of heptachlor/chlordane).

102. Council Directive 2001/18, art. 23 (“safeguard clause”).

103. Aarti Gupta, *Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?*, 9 *IND. GLOBAL LEGAL STUD.* 260.

104. Case C-6/99, *Greenpeace v. Map*, 2000 ECJ CELEX LEXIS 2746, at *30, 31.

105. *See* discussion *infra* Part III.C.2.

106. Tromans, *supra* note 49.

B. Product-based Regulation

In the Better Living Through Chemistry narrative, the potential harms of GMOs are simply a continuation of existing risks, and therefore they are knowable and manageable. The regulatory treatment of GMOs by the United States and the World Trade Organization reflects this approach.

1. The United States

In the United States, regulation of GMOs has followed the Coordinated Framework for Biotechnology that was developed in 1986 by the White House Office of Science and Technology Policy to organize the activities of the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Department of Agriculture (USDA).¹⁰⁷ Each agency already had laws on the books that could in theory reach the uses of biotechnology—as crops, foods, medicines, pesticides, and as potentially toxic substances—and the Coordinated Framework chose to use them. This fundamental choice implies that GMOs are not so new as to require new legislation¹⁰⁸ and that regulation of GMOs should proceed as it does with familiar substances, on a product-by-product basis.¹⁰⁹ These two explicit assumptions fit hand-in-glove with the foundational idea of the Better Living Through Chemistry narrative, that GM technology is simply a continuation of existing breeding and selection technology.

This approach is reflected particularly strongly in the regulation of GMOs by FDA. Its statement of policy on new foods adopts a general presumption that GM foods are not different from their non-GM counterparts,¹¹⁰ and it takes essentially at face value the producer's determination whether the food is the

107. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986). Numerous overviews of the U.S. regulatory regime for GMOs appear in the law review literature, including: Stanley H. Abramson & J. Thomas Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L.J. 241, 244-59 (2001); Adler, *More Sorry*, *supra* note 23, at 181-83; Francer, *supra* note 22, at 265-67; Goldman, *supra* note 66, at 734-54; Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 823-46 (2001); Teel, *supra* note 28, at 662-67 (covers, in addition, the new Plant Protection Act).

108. This assumption was recognized and criticized at the time that the Coordinated Framework was being considered and drafted. See Ruth E. Harlow, Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553 (1986) (arguing for required pre-approval and better information); Thomas O. McGarity & Karl O. Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 537-39 (1983) (arguing for a single statute to provide a unified regulatory structure for GMOs).

109. See Francer, *supra* note 22, at 267.

110. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

same or not.¹¹¹ If it is the same, a GM version of a familiar product is regarded as “generally recognized as safe” (GRAS) and not subject to FDA approval.¹¹²

The strategies of deploying existing legislation and of proceeding product-by-product contribute to another major assumption embedded in the Coordinated Framework: that GMOs pose no social complications that are sufficiently serious to include in the regulatory evaluation.¹¹³ Under FDA’s Statement of Policy—

[t]he regulatory status of a food, irrespective of the method by which it is developed, is dependent upon *objective* characteristics of the food and the intended use of the food (or its components). . . . [T]he key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.¹¹⁴

FDA is here asserting both that the effects of GMOs are determinable from examination of the product alone, and also, implicitly, that the effects to be determined are technical ones. The new Plant Protection Act¹¹⁵ is even more aggressive in rejecting social consequences as a relevant factor. It repeatedly invokes the phrase “sound science” as a kind of mantra to ward off anything smacking of the precautionary principle.

Levidow and Carr note that the Coordinated Framework thus contributes, in their apt phrase, to “normalizing novelty,” that is, to downplaying the newness of GM technologies and highlighting their continuity with conventional methods.¹¹⁶ Sheila Jasanoff observes that this approach “rearranges a potentially limitless

111. See Kunich, *supra* note 107, at 842-44; Francer, *supra* note 22, at 269.

112. See Francer, *supra* note 22, at 269-75; Teel, *supra* note 28, at 665.

113. This is not just a passive assumption. It locates the debate in an arena in which industrial and commercial interests have the greatest advantage over their opponents. Reporter Joe Thornton quotes a presentation from a public relations firm for the industry group Chlorine Chemistry Council, which emphasized the importance of promoting a “science-based” approach to chemical safety. JOE THORNTON, PANDORA’S POISON: CHLORINE, HEALTH, AND A NEW ENVIRONMENTAL STRATEGY 345 (2000). The technocratic approach remains strong in the United States, but it has lost considerable ground in Europe. See Levidow et al., *supra* note 87, at 195-98, 203.

114. Statement of Policy: Foods Derived From New Plant Varieties, *supra* note 110, at 22,984-85 (emphasis added).

115. The Plant Protection Act was enacted as Title IV of the Agricultural Risk Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 358 (2000) (codified at 7 U.S.C. §§ 7701, 7702, 7711-7718, 7731-7736, 7751-58). It replaced for these purposes the Federal Plant Pest Act, 7 U.S.C. §§ 150aa-150jj, and the Plant Quarantine Act, 7 U.S.C. §§ 151-164, 166-167, as well as the late, lamented Halogeton Gomeratus Control Act, 7 U.S.C. §§ 1651-1656, and the Golden Nematode Act, 7 U.S.C. §§ 150-150g.

116. Les Levidow & Susan Carr, *Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA*, 11 RISK 9, 10 (2000).

expanse of scientific unknowns into familiar paradigms of assessment and control” to avoid political or social criticism of GMOs.¹¹⁷ This approach is also the natural consequence of the Better Living Through Chemistry narrative.

The Coordinated Framework also reflects the U.S. government’s commitment to an assumption that GMOs are safe or pose at most manageable risks. FDA has the legal authority to require premarket testing to assure that whole foods are not “adulterated” and that food additives do not pose untoward dangers.¹¹⁸ It does not, however, exercise this authority with foods and additives that are GRAS. USDA takes a similar position. The Animal and Plant Health Inspection Service (APHIS) regulates GMOs as potential plant pests. APHIS may undertake pre-release review, but increasingly it simply requires notification. In either case, authorization is granted as a matter of course, as APHIS has neither the resources nor the degree of concern with GMOs to enable it to undertake serious reviews.¹¹⁹ The Agriculture Risk Protection Act of 2000 expressly adopts the goal of *facilitating* new biological controls for plant pests, and it provides a simple, quick way to introduce GM crops after mere notification to USDA. Both USDA and FDA, in sum, rely primarily on notification and informal consultation to regulate GMOs.¹²⁰

Some commentators have argued that the producers of GM products must in fact submit to extensive regulatory scrutiny under the U.S. system.¹²¹ Bt potatoes, for example, were subject to numerous regulatory hurdles and approval conditions imposed by the interacting regulatory regimes of FDA, USDA, and EPA.¹²² On the other hand, the absence of any significant number of *disapprovals* (or any at all, as far as I can tell) of GM products suggests a system that is strongly conditioned to accept the safety of GMOs and, in relatively rare cases,¹²³ the manageability of any risks that they may pose.

117. Jasanoff, *supra* note 29, at 313; *see also* Jasanoff, *supra* note 4, at 279.

118. *See* 21 U.S.C. §§ 342, 348 (1994).

119. *See* Kunich, *supra* note 107, at 837-41; Teel, *supra* note 28, at 662-63.

120. *See* Abramson & Carrato, *supra* note 107, at 249 (USDA), 252-53 (FDA). The Clinton Administration proposed a mandatory notification of the FDA. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706 (Jan. 18, 2001). However, the Bush Administration has extended the comment period for the regulation. Premarket Notice Concerning Bioengineered Foods; Extension of Comment Period, 66 Fed. Reg. 17,517 (Apr. 2, 2001). The Bush Administration officially lists its intentions as “to be determined.” Long-Term Actions, 66 Fed. Reg. 25,427, 25,435 (May 14, 2001).

121. *See* Abramson & Carrato, *supra* note 107, at 247-56; Goldman, *supra* note 66, at 734-54.

122. *See* Abramson & Carrato, *supra* note 107, at 256-59.

123. *See id.* at 249 (giving statistics on notifications and approvals at the USDA).

EPA has been considerably more aggressive in regulating GMOs than either FDA or USDA, but it, too, has done nothing to slow the development and deployment of GM technology in the United States. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to license pesticides before extensive testing and marketing, and the agency has interpreted the statute to permit it to regulate the pesticidal components of GM plants, such as Bt cotton and Bt maize.¹²⁴ EPA requires permits for the field testing of such products, but, as with the other agencies, it has been liberal in granting experimental use permits and has exempted whole categories of plants that appear to present a low risk of adverse effects.¹²⁵ EPA examines the pesticidal properties of GM plants for the same dangerous qualities it looks for in other pesticides, which is consistent with the continuity element of Better Living Through Chemistry. When it chooses to regulate, EPA balances risks and benefits. Its actions with regard to Bt cotton and Bt maize fit within the paradigm of manageable risks. It extended the registrations of both, but expanded the required measures (mainly size and proximity of refuges) to address pesticide resistance.¹²⁶

While FIFRA has some real potential through its licensing provisions to restrict GMOs where appropriate,¹²⁷ its reach is strictly limited to one type of GMO. As has been recognized for quite some time, the broadest potential source of EPA's regulatory authority in this area is the Toxic Substances Control Act (TSCA).¹²⁸ TSCA was enacted in 1976 with high hopes that it would serve both as a gap-filler and as a template for addressing newly emerging issues.¹²⁹ Its achievements have been modest at best, but it has shown some of the hoped-for flexibility. EPA has taken the fairly aggressive position that GM microorganisms are new "chemical substances," bringing them into the statute's ambit, and it has sought notification and information concerning the deployment and release of microorganisms that were modified across genres.¹³⁰ Nevertheless, there are serious limitations to EPA's approach:

124. See generally *id.* at 253-56; Kunich, *supra* note 107, at 831-37.

125. Teel, *supra* note 28, at 663-64.

126. Time Extensions for Bt Corn and Bt Cotton Plant-Pesticides Expiring Registrations; Registration Process and Public Participation Opportunity, 65 Fed. Reg. 48,701 (Aug. 9, 2000).

127. See Adler, *More Sorry*, *supra* note 23, at 183.

128. See Harlow, *supra* note 108, 563-64; McGarity & Bayer, *supra* note 108, 537-39.

129. See generally John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991).

130. Reporting Requirements and Review Processes for Microorganisms, 40 C.F.R. pt. 725 (2000).

[U]nder newly proposed rules for regulating genetically engineered microorganisms, [EPA] may only gather information about the microorganism's genetic structure—that is, what the microorganism is, not what it does. This may happen for several reasons. First, the genetic engineer who created the microorganism rarely has any direct knowledge about the microorganism's environmental risks, even though that engineer probably knows what strain was engineered, and may have a detailed understanding of the microorganism's genetic structure.

Second, while the new rules list factors that the EPA believes will indicate risk, the new rules fail to identify what parameters determine risk. Third, the new rules cannot require generation of new data which might illuminate risk because these rules will be promulgated under [TSCA], which requires the EPA first to make a finding that the microorganism "may present" an unreasonable risk before testing can be ordered. Thus, the EPA may only be able to gather whatever information is available—microorganism source and genetic structure—which only indirectly and imperfectly illuminates the microorganism's environmental risks.¹³¹

TSCA's pre-market notification procedure (PMN) is limited to information existing at a point when information is *least* available; it gives EPA very little time to react; and any EPA action must be justified under a stringent "substantial evidence" standard.¹³² The courts of appeals have been generally unkind to TSCA, even when it was simply requiring testing of a chemical,¹³³ and the legal hurdles set up by *Corrosion Proof Fittings*¹³⁴ have brought serious regulatory action under TSCA to a virtual halt. It seems unlikely that, given the uncertainty surrounding the effects of GMOs, EPA will be in a position to justify any restrictions on GMOs under TSCA.

131. Robin A. Chadwick, Note, *Regulating Genetically Engineered Microorganisms Under the Toxic Substances Control Act*, 24 HOFSTRA L. REV. 223, 223-25 (1995).

132. See Applegate, *supra* note 129, at 303-04; Harlow, *supra* note 108, at 563-70; Kunich, *supra* note 107, at 824-31.

133. See Applegate, *supra* note 129, at 315-30.

134. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). See also *Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA*, 4 F. Supp. 2d 435 (M.D.N.C. 1998) (remanding a finding by EPA that environmental tobacco smoke is a carcinogen).

The baseline of presumed safety or manageable risks in all of these statutes makes perfect sense in terms of the Better Living Through Chemistry narrative. GM technology is not entirely new and unknown, and so its risks are not entirely new or unknown, either. Accordingly, GMOs are regulated by what Peter Huber has called an “old-risk” standard-setting regime, in which the burden is on the government to demonstrate the existence and degree of well known hazards.¹³⁵ Restrictions on GMOs based on the “the fear of unknown [hazards]” are likely to fail judicial review under such a regulatory structure.¹³⁶

2. *The World Trade Organization*

The World Trade Organization (WTO) takes a similar regulatory approach, though less from a considered view on GMOs in particular than from an institutional commitment to unhindered trade and development. Three WTO-administered agreements potentially apply to GMOs. First, article XI of the General Agreement on Tariffs and Trade (GATT) prohibits “quantitative restrictions”—a category into which environmental, health, and safety regulation falls—on imports, but provides a series of qualified exceptions in article XX.¹³⁷ Second, the subsidiary Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) explicates and tightens the article XX exceptions.¹³⁸ Third, the Agreement on Technical Barriers to Trade (TBT)¹³⁹ applies mainly to labeling and can be seen as a subset of the SPS agreement.

As an initial matter, the GATT has generally been interpreted to apply to products and not to the processes by which they were made. In forbidding the United States to prohibit the import of shrimp that had been caught using methods that harm the endangered sea turtle, the WTO dispute resolution panel forbade

135. See Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025, 1049-50 (1983).

136. *Id.* Huber explained the Supreme Court’s rejection of the Occupational Safety and Health Administration’s (OSHA) regulation of benzene (see *Industrial Union Dept. AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607 (1981)) in these terms: “OSHA did not base the decision to change the benzene exposure standard . . . on the goal of mitigating a known hazard, but rather on the fear of an unknown one,” i.e., cancer.

137. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT], as modified by Marrakesh Agreement Establishing the World Trade Organization, Annex 1A [hereinafter WTO Agreement], LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1154 (1994).

138. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, Annex 1A, 69 (1994) [hereinafter SPS Agreement], available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf (compliance with SPS is presumptively compliance with XX).

139. Agreement on Technical Barriers to Trade, Apr. 15, 1994 [hereinafter TBT Agreement], WTO Agreement, *supra* note 137.

restrictions based on the fishing process. If the shrimp themselves met appropriate health and safety restrictions, that was to be the end of the matter.¹⁴⁰ From the outset, then, the GATT establishes a product-based regulatory scheme.

More generally, the WTO agreements and dispute resolution decisions thereunder display a distinct bias against regulation—it has struck down any number of environment restrictions, including all of the restrictions challenged under the SPS Agreement—and this can be expected to extend to restrictions on GMOs.¹⁴¹ Substantively, proponents of regulation have had to justify the restrictions in terms of several “disciplines.”¹⁴² Two are of particular relevance here. First, all three pieces of WTO legislation require that quantitative restrictions be “necessary”¹⁴³ and adopt the least trade-restrictive measure that will accomplish the same goal.¹⁴⁴ Panel decisions have read “necessary” narrowly.¹⁴⁵ The procedural approach of the WTO allocates to the challenger of a regulation the initial burden of going forward with evidence of a violation, but the ultimate burden lies with the regulator.¹⁴⁶ Moreover, WTO panels give little or no deference to regulatory judgment, which intensifies the impact of the burden of proof.¹⁴⁷

140. WTO Panel Report on United States Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/R, 37 I.L.M. 832 (1998) [hereinafter *Shrimp and Shrimp Products*].

141. See Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 TUL. ENVTL. L.J. 271, 273 (2000). This is more broadly true within the GATT framework. See Lakshman Guruswamy, *The Promise of the United Nations Convention on the Law of the Sea (UNCLOS): Justice in Trade and Environment Disputes*, 25 ECOLOGY L.Q. 189, 196-206 (1998).

142. See Charnovitz, *supra* note 141, at 278-89 (listing eight disciplines: science requirement, risk assessment, national regulatory consistency, least trade restrictive to achieve chosen level of protection, nondiscrimination against other countries, use of international standards where available, recognition of equivalence of regulatory measures by exporting government, and approval and inspection procedures); Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 MICH. L. REV. 2329, 2341-57 (2000) (listing role of science, discrimination provisions, and necessity and least trade restrictive provisions).

143. GATT, *supra* note 137, art. XX(b); SPS Agreement, *supra* note 138, art. 2(1).

144. TBT Agreement, *supra* note 139, art. 2.2; SPS Agreement, *supra* note 138, arts. 5(3), 5(4), 5(6).

145. See, e.g., GATT Dispute Settlement Panel Report on United States Restrictions on Imports of Tuna [Tuna I], Aug. 16, 1991, ¶ 6.3, GATT Doc. DS21/R, GATT B.I.S.D. (39th Supp.) at 155 (1993), *reprinted in* 30 I.L.M. 1594 (1991) (not adopted).

146. WTO Appellate Body Report on Japan—Measures Affecting Agricultural Products, WT/DS76/8 (Mar. 30, 1999) [hereinafter *Japan Quarantine Case*]; *Shrimp and Shrimp Products*, *supra* note 140.

147. With perhaps the exception of what is an acceptable level of risk (SPS), but these must meet a test of consistency within the state. See Charnovitz, *supra* note 141, at 280 (citing WTO Appellate Body Report, Australia—Measures Affecting Importation of Salmon, AB-1998-5, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter *Salmon Case*], available at http://www.wto.org/english/tratop_e/dispu_e/databse_wto_members1_e.htm).

The second important discipline is that trade restrictions must be based on “science.”¹⁴⁸ This is quite typical of the trade regime which, as David Fidler has pointed out, consistently adopts a “science paradigm” for resolving disputes and making decisions.¹⁴⁹ “Science,” in this context, really means existing knowledge, as opposed to extrapolation or speculation about unknown harms. A WTO dispute resolution panel found, for example, that Australia had violated the SPS Agreement because it justified its decision with documented uncertainty, rather than with “science.”¹⁵⁰

The SPS Agreement recognizes, as it must, that many modern hazards are accompanied by a considerable degree of uncertainty, and that much environmental, health, and safety regulation, even (or especially) in nations with highly developed regulatory apparatuses, is based on uncertain knowledge. It acknowledges this, however, not with general acceptance of such regulation, but rather with an *exception* to the general science requirement.¹⁵¹

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information. . . . In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.¹⁵²

Article 5.7 is clearly related to the precautionary principle,¹⁵³ but it contains a host of its own restrictions, the most important of which are that the measure must be provisional and that the member must seek additional information to make a final, “objective” judgment within a reasonable period of time.¹⁵⁴ Again, it is likely that the main motivation for this provision is the WTO’s interest in encouraging trade.

148. SPS Agreement arts. 2(2), 3(3), 5(1).

149. David P. Fidler, *Challenges to Humanity's Health: The Contributions of International Environmental Law to National and Global Public Health*, 31 *Envtl. L. Rep. (Envtl. L. Inst.)* 10,048, 10,070 (Jan. 2001).

150. Chamovitz, *supra* note 141, at 280.

151. The SPS Agreement requires that protective measures be based on science, art. 2(2), and risk assessment, art. 5(1), except where undertaken under art. 5(7). SPS Agreement, *supra* note 138, arts. 2(2), 5(1), 5(7).

152. *Id.* at art. 5(7).

153. As the Hormones case put it with elegant ambiguity, the precautionary principle “finds reflection” in art. 5.7 WTO Appellate Body Report on EC Measures Concerning Meat and Meat Products, WT/DS48/AB/R (Jan. 16, 1998). See also Chamovitz, *supra* note 141, at 289-90.

154. See *Japan Quarantine Case*, *supra* note 146, ¶ 89 (listing requirements for maintaining a measure under art. 5.7).

The insistence on “sound science” is designed to bring predicatability to regulation, which is very important to traders.¹⁵⁵ However, it also, as we have seen, attempts to restrict the legitimate discourse on regulation to narrowly technical issues, unencumbered by consideration of broad social consequences.¹⁵⁶

* * *

The difference between the European and the American and WTO regulation of GMOs goes beyond the mechanical one of process *versus* product. The two regulatory systems see GMOs in entirely different ways, reflecting not merely a technical divergence, but rather a fundamental epistemological “difference in [the] knowability and assessability of risks.”¹⁵⁷ Is genetic modification simply an extension of prior technologies, posing similar risks, manageable with similar regulatory systems under similar standards applied to familiar characteristics? Or is it something entirely new, requiring new structures, new knowledge, and exceptional caution? Can the use of GMOs be resolved technically by applying existing scientific knowledge to existing technical criteria? Or do they present a level of novelty that demands new regulatory structures and the consideration of broad social concerns? Is GM technology an activity in whose basic safety we are confident, and should encourage unless we have strong indications to the contrary? Or is it a new, unpredictable power with unknowable consequences? A regulatory regime has no choice but to confront and resolve these questions of evaluative criteria, acceptable evidence, and burden of proof. We now turn to the question whether the precautionary principle offers a way to reconcile these differences.

155. See Gupta, *supra* note 103, at 264-65; see also Levidow et al., *supra* note 87, at 194 (recognizing predictability as a characteristic of the traditional technocratic approval process).

156. Robert Howse has argued, to the contrary, that the WTO has in fact taken a very broad view of what constitutes science that includes “divergent” scientific opinion. See Howse, *supra* note 142, at 2341-44 (quoting the Beef Hormones Case). Howse also defends the science requirement as a means of forcing true democratic deliberation over risk issues, instead of restrictions based on whim or incorrect facts. *Id.* at 2330, 2333-36.

157. Aarti Gupta, *Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biodiversity*, ENVIRONMENT, May 2000, at 23, 32, 33 n.27; see also Krier & Gillette, *supra* note 62, at 409-13 (demonstrating that the technological optimists and pessimists do not respond to each others’ arguments).

III. BRIDGING THE GAP: THE PRECAUTIONARY PRINCIPLE

Faced with the divergent Frankenstein and Better Living Through Chemistry narratives and the resulting divergence of national regulatory and international trade regimes, international environmental regulation has been forced to try to bridge the gap between them. International environmental law offers three possibilities: prior informed consent (PIC), sustainable development, and the precautionary principle. Each has a substantial international legal pedigree, and each has been proposed or adopted as a way of bridging the broader gap between development and environmental protection. The article now considers the potential of each to afford a framework for harmonizing the regulation of GMOs.

A. *Prior Informed Consent*

I begin with prior informed consent, because it is the mechanism that international environmental law has in fact adopted to reconcile the different views on GMOs. PIC is the centerpiece of the Biosafety Protocol to the Convention on Biodiversity,¹⁵⁸ which was negotiated at Cartagena (for which it is named) and concluded in Montreal on January 29, 2000.¹⁵⁹ PIC has previously been used in a number of international agreements, notably the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal¹⁶⁰ and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International

158. See United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (1992) [hereinafter CBD]. The CBD was adopted at the Earth Summit in 1992. The United States has signed but not ratified the CBD. For a list of signatory parties see <http://www.biodiv.org/world/parties.asp> (last visited Oct. 2, 2001). There was some controversy over the appropriateness of the CBD as the vehicle for regulating GMOs, since biodiversity is only one part of the issues that GMOs raise, but the CBD itself quite clearly anticipates further action on GMOs. In article 8(g) the parties agree to

[e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

Id. art. 8(g), at 825.

159. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000) [hereinafter Protocol].

160. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Mar. 22, 1989, 28 I.L.M. 649 (1989) [hereinafter Basel Convention]; see also Karen M. Graziano, Note, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT'L. ENVTL. L. & POL'Y 179, 208 (1995) (discussing the connection between the Protocol and Basel PIC procedures).

Trade.¹⁶¹ As its name suggests, PIC requires an exporting state to inform fully the importing state of the nature and hazards of a shipment in advance, and it permits the importing state to refuse its consent. Signed by 103 countries, the Cartagena Protocol was supported by both sides of the GMO debate.¹⁶²

The Cartagena Protocol focuses on agricultural GMOs and regulates trade in such products.¹⁶³ It applies to “living modified organisms” (LMOs)—a euphemism for GMOs, insisted upon by the image-conscious United States—which are broadly defined as biological entities capable of transferring genetic material and produced by modern biotechnological techniques.¹⁶⁴ Pharmaceuticals and processed foods are specifically excluded.¹⁶⁵ Covered LMOs are divided into four groups. Those intended for deliberate release into the environment (e.g., seeds) are subject to the full advance informed agreement (AIA)—i.e., PIC; AIA is another euphemism insisted upon by the U.S. to avoid association with hazardous waste—procedure.¹⁶⁶ Those intended for food, feed, or processing (LMO-FFP) are subject to information sharing requirements and notification of approvals and refusals through a central Biosafety Clearinghouse. (Developing countries can also apply AIA to these.¹⁶⁷) Contained uses and transit are not subject to AIA. The labeling provision is a compromise: an importer can require the packaging of LMO-FFPs to state that it “may contain” LMOs.¹⁶⁸ Liability and compensation issues are untouched.

The teeth of the Cartagena Protocol are in the importing country’s ability to refuse consent to importation. Unlike the Basel and Rotterdam PIC procedures,¹⁶⁹ the Cartagena Protocol describes in detail the permissible bases for refusing consent. Pro-GMO states were very concerned that without such detail

161. Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Sept. 11, 1998, 38 I.L.M. 1 (1999), available at <http://www.chem.unep.ch/pic> [hereinafter Rotterdam Convention].

162. Because, the United States has not ratified the underlying CBD, it is not eligible to sign or ratify the Protocol. Nevertheless, as the world’s largest producer of GMOs, the United States took a leading role in the negotiations. See Gupta, *supra* note 157, at 26.

163. For a complete picture of the negotiations leading up to the Protocol, as well as the Protocol’s provisions, see *id.* at 25-27; see also Saigo, *supra* note 28, at 801-11; Schweizer, *supra* note 37, at 586-98.

164. Protocol, *supra* note 159, arts. 3(g), (h), (i), at 1028-29.

165. *Id.* arts. 3(g)-(i), 5, at 1028-29.

166. *Id.* arts. 7-10, at 1030-31.

167. *Id.* art. 11(6), at 1032.

168. *Id.* art. 18(2)(a), at 1035.

169. The Basel Convention speaks of the “right to prohibit import” of hazardous wastes. Basel Convention art. 4(1)(a), at 661; see also *id.* art. 6(2), at 664 (requiring no qualifications on right to refuse consent). The Rotterdam Convention requires only that a refusal be consistent with domestic treatment of the chemical. Rotterdam Convention art. 10(9), at 7.

PIC would become either a disguised form of trade protectionism¹⁷⁰ or, more importantly, an opportunity to raise “unscientific” objections to GMOs. PIC standing alone could be a powerful tool for GMO opponents, as it would allow such states to refuse entry of GMO products on the basis of inchoate concerns or simply fear of the unknown. By limiting the grounds on which consent may be refused, the Protocol steps directly into the center of the debate about the standards for evaluating GMOs, the acceptable evidence, and the burden of proof.

The Cartagena Protocol “takes as its starting point a risk assessment rather than the much feared nonscientific criteria for decision making.”¹⁷¹ If the assessment shows an unacceptable level of risk, then the state may refuse entry. If the risk assessment is inconclusive, the importer may nevertheless withhold consent, based on the protocol’s own version of the precautionary principle:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risk to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects.¹⁷²

As will be discussed below, the precautionary principle has been expressed in a variety of formulations, reflecting a range of positions on a number of aspects of the principle.¹⁷³ The Cartagena version clearly envisions a technical decision, though the socio-economic impacts of harm to biodiversity, and particularly to local and indigenous communities, may be considered.¹⁷⁴

In this respect, the Cartagena Protocol comes closer to the SPS Agreement than to the Rio version of the precautionary principle.¹⁷⁵ However, the Cartagena

170. See Saigo, *supra* note 28, at 811.

171. Gupta, *supra* note 157, at 30; see also Protocol, *supra* note 159, arts. 15(1), (2), annex III, at 1033-34, 1045-46 (setting out detailed requirements for such risk assessments).

172. Protocol, *supra* note 159, art. 10(6), at 1031; see also *id.* art. 11(8), at 1032 (describing a parallel provision for LMO-FFPs).

173. See generally John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 HUMAN & ECOLOGICAL RISK ASSESSMENT 413 (2000).

174. Protocol, *supra* note 159, art. 26(1), at 1039.

175. See Charnovitz, *supra* note 141, at 298-301.

Protocol is deliberately vague about its relationship with the WTO legislation. The application of the WTO is a matter of considerable moment, because, as we have seen, the WTO approach distinctly disfavors trade restrictions on GMOs. The SPS Agreement, for example, treats any precautionary regulation as strictly temporary, to be followed promptly by studies to confirm or obviate the restrictions, a provision that is not found in Cartagena. The Protocol certainly contains no release from the WTO requirements, a specific savings clause was eliminated,¹⁷⁶ and the remaining indications consist of conflicting statements in the preamble.¹⁷⁷ At a minimum, the requirement to give reasons for a decision to deny consent¹⁷⁸ will probably set the stage for trade challenges in a hostile WTO forum.¹⁷⁹ Whether or not Cartagena or SPS controls, it is plain that PIC *per se* does not offer its own substantive regulatory standard for GMOs. The PIC procedure simply enables the application of the precautionary principle by individual states, subject to challenge in the WTO or other forum.¹⁸⁰

B. Sustainable Development

The idea of “sustainable development,” in the words of its inventors, “is development that meets the needs of the present without compromising the ability of future generations to meet their own needs.”¹⁸¹ It aims to protect natural resources, habitat, human health, and intergenerational equity within the constraints of nature and environmentally appropriate innovation.¹⁸² Since its original articulation in the 1987 report of the World Commission on Environment and Development, sustainable development has become the principal way that international environmental law has sought to reconcile the often-conflicting needs

176. Gupta, *supra* note 157, at 30-31.

177. The relevant provisions read:

Recognizing that trade and environment agreements should be mutually supporting with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements[.]

Protocol, *supra* note 159, pmbli., at 1027. To summarize: “maybe, yes, and no.”

178. *Id.* art. 10(4), at 1031.

179. See Paul E. Hagen & John Barlow Weiner, *The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms*, 12 GEO. INT’L ENVTL. L. REV. 697, 713-14 (2000).

180. The Protocol does not establish a dispute resolution mechanism. See Gupta, *supra* note 157, at 32.

181. WORLD COMM’N ON ENV’T AND DEV., OUR COMMON FUTURE 43 (1987) [hereinafter WCED].

182. See John C. Dermach, *Sustainable Development as a Framework for National Governance*, 49 CASEW. RES. L. REV. 1, 24-31 (1998).

of environmental protection and economic development, especially within developing nations. The idea was formally endorsed by the 1992 United Nations Conference on Environment and Development in Rio de Janeiro. The Rio Declaration, together with Agenda 21, a comprehensive plan for actions to implement it, is in effect a statement of the principles of sustainable development.¹⁸³

Sustainable development would seem to be a logical framework within which many of the effects of GMOs on agricultural economies could be considered. It embraces developmental issues like increased dependence on multinationals, self-determination of economic systems, choosing against consumption values, respect for indigenous agriculture, and so on, all of which a purely technical approach sets aside.¹⁸⁴ Sustainable development ought to be a place to examine the larger question of what *kind* of development we want.

In practice, however, sustainable development turns out to be a poor candidate for bridging the gap between the two views of GMOs. As Guruswamy and others have lamented, the pendulum has been swinging toward the development side of environment and development.¹⁸⁵ What we have called a "syncopated sustainable development"¹⁸⁶ offers little comfort that the concerns of sustainability will in fact play a role in the regulation of GMOs. If what the proponents of GMOs say about the potential of these technologies and the manageability of their risks is true, or even half true, one can make a very good case that GMOs are in fact *needed* for sustainable development to be realized—especially if one is emphasizing the development side. Like the original Green Revolution, they could improve crop yields and nutritional value. Even better, GMOs could reduce the dangerous and expensive reliance on pesticides and fertilizers, and slow the growth of agriculture on marginal land.¹⁸⁷ To the extent that sustainable development encourages technological innovation rather than a

183. See *id.* at 21.

184. See Jasanoff, *supra* note 4, at 278-80 (discussing the importance of social and economic consequences to evaluation of GMOs).

185. See Lakshman Guruswamy, *International Environmental Law: Boundaries, Landmarks, and Realities*, NAT. RESOURCES & ENV'T, Fall 1995, at 43, 76-77.

186. See John S. Applegate & Alfred C. Aman, Jr., *Introduction: Syncopated Sustainable Development*, 9 IND. J. GLOBAL LEGAL STUD. 1 (2001).

187. See NAT'L ACAD. PRESS, *TRANSGENIC PLANTS AND WORLD AGRICULTURE* 6 (2000); Buechle, *supra* note 68, at 316-23; GOKLANY, *supra* note 53, at 4-13; see also Adler, *Biosafe*, *supra* note 38, at 772-74 (arguing that GMOs will in fact improve biodiversity).

return to earlier forms of agriculture, the view endorsed by the originators of the term,¹⁸⁸ GMOs are an entirely appropriate—indeed, welcome—response.

The optimistic view of the role of GMOs in sustainable development is not, of course, the view of the opponents of genetic modification. Even accepting the claimed benefits of GMOs (which, by and large, they do not), the opponents see many potentially unsustainable side effects. This, of course, brings us right back to the central problem of uncertainty. Sustainable development, which balances environment and development, present and future, is a strategy that relies heavily on detailed information about environmental hazards and complex natural systems.¹⁸⁹ But the problem with GMOs is the *lack* of fundamental information.

Consequently, sustainable development as such is not particularly helpful in resolving this debate.

That said, the Rio Declaration enumerates several principles of sustainability, and one of them (Principle 15) is the precautionary principle. Avoiding severe, irreversible losses is a logical, even necessary, aspect of sustainability for future generations.¹⁹⁰ In addition, the precautionary principle “is especially important for sustainable development because the carrying capacity of the global environment as well as regional ecosystems is mostly unknown.”¹⁹¹ This describes the GMO dilemma exactly. Given uncertainty whether GMOs are the ally or enemy of sustainable development, a sustainable approach would make its judgment on GMOs by going slowly, within the framework of the precautionary principle or something like it. Thus, as with PIC, sustainable development returns us to the precautionary principle as the operative provision for bridging the GMO gap. It is now time to turn to the precautionary principle itself.

C. *The Precautionary Principle*

1. *A Brief Introduction to the Precautionary Principle*

The precautionary principle has its origins in a German environmental concept, *Vorsorgeprinzip* or “foresightedness principle,” which can be freely

188. The World Commission acknowledged that sustainability imposes limits on development, but held out the prospect that “technology . . . can be both managed and improved to make way for a new era of economic growth. WCED, *supra* note 181, at 8.

189. See Dembach, *supra* note 182, at 73-76.

190. See David A. Wirth, *The Rio Declaration on Environment and Development: Two Steps Forward and One Back, or Vice Versa?*, 29 GA. L. REV. 599, 634 (1995).

191. Dembach, *supra* note 182, at 62; see also Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 854 (1996).

translated as the obligation to “foresee and forestall” environmental harms.¹⁹² Foresight in this context implies looking over the horizon for unexpected dangers,¹⁹³ an idea with obvious resonance for the Frankenstein narrative and technological pessimism generally. Taking “precautionary measures” was central to the Vienna Convention for the Protection of the Ozone Layer in 1985,¹⁹⁴ the parties to which established a framework for reducing emissions of ozone-depleting substances *before* the ozone “hole” had been actually observed.¹⁹⁵ Many regional and global instruments have explicitly adopted the precautionary principle since then.¹⁹⁶ While there is no single statement of the precautionary principle, and the various formulations differ in several respects,¹⁹⁷ it has been adopted by industrialized countries in the charter of the European Union¹⁹⁸ and the fundamental Canadian environmental law,¹⁹⁹ by developing countries in the Bamako Convention on Hazardous Waste in Africa,²⁰⁰ and globally in the Convention on Biological Diversity²⁰¹ the United Nations Framework Convention on Climate Change, and of course the Rio Declaration.²⁰² Most recently, the precautionary principle was adopted by the Stockholm Convention on Persistent

192. Carolyn Raffensperger & Joel Tickner, *Introduction: To Foresee and to Forestall*, in *PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE* 1, 4 (Carolyn Raffensperger & Joel Tickner eds., 1999); see also Sonja Boehmer-Christiansen, *The Precautionary Principle in Germany—Enabling Government*, in *INTERPRETING THE PRECAUTIONARY PRINCIPLE* 31, 38-39 (Tim O’Riordan & James Cameron eds., 1994) (arguing that the German term includes both foresight and action to prevent).

193. Joyce Tait & Les Levidow, *Proactive and Reactive Approaches to Risk Regulation*, *FUTURES*, Apr. 1992, at 219, 221-22.

194. Vienna Convention for the Protection of the Ozone Layer, Mar. 22, 1985, pmbl., 26 I.L.M. 1516, 1529 (1987) (stating in its preamble “[m]indful also of the precautionary measures for the protection of the ozone layer which have already been taken at the national and international levels”).

195. David Hurlbut, *Beyond the Montreal Protocol: Impact on Nonparty States and Lessons for Future Environmental Protection Regimes*, 4 *COLO. J. INT’L. ENVTL. L. & POL’Y* 344, 348 (1993).

196. For catalogues of treaties, see Peter H. Sand, *The Precautionary Principle: A European Perspective*, 6 *HUM. & ECOLOGICAL RISK ASSESSMENT* 445, 445-46 (2000); David VanderZwaag, *The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces*, 8 *J. ENVTL. L. & PRAC.* 355, 363-74 (1999); James E. Hickey, Jr. & Vern R. Walker, *Refining the Precautionary Principle in International Environmental Law*, 14 *VA. ENVTL. L.J.* 423, 432-38 (1995). An exhaustive catalogue can be found in HARALD HOHMAN, *PRECAUTIONARY LEGAL DUTIES AND PRINCIPLES OF MODERN INTERNATIONAL ENVIRONMENTAL LAW* (1994), which documents uses in both international and national law.

197. For useful comparisons of selected versions, see Katz, *supra* note 75, at 957; Gupta, *supra* note 157, at 30. VanderZwaag describes a spectrum from “passionate” to “cool” embrace. VanderZwaag, *supra* note 196, at 358.

198. Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Certain Related Acts, Oct. 2, 1997, O.J. (C 340) 1 (1997), art. 174(2), 37 I.L.M. 56, 117 (1998) [hereinafter Treaty of Amsterdam].

199. Canadian Environmental Protection Act, ch. 33, pmbl., 1999 S.C. 1999 (Can.).

200. Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa, Jan. 29, 1991, art. 4(3)(f), 30 I.L.M. 773, 781 (1991).

201; see also Protocol, *supra* note 159, pmbl., at 1027; CBD, *supra* note 158, pmbl., at 822.

202. UNCED, Framework Convention on Climate Change, May 9, 1992, art. 3.3, 31 I.L.M. 849, 854 (1992).

Organic Pollutants, which was signed by the US, EU, and a host of industrialized and developing states.²⁰³ It is a key feature of the Cartagena Protocol, as we have seen.

While the precautionary principle has become something of a fixture in international environmental treaties,²⁰⁴ the main response in American academia has been dismissive. Unfortunately, much of this criticism is based on a caricature which depicts a draconian, unreasoning, inflexible command that rejects all technologies that have emerged since the Industrial Revolution. For GMOs, it is said to demand absolute proof that no harm could possibly occur, or else the total abandonment of GM technology.²⁰⁵ Some zealous advocates of the precautionary principle have taken positions something like this,²⁰⁶ but the reality of the text, scholarship,²⁰⁷ and real-world implementation is a flexible, pragmatic, and cautious approach to the uncertainty that characterizes new technologies like genetic modification. In short, it is the foresight principle, not the Luddite Principle. It seeks to anticipate the risks of new and existing technologies so as to avoid or minimize them. As implemented, it is neither rigid, nor the enemy of serious scientific inquiry.

203. UNEP, Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, arts. 1, 8(9), Annex C part V(B), 40 I.L.M. 532, 534, 541, 559 (2001) [Stockholm POPs Treaty].

204. The near universal acceptance of the precautionary principle in a variety of treaties has led to a lively debate over whether the precautionary principle should be recognized as rule of customary international law, which would make it binding upon all states. Those who favor such recognition point to the numerous treaties and national laws. See James Cameron & Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, 14 B.C. INT'L & COMP. L. REV. 1, 20-21 (1991); HOHMAN, *supra* note 196, at 12 *passim*. Those opposed point to the recentness of the treaties, the lack of an agreed upon formulation of the principle, and the lack of evidence of actual state behavior consistent with the precautionary principle. See Christopher D. Stone, *Is There a Precautionary Principle?*, 31 *Envtl. L. Rep. (Envtl. L. Inst.)* 10,790, 10,799 (2001); Catherine Tinker, *State Responsibility and the Precautionary Principle*, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION* 53 (David Freestone & Ellen Hey eds., 1996); Daniel M. Bodansky, *Scientific Uncertainty and the Precautionary Principle*, 33 *ENVIRONMENT*, Sept. 1991, at 4. This is not the place to enter that debate. Both the European Union and the United States have agreed to the Rio Declaration, the SPS Agreement, and the Protocol (indirectly, in the case of the United States), so its general applicability to GMOs seems clear.

205. See Adler, *Biosafe*, *supra* note 38, at 777; see also Adler, *More Sorry*, *supra* note 23, at 205; INDUR M. GOKLANY, *APPLYING THE PRECAUTIONARY PRINCIPLE TO GENETICALLY MODIFIED CROPS*, POLICY STUDY NO. 157, 24 (Ctr. for the Study of Am. Bus., Washington University, St. Louis 2000); Abramson & Carrato, *supra* note 107, at 244-45; Cross, *supra* note 191, at 853; Stone, *supra* note 204, at 10,796.

206. Jonathan Adler gleefully quotes some of the more intemperate claims. See Adler, *More Sorry*, *supra* note 23, at 173-74, 178.

207. For generally supportive works, see *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION*, *supra* note 204. See generally *INTERPRETING THE PRECAUTIONARY PRINCIPLE*, *supra* note 192; HOHMAN, *supra* note 196; Hickey & Walker, *supra* note 196. For a variety of perspectives, see generally Symposium, *Perspectives on the Precautionary Principle*, 6 *J. HUM. & ECOLOGICAL RISK ASSESSMENT* 383 (2000).

2. *The Elements of the Precautionary Principle*

The precautionary principle can be broken down into four distinct elements that cut across all of its versions: trigger, timing, response, and iteration.²⁰⁸ Together, they provide a framework for identifying, evaluating, learning more about, and avoiding or minimizing the risks of technology—and for providing the time (“breathing space,” as Levidow and Carr put it²⁰⁹) for doing so.

a. *Trigger*

The trigger incorporates two prerequisites: an anticipated serious or irreversible harm, and a minimum amount of scientific information on the basis of which harm is foreseen. As to harm, some commentators insist on irreversibility, as it most clearly justifies taking regulatory action in advance of proof.²¹⁰ Others keep the focus on uncertainty by limiting the operation of the precautionary principle to situations in which the consequences of an action are so great as to be beyond our capacity to predict with accuracy.²¹¹ The European Commission’s Communication on the Precautionary Principle requires uncertainty to be demonstrated, but sets the seriousness trigger at any level above the member state’s desired level of protection for its citizens.²¹²

The precautionary principle is frequently criticized in the United States for allowing any imagined harm—*Frankenstein* is, after all, just a novel—to trigger regulatory action. The Rio statement of the principle only hints otherwise (“absence of *full* scientific knowledge”), but other statements are clearer that

208. See Applegate, *supra* note 173, at 415-20 (describing elements and strategies).

209. Levidow et al., *supra* note 87, at 191.

210. See generally Philippe Sands, *The “Greening” of International Law: Emerging Principles and Rules*, 1 IND. J. GLOBAL LEGAL STUD. 293-323 (1994); Robin Attfield, *The Precautionary Principle and Moral Values*, in INTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 192, at 152-64. Christopher Stone, who is otherwise quite skeptical of the precautionary principle, recognizes the need to treat irreversible harms with particular care. See Stone, *supra* note 204, at 10,797.

211. See Charmian Barton, *The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine*, 12 HARV. ENVTL. L. REV. 509, 510-12 (1998); see also Bernard A. Weintraub, *Science, International Environmental Regulation, and the Precautionary Principle: Setting Standards and Defining Terms*, 1 N.Y.U. ENVTL. L.J. 173, 191-92 (1992).

212. Comm’n of the Eur. Cmty., Communication from the Commission on the Precautionary Principle, Feb. 2, 2000, at 17. The Member State’s ability to set this level is not unlimited; it must be, among other things, nondiscriminatory and consistent with other domestic risk levels. *Id.* at 19. The Commission’s views on this and other aspects of the precautionary principle are echoed in a discussion paper issued by the Canadian government. See GOV’T. OF CAN., A CANADIAN PERSPECTIVE ON PRECAUTIONARY APPROACH/PRINCIPLE: PROPOSED GUIDING PRINCIPLES (Sept. 2001).

scientific investigation must precede invocation of the principle.²¹³ The European Commission repeatedly emphasizes the need to perform a traditional risk assessment based on available information,²¹⁴ and the EU Treaty's adoption of the precautionary principle is qualified by the parallel requirement to rely on "available scientific and technical data."²¹⁵ Likewise, as we have seen, the Cartagena Protocol "takes as its starting point a risk assessment."²¹⁶ While these are particularly strong statements of the informational prerequisite, most commentators are in agreement that anticipated harms must have some scientific basis.²¹⁷ Jasanoff, for example, argues that the "systematicity" associated with risk assessment brings a healthy discipline to the precautionary principle that helps to avoid capture by "fads and fancies."²¹⁸

b. Timing

The core purpose of the precautionary principle is the management of uncertainty,²¹⁹ and so timing—the relationship between taking regulatory action and the degree of scientific knowledge concerning the risks of concern—is its distinctive feature. The precautionary principle goes beyond preventive regulation, which addresses known risks with a goal of avoiding familiar

213. For example, United Nations, Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, pmbl., 26 I.L.M. 1541 (1987) (entered into force Jan. 1, 1989) [hereinafter Montreal Protocol on Substances that Deplete the Ozone Layer], states unequivocally that the parties are "determined to protect the ozone layer by taking precautionary measures" and also that "measures taken to protect the ozone layer from depletion should be based on relevant scientific knowledge, taking into account technical and economic considerations."

214. "Before the precautionary principle is invoked, the scientific data relevant to the risks must first be evaluated." Comm'n of the Eur. Cmty's., *supra* note 212, at 13-14; *see also id.* at 3 (stating that the Precautionary Principle is mainly relevant to risk management, which follows risk assessment).

215. Treaty of Amsterdam, *supra* note 198, art. 174(2), (3), at 117; *see* Chris W. Backes & Jonathan M. Verschuuren, *The Precautionary Principle in International, European and Dutch Wildlife Law*, 9 COLO. J. ENVTL. L. & POL'Y 43, 47 (1998).

216. Gupta, *supra* note 157, at 30.

217. *See, e.g.,* André Nollkaemper, "What You Risk Reveals What You Value," and Other Dilemmas Encountered in the Legal Assaults on Risks, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION*, *supra* note 204, at 73, 83-84; *see also* John S. Gray, *Integrating Precautionary Scientific Methods into Decision-making*, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION*, *supra* note 204, at 133, 135. Some authors assert, however, that "precautionary science"—that is, science that is not based on traditional, mechanistic proof of cause and effect and whose results are not necessarily quantitative—is an appropriate basis for action. *See* Katherine Barrett & Carolyn Raffensperger, *Precautionary Science*, in *PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE*, *supra* note 192, at 106, 109-12, 117-18.

218. Jasanoff, *supra* note 4, at 281.

219. Royal Soc'y of Can., *supra* note 28, at 197-98.

harms.²²⁰ The timing element permits regulatory action before the causal relationship between the activity and the potential harm has been fully proven; that is, it holds the activity of concern in abeyance in the period between the scientifically credible identification of risks and their characterization sufficient to make a comprehensive regulatory determination.²²¹ The term that best describes this timing is *anticipatory*,²²² the “forestall” part of the “foresee and forestall” interpretation of the *Vorsorgeprinzip*.

The existence of uncertainty is also, in some views, a prerequisite to the application of the precautionary principle. If examination of the existing science reveals a well characterized risk, the precautionary principle is no longer “relevant,” in the words of the European Commission, and a final, reasoned regulatory decision should be reached on traditional grounds.²²³ This is not *total* uncertainty, of course, in the sense of pure speculation or the fevered imaginations of Greenpeace activists. Consistent with the informational prerequisite in the trigger, uncertainty means the lack of a definitive cause-and-effect relationship or a quantifiable dose-response relationship.²²⁴ The “Wingspread” formulation of the precautionary principle focuses on this point: “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”²²⁵ This is hardly a radical position. Indeed, it has been criticized as merely restating the obvious point that true certainty never exists.²²⁶ In fact, however, the precautionary principle would shift the practice, established in the United States in the *Benzene* decision, of demanding a high degree of proof of the existence and magnitude of a risk in advance of regulatory action.²²⁷

220. See Tait & Levidow, *supra* note 193, at 219 (distinguishing between proactive and reactive regulation).

221. David Freestone & Ellen Hey, *Origins and Development of the Precautionary Principle*, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW*, *supra* note 204, at 3, 12-13; Ken Geiser, *Cleaner Production and the Precautionary Principle*, in *PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE*, *supra* note 192, at 323, 323-24, 326.

222. Applegate, *supra* note 173, at 417.

223. See Comm'n of the Eur. Cmty., *supra* note 212, at 13.

224. See Andrew Jordan & Timothy O'Riordan, *The Precautionary Principle in Contemporary Environmental Policy and Politics*, in *PROTECTION PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE*, *supra* note 192, at 15, 17.

225. Wingspread Conference Statement (Jan. 25, 1998), *reprinted in* *PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE*, *supra* note 192, at 353, 353-54.

226. See Stone, *supra* note 204, at 10,790 (characterizing full certainty as a “red herring”).

227. See Wendy E. Wagner, *The Precautionary Principle and Chemical Regulation in the U.S.*, 6(3) *Human & Ecological Risk Assessment* 459 (2000); Applegate, *supra* note 129, at 282-84.

For many observers, it follows from the timing element that the burden of proving the safety of an activity or technology lies entirely with its proponent.²²⁸ The European Commission, however, firmly rejects this position, retaining instead the preexisting burdens of proof, for instance, on proponents of drugs but not on industrial chemicals.²²⁹ The relevant treaty language is silent on this point, though the Rio formulation tends to support the EU position. It states that the precautionary principle operates as a “reason” for not “postponing” regulatory action, suggesting that the precautionary principle relates only to timing and that it otherwise functions within an existing framework of burdens of proof. It cannot be said, therefore, that reversal of the burden of proof is necessarily part of the precautionary principle as actually adopted.

c. Response

The most misrepresented aspect of the precautionary principle is the nature of the regulatory response it mandates. As noted above, its critics are fond of charging or assuming that there is but one response: to ban or forgo an activity or technology altogether.²³⁰ This is transparently untrue. None of the texts of the principle says this. Some speak of avoiding or minimizing the anticipated harms,²³¹ and of course precautionary timing may result in delays in adopting technology,²³² but both are a far cry from entirely abjuring a new, potentially beneficial technology. Moreover, while “minimizing” harm may not satisfy the

228. See Margo Brett Baender, *Pesticides and Precaution: The Bamako Convention as a Model for an International Convention on Pesticides Regulation*, 24 N.Y.U. J. INT'L L. & POL. 557, 588 (1991); see generally Carl F. Cranor, *Asymmetric Information, the Precautionary Principle, and Burdens of Proof*, in PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE, *supra* note 192, at 74, 86-96; Carolyn Raffensperger & Joel Tickner, *Introduction: To Foresee and Forestall*, in PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE, *supra* note 192, at 1, 3-4; Jordan & O'Riordan, *supra* note 224, at 24-25; see David Ozonoff, *The Precautionary Principle as a Screening Device*, in PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE, *supra* note 192, at 100, 101-104; see also Royal Soc'y of Can., *supra* note 28, at 201-03 (explaining that the burden shifts after the opponent presents a prima facie case for a risk); see HOHMAN, *supra* note 196, at 334-35 (explaining that burden shifting represents the “strong version” of the precautionary principle). No serious advocate of the Precautionary Principle, however, suggests that the proponent of the activity must conclusively demonstrate a zero risk of harm.

229. See Comm'n of the Eur. Cmty., *supra* note 212, at 21.

230. See sources cited *supra* note 205.

231. *E.g.*, Protocol, *supra* note 159.

232. Delays, of course, can cause harm to those who would be aided by the new product or technology. Frank Cross has analogized new drugs, delays in which can cost lives. See Cross, *supra* note 191, at 884-86. This is a persuasive argument only in retrospect, as it assumes that the new drug is a penicillin and not a thalidomide. The whole point of the precautionary principle is that *ex ante* we do not know which it is. If we did, we would not need the precautionary principle.

preference of some critics for an economically optimal level of harm, it is not the same as an expectation of zero risk.²³³ The commentary makes it clear that an absolutist view of the precautionary principle is untenable, and instead that it embraces a range of regulatory responses.²³⁴ Bans may be appropriate in some cases, but in others it may mean (in the case of GMOs) process controls, isolation of field tests, limited periods of approval, pre-release testing, investigation of alternatives, or further research. The precautionary principle, in other words, can be a roadblock or simply a speedbump.²³⁵

Treaties have been more explicit about the qualities of the response than its nature. We have seen that the Rio Declaration speaks of “cost-effective” measures.²³⁶ Commentators have even suggested that it requires the “least hazardous alternative,”²³⁷ or that alternative courses of action be available.²³⁸ The qualifier that appears to be in greatest favor among both commentators and governments is “proportionate.”²³⁹ Proportionality—both in the sense of benefits and costs (broadly understood) and of the desired level of protection—is the primary quality that the European Commission expects in implementation of the precautionary principle.²⁴⁰ The use of the term “as appropriate” in the relevant section of the Cartagena Protocol also suggests proportionality.²⁴¹ Moreover, the regulatory authority’s review of the proportionality of the response is to be

233. Cf. *Hazardous Waste Treatment Council v. EPA*, 886 F.2d 355, 361 (D.C. Cir. 1989) (holding that “minimize” in the Resource Conservation and Recovery Act (RCRA) means less than the acceptable risk level).
234. See David Freestone & Ellen Hey, *Implementing the Precautionary Principle: Challenges and Opportunities*, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION*, *supra* note 204, at 249, 250-53; Levidow et al., *supra* note 87, at 189; Nollkaemper, *supra* note 217, at 77-79.

235. Joel A. Tickner, *A Map Toward Precautionary Decision Making*, in *PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE*, *supra* note 192, at 162, 163.

236. See United Nations Conference on Environment and Development: Framework Convention on Climate Change, 31 I.L.M. 849 (1992).

Agenda 21, the action plan appended to the Rio Declaration, speaks of response actions “which are justified in their own right.” *Agenda 21*, at ¶ 35.3, U.N. Doc. A/Conf.151/26 (1992). Presumably, this is an oblique reference to the cost-effectiveness standard.

237. Thomas Lundmark, *Systemizing Environmental Law on a German Model*, 7 DICK. J. ENVTL. L. & POL’Y 1, 10 (1998).

238. Freestone & Hey, *supra* note 234, at 258; Nicholas A. Ashford, *A Conceptual Framework for the Use of the Precautionary Principle in Law*, in *PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE*, *supra* note 192, at 198, 200.

239. Proportionality is said to be central to the original German concept. See Konrad von Moltke, *The Relationship Between Policy, Science, Technology, Economics and Law in Implementation of the Precautionary Principle*, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION*, *supra* note 204, at 97, 102-04.

240. See Comm’n of the Eur. Cmty., *supra* note 212, at 4-5, 18-20.

241. Charnovitz, *supra* note 141, at 298-301.

comprehensive, which allows consideration of the whole range of potential benefits, as well as risks.²⁴² If a new technology shows promise of enormous benefits, say, an AIDS vaccine, there is nothing in the precautionary principle that would slow development, beyond existing requirements of safety and efficacy.²⁴³

d. Iteration

The precautionary principle, focusing as it does on present uncertainty, fairly implies that some action will be taken to reduce the uncertainty to levels appropriate for taking final regulatory action. The Rio formulation leaves open the question of who is to produce the new information and when it is to be produced. If the burden of proof is allocated to the proponent of the activity, for example, one would expect that the principle would create an incentive for the early, private development of such information. The SPS Agreement appears to contemplate a different scenario:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information. . . . In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.²⁴⁴

Here, the burden of producing the new information clearly lies with the regulator. The Cartagena Protocol is similarly structured, but it does not use the term “provisional” and gives no indication of a time limit. The European Commission in effect splits difference. It requires that precautionary measures be “periodically

242. See Comm’n of the Eur. Cmty., *supra* note 212, at 19-20; *see also* Nollkaemper, *supra* note 217, at 77-79, 91-93.

243. This may not satisfy the complaint of critics of the precautionary principle that it fails to consider adequately countervailing risks (e.g., the risks of forgoing or delaying a useful technology). *See, e.g.*, Stone, *supra* note 204, at 10,791. It would provide the proponent of a new technology the opportunity to demonstrate that a tremendous need for the product exists, as would be the case with an AIDS vaccine. Nothing in GMO agriculture comes remotely close to that level of urgency. *See* Cross, *supra* note 191, at 861; *see also* Julian Kinderlerer, *Genetically Modified Organisms: A European Scientist’s View*, 8 N.Y.U. ENVTL. L.J. 556, 557 (2000) (asserting that biotechnology has “not yet delivered” on anticipated great benefits for the world’s people). The precautionary principle has never to my knowledge been actually used to thwart the discovery of a major vaccine—or, for that matter, any technological discovery at all.

244. SPS Agreement, *supra* note 138, art. 5.7.

reviewed” in light of available scientific information, and that such measures “may assign responsibility for producing the scientific evidence necessary for a comprehensive risk evaluation.”²⁴⁵

The common feature of all of these variations is that the precautionary principle anticipates revisiting the judgments that are based on it. Uncertainty may be unavoidable, but it is not desirable, and efforts to reduce uncertainty are worthwhile (up to a point).²⁴⁶ Science policymakers are increasingly recognizing that toxic substances cannot be evaluated or regulated once and for all. Two recent American studies of risk assessment and management have recommended an iterative or cycling process of investigation, regulation, and learning,²⁴⁷ that is the kind of feed-back loop that is standard in science.²⁴⁸ Jasanoff argues that the precautionary principle should be a “framework for learning in the face of uncertainty.”²⁴⁹ In some cases, for instance, saccharin,²⁵⁰ we will learn that the hazard is less than expected; in others, for example, stratospheric ozone, the hypothesized harm will be later confirmed.

3. *GMOs and the Precautionary Principle*

GMOs are a good candidate for the application of the precautionary principle. With respect to the trigger, serious hazards have been identified. While most are still “over the horizon,” they are not without a basis in scientific theory or unsupported by empirical evidence. Moreover, GMOs are not just persistent, a characteristic of which we are already particularly wary; they *propagate* in the

245. Comm’n of the Eur. Cmty., *supra* note 212, at 20-22.

246. After a certain point, efforts to generate more information have significant costs of their own and can be counterproductive. See John S. Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decision-making*, 63 U. CIN. L. REV. 1643, 1648-50 (1995).

247. PRESIDENTIAL/CONGRESSIONAL COMM’N ON RISK ASSESSMENT & RISK MGMT., FINAL REPORT: 2 RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION-MAKING 7, 32 (1997), available at <http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/pdf/v2epa.pdf>; COMM. ON RISK CHARACTERIZATION, NAT’L RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 163-64 (Paul C. Stern & Harvey V. Fineberg eds., 1996), available at <http://books.nap.edu/books/030905396X/html/163.html>.

248. Gray, *supra* note 217, at 144-46.

249. Jasanoff, *supra* note 4, at 277.

250. Saccharin was banned in the United States on the basis of animal carcinogenicity. Two decades of further study determined that it is *only* an animal carcinogen, not a human one. See U.S. DEP’T OF HEALTH & HUMAN SERVS, NAT. TOXICOLOGY PROGRAM, NINTH REPORT ON CARCINOGENS, app. B, at 5-7 (2001), available at <http://ehis.niehs.nih.gov/roc/toc9.html>.

environment, raising the serious potential for irreversibility on the model of exotic species.²⁵¹

As to timing, uncertainty surely exists in the imprecision of the technologies, in the size of the genetic leaps that GM technology can make relative to conventional breeding, and in the complexity of the genetic and ecological systems into which these substances are introduced. This situation was forecast, and precautionary measures ratified, in the landmark *Ethyl Corp.* case:

Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served. Of course, we are not suggesting that the Administrator has the power to act on hunches or wild guesses. . . . However, we do hold that in such cases the Administrator may assess risks. He must take account of available facts, of course, but his inquiry does not end there. The Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as “fact,” and the like. We believe that a conclusion so drawn may, if rational, form the basis for health-related regulations under the “will endanger” language [of the Clean Air Act].²⁵²

Ethyl does not anticipate a shift in the burden of proof, but it, like the precautionary principle, permits regulation in the face of uncertainty. GMOs do push the envelope of the precautionary principle, because *both* the causal relationships and the harm itself are uncertain. This is not, for example, like endocrine disrupters, where endocrine-based harms have been observed and only

251. See, e.g., Stockholm POPs Treaty, *supra* note 203.

252. *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976) (en banc), *cert. denied*, 426 U.S. 941 (1976).

the relationship to chemicals is unproven.²⁵³ But it is closely analogous to the original ozone controls, which were adopted in advance of observed effects, on the basis of a scientific theory of the causal interaction between chlorofluorocarbons and stratospheric ozone.²⁵⁴

The precautionary principle envisions a range of regulatory responses, and so a precautionary regime could respond to GMOs in several ways. While serious concerns have been raised about the technology, there is little to indicate that all (or even most, or any) uses will result in an uncontrolled, catastrophic chain reaction. If we are concerned with the irreversibility of introducing GM species into the wild, very strict prerelease testing may be quite sufficient to address the risk.²⁵⁵ In addition, some products or species may pose more serious risks than others.²⁵⁶ The recently released studies of Bt maize showed that the pollen of one GM variety was far more toxic to nontarget butterflies than others.²⁵⁷ Clearly, it would be entirely reasonable to regulate that variety more strictly or even to prohibit it.²⁵⁸ Similarly, GM fish are nearly impossible to contain and may have particularly undesirable effects on wild populations.²⁵⁹ They, too, could reasonably be subject to special controls or entire restriction, even though other, less mobile species (plants, for example) are not.

Countervailing risks²⁶⁰ are also relevant to response. Regulation of risk tradeoffs may be implicit in the absence of public outcry over GM insulin, and no sensible regulatory scheme would reject an effective AIDS vaccine merely because of its GM origin. Even where the benefits are great, however, the precautionary principle counsels at least as much skepticism in evaluating claimed benefits (a characteristic notably absent in the pro-GMO literature) as claimed

253. See generally SHELDON KRIMSKY, *HORMONAL CHAOS: THE SCIENTIFIC AND SOCIAL ORIGINS OF THE ENVIRONMENTAL ENDOCRINE HYPOTHESIS* 124-31 (2000).

254. Elizabeth R. DeSombre, *The Experience of the Montreal Protocol: Particularly Remarkable, and Remarkably Particular*, 19 J. ENVTL. L. 49, 50 (2000/2001) (characterizing the initial ozone regulation as "truly precautionary").

255. Stone, *supra* note 204, at 10,796.

256. Wolfenbarger & Phifer, *supra* note 28, at 2092.

257. See Zangerl et al., *supra* note 43.

258. One of the co-authors of the study points out that this variety had already been withdrawn from the market, though apparently not for its toxic effects. David N. Leff, "Iconic Insect" Beats Back Biotech Rap, *BIOWORLD TODAY*, Sept. 11, 2001 (quoting May Berenbaum).

259. Royal Soc'y of Can., *supra* note 28, at 150-70 (discussing GM salmon).

260. See generally JOHN D. GRAHAM & JONATHAN BAERT WIENER, EDs., *RISK VS. RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT* (1995) (describing a general theory of countervailing risks).

risks.²⁶¹ Thus, the precautionary principle offers an alternative to the product-*versus* process-based regulatory regimes. While the principle may be triggered on a process basis, individual products can be separately evaluated.²⁶² The initial concern is raised by the GM process, but the danger is expressed by individual products. Those dangers may vary for any number of reasons, and the response should vary accordingly.

Finally, decisions to permit or restrict GMOs should be subject to revisitation. The new EU directive on GMO releases, for example, affirms an iterative approach, specifying that initial rejection is without prejudice to later acceptance.²⁶³ If, as anti-GMO activists like to say, we are engaged in a huge experiment with genetic modification, then presumably we will learn something from it. What we see (or do not see) now or in five or ten years will not, of course, be definitive—but it will be more than we know now, and it should be part of our ongoing decisions. From this perspective, both proponents' haste to bring GMOs to market and opponents' destruction of field tests prevent the kind of learning that is necessary to assure safety.²⁶⁴

The precautionary principle, in sum, can help to bridge the gap between the Frankenstein and Better Living Through Chemistry legal regimes, because it recognizes the regulatory validity of unproven (but not unfounded) dangers, and it sets in motion a process for resolving them, all the while holding the activity in appropriate abeyance to avoid irreversible harm. The precautionary principle may be a call to move slowly with GMOs, but it is by no means a call to ban them in all cases and forever.

IV. CONCLUSION: THE PROMETHEUS NARRATIVE

I have argued that the divergent regulatory regimes for GMOs are rooted in two radically different narratives of science and knowledge, and that this accounts for the absence of common ground between the two points of view. I have further suggested that the precautionary principle, properly understood and applied, can reconcile the differences exhibited by the regulatory systems for

261. One recent review notes that "confirming environmental benefit is tricky. Virtually no peer-reviewed papers have addressed such advantages, which would be expected to vary from place to place." Brown, *supra* note 44, at 52.

262. Kinderlerer, *supra* note 48, at 558-59.

263. Council Directive 2001/18/EC, *pmbl.*, 2001 O.J. (L 106) 38.

264. Palumbi, *supra* note 32, at B9.

GMOs. The precautionary principle, however, lacks an animating narrative that underpins and gives ideological coherence to its approach. That is my concluding task.

“Frankenfoods” is usually a mere soundbite, a throwaway epithet, for biotechnology. In the first part of this article, I took the analogy literally and argued that in fact *Frankenstein* has serious descriptive power for one of the positions on GMOs. Indeed, it helps to explain the reason that the anti-GMO position is so widely held despite the absence of demonstrable harms. I now want to take the examination of *Frankenstein* a step further, in the hope of finding an alternative to its narrative for GMOs. *Frankenstein*, despite its subtle and even sympathetic portrayal of the monster, has an unambiguous message—Do Not Presume to Tinker with Life Itself—which accounts for its enduring power as a metaphor. However, the usually forgotten subtitle of *Frankenstein*, is *The Modern Prometheus*, and the latter offers a new perspective.

In one version of the Greek creation myth, Prometheus formed human beings out of clay and had Athena breathe life into them.²⁶⁵ The more familiar Prometheus story continues from there. Prometheus, feeling sorry for the solitary, poor, nasty, brutish, and short lives of the humans, stole fire from Olympus and brought it to humans, teaching in addition all the technical arts. (In fact, substitute Prometheus for Chemistry in the DuPont mural, and you get the picture.) Zeus was displeased that mere mortals had acquired these Olympian conveniences, but he was mollified by the offerings that people made to him, because they were now cooked and so wafted a far better aroma up to Olympus.

Prometheus, apparently not satisfied, then conspired with the human beings to cheat Zeus of the best parts of the sacrificial animals. They made two piles of meat: one was bones and gristle, but covered with the rich fat that is particularly pleasing as a burnt offering; the other was the good meat, but stuffed into the animal’s stomach and the whole covered with the offal. Given the choice, Zeus chose the pile covered with fat. When he discovered his mistake, Zeus was enraged and had Prometheus chained to a mountain peak, where an eagle daily

265. For the Prometheus myth I have relied on H. J. ROSE, *A HANDBOOK OF GREEK MYTHOLOGY* 54-56 (1959), EDITH HAMILTON, *MYTHOLOGY* 85-93 (1942), HESIOD, *WORKS AND DAYS*, available at <http://sunsite.berkeley.edu/OMACL/Hesiod/works.html>, and HESIOD, *THE THEOGONY* [hereinafter HESIOD, *THEOGONY*], available at <http://sunsite.berkeley.edu/OMACL/Hesiod/theogony.html>.

pecks out his liver only to have it regenerate each night for another day of torture.²⁶⁶

Prometheus, however, was not the only one punished by Zeus for the sacrifice trick. Hephaestus made a figure out of clay, Athena breathed life into her, Aphrodite gave her beauty, and Hermes gave her guile. Her name was Pandora.²⁶⁷ She married Prometheus' brother, Epimetheus, and the rest is (so to speak) history. She brought with her a beautiful box, could not resist opening it, and a world of trouble was released to punish humans for tricking Zeus.

Victor Frankenstein was the modern Prometheus, first, because he was the creator of a new species. This analogy offers us little illumination, however, because, unlike the malformed and malevolent species that Frankenstein created, the creation of human beings in the Greek story was at worst morally neutral. Furthermore, the myth contains no suggestion that Prometheus was punished for the act of creation. The theft of fire and tricking of Zeus, on the other hand, are directly relevant. Shelley undoubtedly saw in Prometheus' theft and hideous punishment a story of hubris and retribution,²⁶⁸ and she is not alone in this understanding of the legend.²⁶⁹

The theft and punishment part of the Prometheus story is, it seems to me, considerably more complex and ambiguous than Shelley would have it. It is quite remarkable in the myth that Zeus did not punish humans as symmetry or irony would seem to demand, that is, either by removing fire and technology or by using fire and technology to strike at the humans. Instead, the symmetry is of an entirely different kind: the beauty of Pandora and the box she bore, like the rich fat covering bone and gristle, belied what lay within. The fire itself was not the source of the harm, nor was it Prometheus himself whose gullibility introduced Pandora to humankind. (As to the latter, Prometheus had a literally ironclad alibi: he was chained to the mountain at the time.) Trouble and danger, therefore,

266. A more optimistic version is that Prometheus was eventually rescued by Herakles. It is also the more probable version, since climbers have never to my knowledge actually run across Prometheus in the mountains of eastern Turkey.

267. At least one author has used the Pandora myth to describe GMOs, though the author's position is supportive of GMOs. See ALAN MCHUGHEN, *PANDORA'S PICNIC BASKET: THE POTENTIAL AND HAZARDS OF GENETICALLY MODIFIED FOODS* (2000); *but cf.* THORNTON, *supra* note 113 (describing chlorine as "Pandora's Poison" in the title of his book).

268. She may have changed her mind about him in later years. See WOLF, *supra* note 12, at xxviii.

269. For example, Donovan Webster's powerful book about the aftermath of war (unexploded ordnance, land mines, nuclear waste) equates Prometheus and Alfred Nobel. "The chain of technology Nobel initiated has led to more than 100 million deaths by war since he died, making this—by hundreds of times—the bloodiest century in the history of the world." DONOVAN WEBSTER, *AFTERMATH: THE REMNANTS OF WAR 8-9* (1996).

come *with* technology, but they are fundamentally *separable* from the technology. Prometheus is the bringer—but not the author—of our troubles.²⁷⁰

This interpretation stands in distinct contrast to Frankenstein's monster and the Frankenstein narrative, in which the technology itself is the source of our woes. In the myth, fire is an unalloyed good, and humans were perfectly capable of using fire properly. It was not the fire, but the humans' greed, that brought down Zeus' wrath, and it was the human willingness to be misled by beautiful appearances that provided the instrument of the punishment. The lesson of Prometheus' story, then, is retribution for the greedy choice, not retribution for technology as such.²⁷¹

Ted Taylor, a former nuclear weapons designer who shared in the 1995 Nobel Peace Prize for his anti-nuclear activism, drew precisely this lesson from the Prometheus myth:

The weapons are a symptom of something deeper. It's not a biological need, like for food. It's a boundless desire for power.

These days, we understand the destructiveness of nuclear weapons—and we can save ourselves or destroy ourselves with that knowledge. The world, as a global population, has become Prometheus. The choice is ours.²⁷²

Likewise GMOs, "No unequivocal conclusions can be drawn about the overall effect of genetic engineering technologies. It is clear that any manipulation of organisms, whether by conventional means or by genetic engineering, poses some danger to human health, to present systems of agricultural production, and to the natural environments."²⁷³ The challenge is not in the technology itself, but in the care with which we use the technology, and in our ability to resist the lure of profit without considering consequences.

270. Hesiod's timing has humans already in possession of fire, and *removal* of fire was punishment for the sacrifice trickery (which was Prometheus' connivance, but motivated by some other dispute). *Then* Prometheus steals fire back, which is followed by Pandora and Prometheus' rock punishment. In either case, it was not fire per se that brought down Zeus' punishment, but rather a display of human greed; in neither case, is fire the bringer of *both* good and of punishment. See HESIOD, THEOGONY, *supra* note 265.

271. The story of Icarus and Daedalus story has a similar lesson: the tool (wings made of feathers, string, and wax) can be used wisely, as Daedalus himself did, or hubristically, as Icarus did by flying too high and close to the sun. Daedalus is still honored as a craftsman, and Icarus suffered for his pride (as opposed to greed). See German Nat'l Merit Found., Legend of Daedalus, <http://www.studienstiftung.org/daedalus.html> (last visited Dec. 16, 2001).

272. WEBSTER, *supra* note 269, at 142.

273. Lewontin, *supra* note 28, at 83.

Over fifteen years ago, Krier and Gillette critiqued the dominant paradigm of technological optimism. Prefiguring the claims of genetic modification, they offered this example of the optimistic view: “If the world is running short of food, we can count on technological innovation to increase the productivity of agricultural land . . . through better seeds, better fertilizers, herbicides and pesticides.”²⁷⁴ But, they warned, “technology is, after all, a mixed blessing.” The seeds and pesticides may be better, but they may have unexpected and undesirable side effects. Technological optimists tend to ignore these consequences, yet there is every reason to think that “the forces behind technological development are systematically biased in the direction of generating and neglecting certain kinds of undesirable consequences, pollution chief among them.”²⁷⁵ Krier and Gillette focused on the ability to externalize pollution costs that affect a common good, but the same is true of harms that are externalized because they are insufficiently defined (or even known) to permit internalization through markets, the tort system, or regulation.²⁷⁶ The latter is ignorance, and it is also the greed of which the Greeks warned. Technology, as the Prometheus legend tells us, brings both good and bad, and where profits (a desire for the best meat) drive the deployment of a technology and there is no profit in identifying its harms, there is no reason to think that the technologists will spend adequate resources to identify the harms.²⁷⁷

The Prometheus legend, in this sense, undergirds the precautionary principle. It accepts technology’s existence—fire and the technical arts are good things—but it also recognizes the tendency of human beings to misuse technology out of greed. The allergenic potential of soybeans modified with genetic material from Brazil nuts, which is often cited for the detectability and manageability of GMO risks, was in fact known *before* the variety was even developed; the project was stopped only when regulatory scrutiny was imminent.²⁷⁸ The social critique of GMOs is also relevant here. Most GM investment is in technologies that improve profits rather than relieve human suffering. The value of the investment, in turn, is based on the continuing domination, through intellectual property, of the next generation of agriculture by a small number of already wealthy American and

274. Krier & Gillette, *supra* note 62, at 407.

275. *Id.* at 413.

276. Krier & Gillette describe both latency, irreversibility, and zero-infinity (unlikely but catastrophic effects) as having these characteristics. *Id.* at 427. Clearly, all apply to GMOs.

277. See Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 790-96 (1997).

278. Lewontin, *supra* note 28, at 82.

European corporations.²⁷⁹ Greed makes new technology dangerous and warrants caution in adopting it.

The precautionary principle also emphasizes the importance of unintended, unexpected, and unwanted consequences—and hence the critical need for foresight²⁸⁰—in evaluating beautiful packages. Krier & Gillette continued their critique: “The gambles implicit in the optimistic outlook are made tempting by a variety of considerations, some of them of indisputable allure. There are the optimists themselves, whose credentials and authority take on all the more weight because they stand behind a story each of us wishes to hear.”²⁸¹ It is dangerously inadequate to respond only to those effects that look dangerous, that is, that have already been demonstrated—by “sound science” or otherwise—to be so. Instead, we must look forward to anticipate problems not now evident but which, with hindsight, we would have wished to have known about. In bringing Pandora to live among people, Epimetheus did something that, in retrospect, he must have wished he hadn’t done. Appropriately, his name means “afterthought.” The precautionary principle, in contrast, is the foresight principle—*Vorsorgeprinzip*—and it is only fitting that its patron and narrative should be Prometheus, whose name in Greek means “foreseeing.”

279. A number of the contributors to this conference have expressed the concern that the huge potential of GM agriculture will not benefit those most in need of assistance. See Messer, *supra* note 69; Brush, *supra* note 71; Yvonne Cripps, *Patenting Resources: Biotechnology and the Concept of Sustainable Development*, 9 IND. J. GLOBAL LEGAL STUD. 119 (2001).

280. As Kenneth D. Pimple nicely puts it: “we fear the vengeance of a higher power—whether God or fate—or our own invariable inability to take account of all factors and foresee all consequences.” Kenneth D. Pimple, *The Ethics of Human Cloning and the Fate of Science in a Democratic Society*, 32 VALP. U.L. REV. 727, 732-33 (1998).

281. Krier & Gillette, *supra* note 62, at 428.

