

RISK: Health, Safety & Environment (1990-2002)

Volume 11 | Number 1

Article 4

January 2000

Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA

Les Levidow

Susan Carr

Follow this and additional works at: <https://scholars.unh.edu/risk>



Part of the [Administrative Law Commons](#), [Agriculture Commons](#), [Biotechnology Commons](#), and the [Food Biotechnology Commons](#)

Repository Citation

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

This Article is brought to you for free and open access by the University of New Hampshire – School of Law at University of New Hampshire Scholars' Repository. It has been accepted for inclusion in RISK: Health, Safety & Environment (1990-2002) by an authorized editor of University of New Hampshire Scholars' Repository. For more information, please contact ellen.phillips@law.unh.edu.

Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA*

Les Levidow & Susan Carr**

Introduction: Disputed Novelty

Biotechnology provokes wide-ranging debate about social, political and environmental risks. For genetically-modified organisms (GMOs), often these risks have been attributed to the novelty of genetic modification (GM) techniques, their commercial products and the consequent means to industrialize agriculture. In such ways, GMOs have been stigmatized as abnormal. They are portrayed as violating natural processes — or else as benignly simulating Nature — amid contending visions of the social order.¹

Since the 1980s GMOs have been promoted as “environmentally-friendly products.”² According to proponents, such products offer a natural extension of traditional breeding, precise genetic changes, and remedies for the problems caused by intensive agriculture. The biotechnology industry has adopted the language of environmental sustainability; for example, “in-built genetic information” helps GM crops to protect themselves from pests and disease, thus reducing dependence upon agrochemicals.³

* This essay arises mainly from two studies funded by Britain’s Economic and Social Research Council: *Regulating the Risks of Biotechnology* (1989-91) and *From Precautionary to Risk-Based Regulation: the Case of GMO Releases* (1995-96). Follow-up research was done during a Europe-based study, *Safety Regulation of Transgenic Crops: Completing the Internal Market?* funded by the European Commission, DG XII/E5, Ethical, Legal and Socio-Economic Aspects, Biotechnology horizontal programme (1997-99). We thank the ten interviewees quoted here, including several at the EPA. For editorial suggestions, we thank Jane Rissler, Helge Torgerson, Roger Wrubel and anonymous referees of this journal.

** Dr. Carr received her Ph.D. from the Open University where she is a Senior Systems Lecturer. E-mail: S.Carr@open.ac.uk.

Dr. Levidow received his Ph.D. from the Open University where he is a Research Fellow at the Centre for Technology Strategy. E-mail: L.Levidow@open.ac.uk.

¹ See Les Levidow, *Simulating Mother Nature, Industrializing Agriculture*, in *Future Natural: Nature, Science, Culture* 55 (G. Robertson et al., eds., 1996).

² See Les Levidow & Joyce Tait, *The Greening of Biotechnology: GMOs as Environment-Friendly Products* 18(5) *Sci. & Pub. Pol.* 271 (1991).

According to critics, however, GMOs will aggravate the hazards of intensive agriculture, e.g., by extending dependence upon agrochemical or single-gene solutions, by accelerating resistance to pests, and by imposing new hazards. From the critics' standpoint, the basic problem is intensive monoculture, which generates the need for chemical or genetic fixes: "Biotechnology offers an apparent respite for monoculture by lowering the pesticide input, offering an acceptable environmental cost, for a while, if they are lucky," according to a U.S. campaigner.⁴

As GMOs carry the stigma of abnormality, risk regulation has the implicit task of symbolically normalizing them.⁵ In the U.S., disputed accounts of novelty have been central to regulating GMOs. U.S. regulatory debate revolves around the following questions: What genetic combinations should be classified as novel? What novel effects warrant regulatory controls and further research? If an effect is already acceptable for conventional agricultural products, then why shouldn't it be acceptable for GM products too?

This essay analyses how the U.S. Environmental Protection Agency (EPA) regulates GMOs. As is suggested here, the EPA devised scientific criteria for genetic novelty which indicates "risk" — really meaning greater uncertainty about risk. In approving products, the EPA evaluates their potential effects, relative to a baseline influenced by public debate. By selectively normalizing biotechnological novelty, the regulatory procedure sets standards for a future environment. Those dynamics are illuminated by two analytical perspectives — national regulatory styles and symbolic language in regulatory debates.⁶

³ See John Magretta, *Growth Through Global Sustainability: An Interview with Monsanto's CEO, Robert Shapiro*, Harv. Bus. Rev. Jan-Feb 1997 at 79; Monsanto Company, *Report on Sustainable Development* (1997).

⁴ Interview with representative from the Union of Concerned Scientists (Oct. 24, 1995).

⁵ See Les Levidow, *Biotechnology Regulation as Symbolic Normalization*, 6(3) Tech. Anal. & Strat. Mgmt. 273 (1994).

⁶ For a comparison to European approaches see Les Levidow, *Regulating Bt Maize in the USA and Europe: A Scientific-Cultural Comparison*, 41 Environment 10 (1999); see also Les Levidow & Susan Carr eds., *Precautionary Regulation: GM Crops in the European Union*, 3(3) J. Risk Res. (forthcoming 2000).

U.S. Regulatory Culture

Theories of “national regulatory style” have been developed to investigate the sources of legitimacy for policy. Analytical questions include the following: How are the policy process and public debate managed? What channels are available for various constituencies to influence or challenge regulatory policies? How is scientific expertise constituted and portrayed to legitimize regulatory policy?

In each national style, a different image of science dominates the process of legitimation and social authority. U.S. regulation presents a formalistic rule-bound image. By contrast, for example, regulators in the U.K. regard such a formal scientific method as mere “competence”; their true expertise entails an informal negotiation which builds trust with those being regulated.⁷

U.S. risk regulation has been theorized as “adversarial”. Regulators are expected to devise detailed rules, to justify them in clear scientific terms, and to enforce compliance.⁸ The scientific basis of risk assessment readily comes under challenge from outsiders, such as industrialists or environmentalists. External challenges are facilitated by the U.S.’s constitutional separation of powers — especially since the 1970s, when Congress established stronger regulatory mandates.

In general agencies publish proposals for new rules and product approvals in the Federal Register. That affords a means for soliciting comments, to which agencies usually must reply. Historically, that procedure expressed a distrust of regulators, who can gain trust only by being held publicly accountable for every detail of their policy.⁹

In regulating hazardous chemicals and drafting new rules, the EPA had long disputes over the scientific basis for policy. To justify treating a substance as carcinogenic, it had to extrapolate from animal studies to humans, and/or extrapolate from documented high-dose harm to hypothetical low-dose harm. Those predictive uncertainties remained inherently untestable and thus more vulnerable to challenge.¹⁰

⁷ See Tim O’Riordan & Brian Wynne, *Regulating Environmental Risks: A Comparative Perspective*, in *Insuring and Managing Hazardous Risks: From Seveso to Bhopal and Beyond* 389 (P.R. Kleindorfer & H.C. Kunreuther eds., 1987).

⁸ *Id.* at 398.

⁹ See David Vogel, *National Styles of Regulation: Environmental Policy in Great Britain and the United States* (1986).

Eventually the EPA devised a “science policy” — i.e., specific criteria for the scientific evidence which would warrant imposing or deferring regulatory controls. Yet, its rules were criticized for representing political judgements as science. In response, it developed “peer review” procedures involving independent scientists, e.g., through its advisory committee. The EPA, thus, sought authority for decisions as outcomes of a fair consensual procedure, rather than as truth-claims about predicted harm. However, the committee procedure itself was adversarial, and conflicting constructions of science were pitted against each other.¹¹ In U.S. regulatory culture, political divergences are often expressed as disputes about the acceptability of evidence, or a proxy for the acceptability of risk or of a technological choice.¹²

In the case of agricultural GMOs, both the R&D and the risk debate originated in the U.S., where the issues went beyond biophysical risk. Early regulatory measures intensified disputes among experts, each framing the risk issues according to their own scientific discipline; in general, molecular biologists emphasized the familiarity of GMOs, while ecologists emphasized their novelty and unpredictability.¹³ Moreover, the controversy became a social assessment of a new technology, involving diverse actors beyond the official experts.¹⁴

As Sheila Jasanoff argues, U.S. biotechnology regulation was structured to minimize opportunities for public influence. Risk-based rhetoric was deployed to keep GMO regulation within existing statutory-bureaucratic frameworks. As intended, the absence of new legislation foreclosed new opportunities for judicial review and sharply restricted the dissenting public’s least constraining avenue of success. Relative to the broad public debate, decision making was narrowed to questions of physical risk and safety; new rules focused upon

¹⁰ See Sheila Jasanoff, *Science, Politics and the Renegotiation of Expertise at EPA*, 7 *Osiris* 2nd 195 (1992).

¹¹ See Jasanoff, *supra* note 10; Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (1990).

¹² See Sheila Jasanoff, *Acceptable Evidence in a Pluralistic Society*, in *Acceptable Evidence: Science and Values in Risk Management* 29 (D. Mayo & R. Hollander, eds., 1991).

¹³ See Sheldon Krimsky, *Biotechnics and Society: The Rise of Industrial Genetics* (1991).

¹⁴ See Camille Limoges et al., *Controversies Over Risks in Biotechnology (1973-89): A Framework of Analysis*, in *Managing Environmental Risks* 155 (1990).

identifiable product characteristics. As all sides accepted that U.S. regulation must be “based on science,” scientific disputes thus become a surrogate for unstated ethical or economic conflicts.¹⁵

In the wider public debate about biotechnology, such conflicts have arisen from contending visions of future farming. GMOs are promoted as a naturally-based means to exercise a benign control over nature, towards more efficient agricultural methods. Such claims provoke arguments about whether biotechnology is “un/natural,” as well as whether “genetic power” is a friend or foe. This symbolic language expresses secular techno-myths, which serve as a proxy for risk concerns. Krinsky and Wrubel argue that such language will subside as the risks issues are managed by safety regulation.¹⁶

However, U.S. regulators rarely required applicants to supply new ecological information for safety claims. The U.S. government operated a minimalist, cost-effective approach requiring a burden of proof that regulation is warranted.¹⁷ Consequently, the U.S. procedures had a weak basis for clarifying the risk issues.

For risk regulation, this essay asks the following questions: How are some GMOs defined as novel? At the commercial stage, how are they ultimately treated as normal or abnormal? How are the risk-assessment criteria influenced by pressure groups, and by accounts of sustainable agriculture? How does symbolic language wane and/or arise in regulatory arguments?

Framing “Product-Based” Regulation

Regulatory issues were initially framed by the “process versus product” debate. In general, environmentalist critics argued that all GMOs should be regulated via new legislation because they result from genetic modification. Biotechnology proponents argued that GMOs

¹⁵ See Sheila Jasanoff, *Product, Process, or Programme: Three Cultures and the Regulation of Biotechnology*, in *Resistance to New Technology* (Martin Bauer ed., 1995). Her later analysis emphasized how such disputes were avoided: ‘U.S. regulatory practices fostered the impression that the safety of GM crops could reliably be determined case by case, by technical experts, on the basis of science untainted by social or political considerations.’ See Sheila Jasanoff, *Between Risk and Precaution: Reassessing the Future of GM Crops* 3(3) J. Risk. Res. (forthcoming 2000).

¹⁶ See e.g., Sheldon Krinsky & Roger Wrubel, *Agricultural Biotechnology and the Environment: Science, Policy and Social Issues* (1996).

¹⁷ *Id.* at 251.

should be regulated only on the basis of specific product characteristics. Rather than enact new GMO legislation, the U.S. devised “product-based regulation.” In 1986 the Office of Science and Technology Policy (OSTP) issued a Coordinated Framework. It set guidelines for classifying GMOs according to their product categories, for assigning each category to the relevant federal agency, and for adopting consistent scientific criteria among the agencies.

Under the Coordinated Framework, GMOs would be regulated (if at all) like their unmodified counterparts, under existing product legislation. U.S. agencies could not impose “additional” regulatory oversight, e.g., by requesting extra data, unless warranted by novel product characteristics. Agencies were offered only two criteria for such novelty: “pathogenic” characteristics and “intergeneric organisms.”¹⁸

Soon the Department of Agriculture (USDA) cited the OSTP “pathogenic” criterion to regulate all genetically modified plants. New rules were issued under its pre-existing legislation for “plant pest risks.” Since then it has granted numerous requests to classify specific GM plants as “non-regulated articles,” thus permitting commercial use without further controls under its legislation.

In contrast to the USDA, the EPA had political and scientific difficulties in satisfying the OSTP criteria. Influenced by Vice President Quayle, new OSTP guidelines imposed more severe constraints on federal agencies. They had to base requirements upon “identified risk” from specific product characteristics; they had to show that “the value of the reduction in risk obtained by additional oversight is greater than the cost imposed.”¹⁹ These constraints deterred the EPA from publishing draft rules for GMO regulation.

The political climate changed with the Clinton Administration. Safety regulations became a means to promote environment-friendly, publicly acceptable biotechnology. It sought to develop a regime which

¹⁸ See *Coordinated Framework for Regulation of Biotechnology*, Office of Science and Technology Policy, 51 Fed. Reg. 23302 (1986).

¹⁹ See *Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms With Modified Hereditary Traits*, Office of Science and Technology Policy, 55 Fed. Reg. 31118 (1990); see also *Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment*, Office of Science and Technology Policy, 57 Fed. Reg. 6753 (1992).

would be reassuring to the public, predictable and expeditious for industry, and free of unnecessary political hurdles.²⁰ Regulatory procedures were re-oriented towards a state-industry partnership, on the premise that "biopesticides offer a real opportunity to reduce chemical-insecticide risks." EPA assistant administrator Lynn Goldman stated that "We want the crop-protection industry to feel that they are partners with the EPA in producing substances to control pests."²¹

The OSTP constraints were soon removed so that the EPA could issue draft rules, e.g., under its legislation for pesticides and toxic substances (see subsequent sections). Such legislation gives the EPA a potentially broad remit for what organisms to regulate; it requires an explicit risk-benefit analysis, and so allows the EPA much discretion about what data to request.

Environmentalist campaigners preferred that more regulatory authority be taken by the EPA, partly because it would be more likely to request new knowledge to clarify risks. The meaning of a risk-assessment criterion depends upon which agency is responsible. "If sexual compatibility [hybridization capacity] isn't known, then the Animal and Health Plant Inspection Service (APHIS) branch of the USDA, simply says that there is no scientific information which should worry us, whereas the EPA may take a more cautious approach," according to one Non-Governmental Organization (NGO).²²

Mainstream industry too preferred that the EPA take greater authority, partly for reasons of public credibility: "A regulatory regime is warranted to deal with the uncertainty about assuring the predictiveness of the technology, at a stage when we lack experience in the field," according to the Bio-Industry Organization.²³ Indeed, sometimes companies have sought an official safety imprimatur even before approval was legally required for their GMO releases.

²⁰ See Greg Simon, *Technology, Trade and Economic Growth*, in BioEurope '93, International Conference and Proceedings 17 (Senior Advisory Group for Biotechnology, 1993).

²¹ See e.g., Ronald Hoyle, *EPA Okays First Pesticidal Transgenic Plants*, 13 Nat. Biotech. 434 (1995).

²² Interview with representative from the Environmental Defense Fund (Oct. 27, 1995).

²³ Interview with representative from the Bio-Industry Organization (Oct. 18, 1995).

In devising its new rules and assessing commercial products, the EPA used its advisory committees as a forum for concerns to be accommodated. Part of each committee meeting has been public, attended by various constituencies, e.g., industry lobbyists, applicants, environmental NGOs. The committee meetings have proved less useful to legitimize specific decisions, which sometimes provoke disagreements, even within the EPA itself. At best, peer review has provided a fragile way to base policy on authoritative science. The Biotechnology Science Advisory Committee (BSAC) was intended to advise on overall policy, and the Scientific Advisory Panel (SAP) was to advise on pesticidal substances.

In describing the roles of its "committees," the EPA distinguishes between science and policy: "The SAP is asked scientific questions about risk assessment of pesticides, not how to regulate pesticides; that is our decision."²⁴ The science/policy boundary has been more flexible, depending upon the context and breadth of consensus. Regulatory criteria for novelty have remained contentious, contingent upon new GMOs, new scientific knowledge, and new political pressures.

U.S. agencies have been under deregulatory pressure to base all decisions upon "sound science." That political slogan was intended to ensure that the burden of evidence falls upon those who make risk claims, rather than those who claim safety. Although the slogan put the EPA on the defensive, the meaning has been broadened in practice. Sometimes the agency has sought more evidence of safety, and for a broader range of environmental effects than before, in response to environmentalist pressure.

Such pressure was catalysed mainly by the Environmental Defense Fund (EDF) and the Union of Concerned Scientists (UCS). In response, the EPA extended its authority to microbial GMOs, and then to pesticidal and insecticidal genes in GM plants (see below). Environmental NGOs also proposed that the EPA regulate herbicide-tolerant crops for their herbicide implications, but the agency regarded such a measure as unnecessary for protecting the environment.²⁵

²⁴ Interview with representative from the Office of Pesticide Programs branch of the EPA (June 17, 1996).

²⁵ See Rebecca Goldberg & Doug Hopkins, *Addressing Environmental Risks of*

Extending TSCA to “Intergeneric” Micro-organisms

On what statutory basis could the EPA regulate genetically modified microbes? The 1976 Toxic Substances Control Act (TSCA) mandates the EPA to regulate new chemical substances which present an “unreasonable risk of injury to health or the environment.” The EPA regarded chemical legislation as an inadequate basis for regulating GMOs, but Congress would not enact any new law to cover GMOs.²⁶

As early as 1983, the agency announced that it would regulate microbial GMOs under TSCA. This law normally excluded small-scale experiments, so the EPA had to devise criteria specifying which GMOs would be subject to “additional regulation.” It defined novelty by specifying types of genetic insert which could cause a behavioural change.

“Intergeneric” Criterion

As a preliminary measure in 1986, following the Coordinated Framework, the EPA proposed to regulate all “intergeneric” organisms under TSCA. The EPA implicitly attributed a “high risk potential” to these organisms.²⁷ In practice, the “intergeneric” criterion proved difficult to implement, partly because biological knowledge could not always define the boundaries of microbial genera.

Officials preferred simply to issue a process-based rule, i.e., covering all micro-organisms which result from the genetic modification process, but this option was blocked by the OSTP guidelines.²⁸ The TSCA rule was delayed by long discussions over how to regulate GMOs — i.e., by the “product vs. process” debate.²⁹ When EPA draft rules sought to accommodate the “product-based” criterion during the Bush Administration, they were blocked by the Executive Office.

After the OSTP constraints were eased by the Clinton Administration, the EPA eventually adopted the “intergeneric”

Commercializing Herbicide-Tolerant Plants: EPA’s Options for Regulating Herbicide-Tolerant Plants Under FIFRA, in *Herbicide-Resistant Crops: Agricultural, Economic, Environmental, Regulatory and Technological Aspects* (1995).

²⁶ See Krimsky, *supra* note 13 at 188.

²⁷ Interview with representative from EPA’s Office of Toxic Substances (June 17, 1996).

²⁸ *Id.*

²⁹ See OPP Interview, *supra* note 24.

criterion, for lack of a workable alternative.³⁰ Its proposed rule received a mixed response, even from within industry. Some small companies opposed the EPA's basic solution — indeed, opposed any greater authority for the EPA — by denying that GMOs could be regarded as new “chemical” substances. Those arguments were promoted in the trade and scientific press.³¹

By contrast to those critics, the main industry lobbyists accepted the EPA's basic solution, while criticizing some details. For example, they argued that “newness” requires scientific criteria for “whether there has been an intergeneric transfer of a new phenotypic trait.”³² That proposal generated further debate about what GMOs warrant a requirement for EPA approval prior to small-scale trials.

Particularly controversial were antibiotic-resistance genes, used routinely as a marker to identify the GMO in the laboratory. Scientists debated whether the antibiotic-resistance gene could plausibly transfer to gut pathogens, thus undermining the efficacy of the corresponding antibiotic. Eventually the EPA proposed that antibiotic-resistance genes would not warrant requiring a permit for small-scale trials.³³ Earlier the EPA's advisory committee had urged the agency to discourage the use of such markers, especially those for resistance to antibiotics currently in clinical use.³⁴ When the EPA exempted these from its draft rule, the committee did not see the draft before publication.³⁵ Environmental NGOs criticized the broad exemption for encouraging the indiscriminate use of antibiotic-resistance markers, while disadvantaging safer alternatives.³⁶ As an EPA official stated, “Yes, in effect, the rule would steer marker techniques in that direction,” though he defended the rule as validly generalizing from previous safety

³⁰ See Proposed Regulation Under TSCA for Microbial Products of Biotechnology, 59 Fed. Reg. 45525 (1994).

³¹ See e.g., Henry Miller, *The EPA's War on Bioremediation*, 15 Nat. Biotech. 486 (1997); Jeffrey Fox, *EPA Issues, USDA Amends Respective Biotech Rules*, 15 Nat. Biotech. 503 (1997).

³² See Bio-Industry Organization response to Proposed Regulation, *supra* note 30.

³³ See Proposed Regulation, *supra* note 30.

³⁴ See EPA Report, Meeting of the Biotechnology Science Advisory Committee, Antibiotic-Resistance Markers Subcommittee (Jan. 19, 1989).

³⁵ See OTS Interview, *supra* note 27.

³⁶ See e.g., EDF (1994) reply to EPA-OPPT Oct.

assessments.³⁷ By implicitly accepting such genetic inserts as normal, regulators set the stage for later scientific dissent.

Rhizobium Controversy

Later in 1994, a high-profile controversy erupted over such an antibiotic-resistance gene, in the first product proposed for commercial approval under TSCA. Research Seeds requested commercial approval of its *Rhizobium* as an alfalfa inoculant designed to reduce chemical fertilizer usage. Having approved small-scale trials of the product, the EPA now considered any additional uncertainties about large-scale use.

The EPA posed several questions about the potential effects of the inserted genes for enhanced nitrogen-fixation and for antibiotic resistance. For example, the microbe could colonize leguminous weeds and confer greater fitness; or the antibiotic-resistance gene could transfer to other microbes and harm human health.³⁸ However, eventually the EPA reframed the original questions in a more narrow way. Rather than ask simply whether the organism could cause harm, it asked the advisory committee whether the organism would have a greater potential for novel behaviours, and whether these would be caused by the genetic insert as such.³⁹

The EPA's advisory committee requested more research on a wide range of uncertainties, e.g., regarding the stability, transfer and potential effects of both genetic inserts.⁴⁰ Advisors disagreed about which uncertainties warranted more testing.⁴¹ Subsequently an EPA official acknowledged the committee's concern about the nitrogen-fixation gene, but not about the antibiotic-resistance gene.⁴²

The EPA regarded the spread of the antibiotic-resistance genes as unlikely, while noting that these particular antibiotics have little clinical use anyway.⁴³ Although environmental NGOs accepted the "low-risk"

³⁷ See OTS Interview, *supra* note 27.

³⁸ See Krimsky & Wrubel, *supra* note 16 at 151.

³⁹ See Genetic Genie: The Premature Commercial Release of Genetically Engineered Bacteria 20 (Public Employees for Environmental Responsibility (PEER) ed., 1995).

⁴⁰ See Biotechnology Science Advisory Committee, Subcommittee on Premanufacture Notification, *Review of Nitrogen-Fixing Rhizobium meliloti: A Review of the Risk Assessment Prepared by the EPA*, (BSAC ed., 1995) Mar. 6, Appendix I.

⁴¹ Interview with representative from New Scientist (Jan. 4, 1995).

⁴² See OTS Interview, *supra* note 27.

assessment for this product, they criticized the EPA for implicitly accepting the clinical loss of an antibiotic, given that such a judgement had a more general relevance to marker genes.⁴⁴

Also in dispute was the “benefits” assessment which is required by TSCA for each decision. Product efficacy depended upon the competitive advantage of the product in the rhizosphere, which in turn depended somewhat upon environmental conditions in the field — more variable than in the greenhouse. Benefits were inherently difficult to demonstrate on a consistent basis.⁴⁵

NGOs disputed the EPA claim for benefits and thus its interpretation of the TSCA requirements.⁴⁶ “The transgenic *Rhizobium* has been approved without any evidence of [improved] efficacy.... If the ‘benefits’ are so unappealing, then why take undefined risks?” asked one officer.⁴⁷

As an EPA official acknowledged, the agency presumes general benefits from biotechnology research, as well as making a specific claim for this product:⁴⁸

We start from the assumption that conducting R&D benefits society, though we also look at potential risks and perhaps modify the way in which R&D is proposed to be done. The 1995 data for this *Rhizobium* shows an improved yield (of statistical significance) under specific soil conditions, e.g., with low nitrogen levels.

Eventually the EPA’s own advisory committee questioned the agency’s claim for benefits from this *Rhizobium* product.⁴⁹

Moreover, EPA claims were challenged by some staff members in the western U.S., where alfalfa growers provided the main prospective market for the product. In an unprecedented move, some staff

⁴³ See EPA-OPPTS, *Risk Assessment: Commercialization Request for P-92-403 Rhizobium meliloti RMBPC-2*, Dec. 1994; see also OTS Interview, *supra* note 27.

⁴⁴ See e.g., EDF, *Comments on Research Seeds application for BSAC meeting*, Environmental Defense Fund, January 1995.

⁴⁵ See Krinsky & Wrubel, *supra* note 16 at 146.

⁴⁶ See Gene Exchange (1994-98) semi-annual publication by the Union of Concerned Scientists (formerly by the National Wildlife Foundation).

⁴⁷ See UCS Interview, *supra* note 4.

⁴⁸ See OTS Interview, *supra* note 27.

⁴⁹ See Krinsky & Wrubel, *supra* note 16 at 151.

anonymously published a booklet attacking the agency for unwarranted claims about both of the inserted genes. In their view, the EPA posed leading questions to BSAC, and thus pre-empted the terms of reference for scientific inquiry. They diagnosed the problem as a “breakdown in independent peer review,” and thus a loss of scientific integrity for decision-making.⁵⁰

In this case, the EPA had recast the original risk issues as the novelty of harm and its genetic causes. This shift increased the burden of evidence for risk, rather than for safety.⁵¹ Despite dissent from its own advisors and staff, the EPA decision met no wider challenge, thus facilitating commercial approval.

Extending FIFRA to GM Pesticides

On what statutory basis could the EPA regulate GM pesticides? Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the EPA regulates all such agents; it must ensure that they cause no “unreasonable adverse effects” on the environment, while balancing risks against benefits. FIFRA exempted biocontrol agents from a requirement for an Experimental Use Permit (EUP); this exemption would have precluded the EPA from regulating small-scale field trials of genetically modified biopesticides. In order to warrant such regulation, the agency had to define novelty.

Microbial Pesticides

For GM pesticides, initially the major new category was micro-organisms. From the mid-1980s onwards, insecticidal genes were

⁵⁰ According to a BSAC member who subsequently resigned, ‘I sensed that EPA was under tremendous pressure to approve the *Rhizobium* for commercial use. I don’t know what forms this pressure took and whether it originated mostly internally at EPA or externally. EPA did try to control the BSAC report. They wrote almost all of it before the committee met and did try to suppress criticism from within EPA. For me the biggest problem was that the EPA-prepared report drew conclusions that could only be based on solid scientific information, but there either was no such evidence at all, or some evidence contrary to what the EPA wanted BSAC to conclude. I resigned because I could never sign a document so weak scientifically.’ Dr Conrad Istock, personal communication, July 1997.

⁵¹ An opposite shift can be found in chemicals regulation. During the earlier disputes over whether to ban particular chemicals, the EPA recast the safety issue in ways which lowered the burden of evidence for risk under FIFRA. For example, it asked the Scientific Advisory Panel whether chemicals were qualitatively ‘carcinogenic in animals,’ while the committee preferred to scrutinize the available evidence in quantitative terms. See Jasanoff *supra* note 10 at 146.

isolated from the naturally occurring bacteria *Bacillus thuringiensis* (Bt) and inserted into other microbes, especially *Pseudomonas*, which would persist longer on the plant. Given such persistence, a major concern was potential harm to non-target insects. After much argument over how to fill the regulatory gap, the EPA conceptualized the Bt gene as a "chemical"; draft rules required an Experimental Use Permit (EUP) for small-scale field trials of GM microbial pesticides.⁵²

After all that difficulty, few products needed assessment under the new FIFRA rule, for several reasons. R&D efforts were shifted from microbes to plants. By the early 1990s a major investor in microbial pesticides, the Monsanto Company, concluded that GM plants would provide a more profitable market.⁵³ Also, the EPA discouraged the development of genetically modified microbial pesticides in a live form.⁵⁴ According to an EPA official:

When one company [Mycogen] proposed to market a recombinant Bt *Pseudomonas*, we queried whether this would be advisable, in view of environmental concerns. We had decided that the transfer of genes across the gram positive/gram negative boundary was not documented to occur in nature and, thus would require either a cautious approach for containment or full testing for non-target effects. Also, Jeremy Rifkin's Foundation on Economic Trends could delay the company by seeking an injunction on procedural grounds, though most likely the court would reject the request. In response to our query, the company offered to kill the microbe before marketing it. EPA helped to ensure that 100% of the microbes were really killed.⁵⁵

Following that strategy, the Mycogen Company obtained commercial approval for the dead microbe.⁵⁶ Any controversy was pre-empted by altering the product to avoid novel risks.

Plant Pesticides

Another new category of GMO was plants with Bt genes or virus-resistance genes. Initially the EPA did not intend to regulate plants,

⁵² See Microbial Pesticides; EUPs and notifications [FIFRA], 59 Fed. Reg. 45600 (1994).

⁵³ See Krinsky and Wrubel, *supra* note 16 at 118.

⁵⁴ *Id.* at 122, 132.

⁵⁵ See OPP Interview, *supra* note 24.

⁵⁶ See Anon. 156 Agrow 28 (1992).

though it assessed Bt tobacco plants for trial release in 1986-87. However, environmental NGOs pressurized the EPA to use FIFRA for regulating plant pesticides, i.e., pesticidal genes which have been inserted into plants.

In addition to FIFRA, the EPA also had authority under the Federal Food, Drug and Cosmetic Act (FFDCA) to regulate pesticide residues for "tolerance limits." Although nominally intended to safeguard food safety, this law could be used indirectly to regulate environmental effects too. So NGOs urged the agency to extend the FFDCA for regulating pesticidal inserts in plants.

Between 1992-94 the EPA held several consultative meetings to develop new rules under both FIFRA and FFDCA. Eventually the agency decided that the biocontrol agents exemption does not extend to pesticidal substances in plants.⁵⁷ On that basis, the agency issued a draft rule for regulating GM pesticidal substances in plants, on grounds that the genetic inserts are "chemicals."⁵⁸ Industry lobbyists regarded the EPA as the proper authority for this task and supported its basic proposal.⁵⁹

There were some disagreements over details, e.g., over exactly what genetic inserts might generate novel pesticidal substances and which ones therefore warranted regulatory oversight. Industry and environmental groups submitted countervailing proposals for appropriate exclusions from the requirements.⁶⁰ At issue here was the presumed normal baseline for judging a trait as "novel" and thus for regarding its effects as less predictable. In the U.S. Congress some members sought to block the EPA rule, partly on the misconception that it would regulate the entire plant, not simply the pesticidal substance. The Congress now had a right-wing Republican majority, being advised by former staff members of Dan Quayle's Council on Competitiveness. They took encouragement from professional societies which denounced the draft rule — as "scientifically indefensible," as regulating "hypothetical risks," and as a deterrent to innovation.⁶¹

⁵⁷ See OPP Interview, *supra* note 24.

⁵⁸ See Plant-pesticides subject to FIFRA and FFDCA, 59 Fed. Reg. 60496 (1994).

⁵⁹ See BIO Interview, *supra* note 23.

⁶⁰ *Supra* note 30.

⁶¹ See Jeffrey Fox, *Minnows and Academics Hold Up EPA Rules*, 15 Nat. Biotech. 838 (1997).

However, the main industry lobby group — the Biotechnology Industry Organization (BIO) — asked critics not to obstruct the EPA rule in Congress.⁶² BIO pursued its minor disagreements discretely, via written submissions to the EPA. The EPA argued, “We hope to convince the American people that the technology is safe and to ensure it’s accepted.”⁶³

Potential harm to non-target insects clearly fell within the EPA’s remit under FIFRA. Eventually, when laboratory evidence indicated risks to Monarch butterfly larvae, NGOs demanded a moratorium or extra controls for protecting them.⁶⁴ The EPA was petitioned to require farmers to plant buffer zones around Bt maize.⁶⁵ Under environmentalist pressure, the agency announced two extra measures. On a voluntary basis, “we suggest farmers locate refugia in such a manner as to serve to protect potentially vulnerable non-target insects,” since refugia areas can serve as buffer zones between the cornfields and the habitat of non-target insects. On a mandatory basis, registrants had to submit protocols outlining their strategies for collecting data on the various factors relevant to non-target harm.⁶⁶ A clear scientific basis is the goal, not the explanation, for more stringent controls.

Managing Insect Resistance

When Bt genes were first inserted into other microbes, and then into plants, such R&D provoked debate over insect resistance (as well as harm to non-target insects). Environmentalists and various scientists warned that insecticidal plants would intensify selection pressure for resistant insects, thus shortening the useful lifespan of the product. Such resistance could also undermine the efficacy of naturally occurring Bt, thus losing an invaluable resource for sustainable agriculture. Debate ensued on how to minimize the selection pressure, e.g., through high-

⁶² See BIO Interview, *supra* note 23.

⁶³ See Fox, *supra* note 61.

⁶⁴ See John E. Losey, Linda S. Rayor & Maureen E. Carter, (1999) *Transgenic Pollen Harms Monarch Larvae*, 399 *Nature* 214 (1999).

⁶⁵ Petition to the EPA to require the planting of buffer zones by the New York Environmental Defense Fund, (July 1999) (on file with the Environmental Defense Fund).

⁶⁶ Letter to Bt corn registrants by the EPA, (Dec. 1999) (available on the EPA website at <http://www.epa.gov/pesticides/biopesticides>).

dose strategies to kill all the pests, and/or through statutory controls on the design of Bt plants. The USDA held a conference which brought together scientists from industry and academia.⁶⁷

Meanwhile biotechnology companies were devising their own resistance-management strategies. For example, "genetic treadmill" solutions sought to develop new Bt toxins faster than insects could develop resistance to the old ones.⁶⁸ Even if insect resistance developed in five years, the company might gain an adequate return on its investment by then.

The EPA initially stayed aloof from the resistance problem, but the agency eventually accepted some responsibility, for several reasons.⁶⁹ Environmental NGOs were able to cite a real problem facing farmers and perhaps the companies themselves. The U.S. has increasingly serious pest problems, so farmers have greater interest in non-chemical control methods. Microbial Bt symbolized an irreplaceable resource for the future of organic agriculture, though it was being sprayed on only 8% of U.S. cotton fields, and less than 1% of corn.⁷⁰

Moreover, FIFRA assigned the EPA a remit for explicitly balancing risks against benefits. EPA officials argued that pesticidal crops would bring a significant "reduction in risk" by substituting for chemical insecticide usage.⁷¹ That claim would be undermined by insect resistance, so the EPA more readily accommodated pressures to avert such an outcome.

Conditional Registration

For guiding Insect Resistance-Management (IRM), the EPA consulted its relevant advisory committee. The EPA stated:⁷²

We consulted the SAP on criteria for successful management of insect resistance. The specialists did not

⁶⁷ Conference hosted by the Agricultural Research Service of the USDA, Scientific Evaluation of the Potential for Pest Resistance to the Bt Delta Endotoxin: A Conference to Explore Resistance Management Strategies.

⁶⁸ See Les Levidow, *Agricultural Biotechnology as Clean Surgical Strike*, in Susan Elworthy et al. eds, *Perspectives on the Environment II*, p. 31-44, (1995).

⁶⁹ See Jeffrey Fox, *Biotech Regulatory "Scope" Set*, 10 *Biotech*. 358 (1992).

⁷⁰ See Union of Concerned Scientists, *Now or Never? Serious New Plans to Save a Natural Pest Control* (1998) <<http://www.ucsusa.org>>.

⁷¹ See Hoyle, *supra* note 21.

⁷² See OPP Interview, *supra* note 24.

always agree with each other, though their discussion was useful; it confirmed that our approach considered their concerns. We want our policy to be based upon sound science.

That official acknowledged that regulatory decisions are also influenced by “legal and practical issues,” while emphasizing the importance of “sound science,” i.e., “to use the resources at our disposal.”⁷³ The EPA had to gather and create such resources — new expert networks for Bt resistance, plausible cause-effect models, and a partnership with industry. Such efforts were catalysed by EPA decisions and public controversy over registering pesticidal agents in three different Bt crops in 1995.

The first case was Monsanto’s Bt potato. The EPA registered the pesticidal gene without imposing any specific obligation for resistance-management.⁷⁴ The company adopted voluntary guidelines, while continuing research on the optimal refugia strategies.⁷⁵ The company also included the IRM plan in its contracts with individual farmers.

Environmental NGOs raised an “action alert,” in turn publicized by the magazine *Organic Farming*. Consequently the EPA received several hundred letters criticizing it for prematurely allowing commercialization and thus the potential loss of Bt. This protest influenced the EPA response to proposals for commercializing Bt corn and cotton.

The EPA did not expect Bt corn products from Ciba-Geigy and Mycogen to dominate the market in the early years, when there would be natural non-Bt refuges between fields; therefore “market-driven unstructured refuges” would be adequate to delay resistance. The EPA required IRM measures to preserve the efficacy of Bt sprays as well as the Bt crop itself. These IRM plans required registrants to monitor large-scale use and to devise resistance-management strategies.⁷⁶

⁷³ *Id.*

⁷⁴ EPA, *Pesticide Fact Sheet: Plant pesticide Bt CryIII(A) delta-endotoxin and the genetic material necessary for its production in potato: conditional registration [Monsanto]* (1995).

⁷⁵ Monsanto, *Helping Nature’s Bounty: A Discussion of Insect-Control Potato Plants* (1994).

⁷⁶ EPA, *Pesticide Fact Sheet: Bt CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn: significant new use [Bt-176,*

Compared to the Bt potato case, EPA officials justified their more stringent approach on several grounds. The corn earworm is also the cotton bollworm, so resistance in cornfields could pose a problem for cotton too. The EPA conditions would provide credibility for the companies' efforts at product stewardship.⁷⁷

The IRM plans required farmers to conduct "close monitoring" of the plant-pesticide to determine if resistance is developing. The company would test them for any increased resistance and, if detected, would implement a refugia strategy.⁷⁸ According to regulators, the company's plan "would reduce the possibility of resistance developing for three to five years."⁷⁹ Registrations were to expire in 2001; the companies were required to submit specific IRM plans before then, so the EPA could consider controls when renewing the registrations.

The third case, Monsanto's Bt cotton, was to produce a high dose of toxin to kill all the insect pests, generating no selection pressure for resistant ones. Nevertheless, each field had to include refugia of non-Bt plants so that some Bt-susceptible insect would survive and interbreed with resistant ones. Refugia had to cover 4% of the cultivated area, or 20% if sprayed with chemical insecticide.⁸⁰ This plan changed the method of seeds marketing and field cultivation.⁸¹

Limits of IRM

In the overall risk debate, Bt resistance is often compared to the "pesticide treadmill," whereby companies have tried to develop new agrochemicals faster than pests develop resistance to the old ones. This analogy plays a double-edged role: an advance warning of Bt resistance, but also an acceptable baseline for regarding a "genetic treadmill" as a normal feature of technological progress.

Ciba/Novartis and Mycogen] (1994).

⁷⁷ Interview with representative from the Office of Pesticide Programs, EPA (Oct. 23, 1995).

⁷⁸ See EPA, *supra* note 76.

⁷⁹ Interview with representative from the EPA statement, (Aug. 11, 1995).

⁸⁰ EPA, *Pesticide Fact Sheet: Bt CryIA(c) delta-endotoxin and its controlling sequences as expressed in cotton: conditional unlimited registration [Monsanto]* (1995).

⁸¹ Monsanto, *Corn Borer Protection Through Biotechnology: Technical Guide for Yield Guard Insect-Protected Corn*. (1996).

Some EPA staff were ambivalent about what they could achieve through resistance-management strategies. Field inspectors are trained mainly to detect harm to non-target insects, not survival of resistant insects, much less to interpret their significance. One staff member noted that⁸²

EPA's requirements are difficult to enforce, especially the monitoring. How to assess the presence of corn borers and to explain their presence? It could be due to bad seed, rather than to farmers violating the rules. Some staff feel that we shouldn't be involved in resistance management.

Other officials acknowledged inherent limits of resistance-management strategies. According to a USDA official working with the EPA on such efforts⁸³

We have made an agreement to implement 'reasonable measures' to minimize the development of resistant insects, not to prevent their development, which is taken as a given for Bt crops.

Industry also regarded insect resistance as an acceptable, normal effect. According to an industry lobbyist, the EPA's conditions were unwarranted on several grounds.⁸⁴ First, insect resistance is no new problem. Next, companies can find more Bt genes to replace ones which become ineffective. Additionally, they don't need regulation to reassure the public about this problem. Finally, few farmers use microbial Bt sprays anyway. In any case, companies did not protest at the EPA conditions, perhaps assuming that the conditions could be readily fulfilled, regardless of whether insects develop Bt resistance.

Resistance-management strategies provided the main opportunity for influence by environmentalist critics. They were joined by organic farmers' advocates, e.g., at a USDA "National Forum on Bt resistance."⁸⁵ Together they successfully pressed the EPA to treat Bt as a "public good," not an expendable resource.

⁸² See OPP Interview, *supra* note 77.

⁸³ Interview with representative from the Animal and Health Plant Inspection Service, USDA (June 18, 1996).

⁸⁴ See BIO Interview, *supra* note 22; Anonymous author, *Monsanto Battles Resistance*, 15 Nat. Biotech. 1229 (1997).

⁸⁵ See Jeffrey Fox, *Insecticide Preservation Policy: To Be or Not Bt*, 14 Nat. Biotech. 697 (1996).

In their view, the EPA's conditional approval rested upon optimistic assumptions about the refuge/high-dose strategy, and thus about long-term environmental benefits of Bt crops: "The three Bt resistance plans basically represent large-scale experiments on an unproven but promising strategy."⁸⁶ The EPA assumed that Bt crops would reduce chemical usage, while ultimately depending upon a "genetic treadmill" solution.⁸⁷ Organic farmers and environmental NGOs widely publicized the expert arguments about the limits of IRM strategies.⁸⁸

Some industry officials argued that IRM strategies should remain voluntary, under their "product stewardship" program. They questioned whether FIFRA gave the EPA statutory authority to regulate Bt resistance according to a "public good" criterion.⁸⁹ Other companies appreciated the political role of government in accommodating protest. Although it was cumbersome for a company, such a requirement could help deal with public concerns.⁹⁰

Mishaps with Bt crops soon reinforced doubts about their long-term benefits. In July 1996 Monsanto's Bt cotton failed to protect the crop from cotton bollworm in some southern states. The IRM plan had presumed that a high dose would kill virtually all the pests, so critics questioned whether the plan was adequate to delay resistance.⁹¹ This pest is less sensitive than others to the Bt toxin, "so it is misleading to

⁸⁶ See Gene Exchange, Dec. 1995 at 7, 10.

⁸⁷ See EDF Interview, *supra* note 22.

⁸⁸ In September 1997 an NGOs coalition accused the EPA of gross negligence on several grounds, e.g. that the agency had not proven the safety of the Bt crops before registering them. see Greenpeace, *Greenpeace, farmers and scientists file legal action against USA EPA over its approval of genetically engineered plants*, (1997).

As a stronger legal basis, the coalition also cited the EPA failure to prepare an Environmental Impact Statement under the 1969 National Environmental Protection Act (NEPA). This petition was the first step towards filing litigation against the EPA in the Federal Court in February 1999. The coalition did not include the Environmental Defense Fund or Union of Concerned Scientists — the main organizations which had been making detailed criticisms of EPA risk assessments. 'A primary reason we did not join the petition is that it was asking for something — that EPA rescind its registrations of Bt plants — that has very little chance of happening' (personal communication, EDF officer, Oct. 1997).

⁸⁹ See Jeffrey Fox, *EPA Seeks Refuge From Bt Resistance*, 15 Nat. Biotech. 409 (1997).

⁹⁰ Interview with representative from Novartis Corporation (Jan. 27, 1998).

⁹¹ See e.g., Fox, *supra* note 89; see also Jocelyn Kaiser, *Pests Overwhelm Cotton Crop*, 273 Science 423 (1996) & Colin MacIlwain, *Bollworms Chew Hole in Gene-Engineered Cotton*, 382 Nature 289 (1996).

use this cotton in a high-dose/refuge approach for the bollworm,” argued a leading entomologist. In August 1996 the EPA restricted cultivation of Bt corn in the South, on grounds that it could generate Bt resistance in corn earworm — the same pest as the cotton bollworm.⁹²

Tighter IRM

The adequacy of IRM strategies became more contentious through further scientific evidence and debate. Bt resistance may not always be a recessive trait and could spread more rapidly in target insects.⁹³ Some insect pests were found to have single-gene resistances to four different types of Bt.⁹⁴ Citing this cross-resistance, experts questioned the contingency plan of substituting alternative Bt genes if insects developed resistance to the initial one. If a pest already has high background levels of resistance genes, then considerable resistance may develop within three to four years, despite the prevalent refugia strategy.⁹⁵ According to other scientists, the rate of resistance-development depends less upon the initial frequency than upon the survival rate of heterozygously-resistant insects.⁹⁶ That model raises the stakes for ensuring the efficacy of the refuge/high-dose strategy. Towards protecting Bt as a “public good,” government and companies were urged to cooperate: “a public-private partnership approach to conducting and reporting research will be more credible than privately sponsored research,” argued USDA scientists.⁹⁷

In response to these concerns, the EPA’s Scientific Advisory Panel emphasized the difficulties of IRM strategies. “There is disagreement as to what is the necessary arrangement and relative size of Bt and refuge field plots, the nature and objective of performance-monitoring

⁹² See Jeffrey Fox, *Bt Cotton Infestations Renew Resistance Concerns*, 14 Nat. Biotech. 1070 (1996).

⁹³ See Fox, *supra* note 89.

⁹⁴ See Bruce Tabashnik, *One Gene in Diamondback Moth Confers Resistance to Four Bt Toxins*, 94 PNAS 1640 (1997).

⁹⁵ See Fred Gould et al., (1997) *Initial Frequency of Alleles for Resistance to B.t. Toxins in Field Populations of Heliothis virescens*, 94 PNAS 3519 (1997); Bruce Tabashnik, *Seeking the Root of Insect Resistance to Transgenic Plants*, 94 PNAS 3488 (1997).

⁹⁶ See Richard Roush & Anthony Shelton, *Assessing the Odds: The Emergence of Resistance to Bt Transgenic Plants*, 15 Nat. Biotech. 816 (1997).

⁹⁷ See William McGaughey, Fred Gould, & Wendy Gelernter, *Bt Resistance Management*, 16 Nat. Biotech. 144 (1998).

activities....”⁹⁸ The UCS published a report in which some of the same experts made specific recommendations for tightening the IRM strategies. UCS added its own warning: “Immediate action is required because U.S. agriculture is already three years into what has become a multi-million acre experiment on resistance development and transgenic [GM] crops.”⁹⁹ Criticizing intensive monoculture, it reiterated previous calls for a shift to multi-year rotations which would minimize the need for pesticides: “To the extent that Bt crops further entrench the present system, they impede that important transition.”¹⁰⁰

In May the SAP further recommended that refugia be mandatory, much larger than previously presumed adequate, and closer to the Bt crop — both for corn and cotton. According to the SAP, requirements should be even more stringent for those crops which do not maintain high Bt levels throughout the growing season, e.g., Ciba/Novartis’ first Bt corn. In order to delay insect resistance, whose risk is “real,” the EPA should “require the use of structured refuges” — i.e., with specified patterns, sizes, and proximity to the Bt crop. This “sustainable approach” would be necessary in order to protect “this very valuable and environmentally-friendly technology.”¹⁰¹

Following that advice, the EPA tightened its controls when granting two further authorizations for Bt corn. Under the earlier approvals, the EPA had accepted the adequacy of unstructured, market-driven refugia, especially given that most farmers had not yet adopted Bt crops. Now the EPA required non-Bt refugia of 20-30%, or 40% if sprayed with insecticide. As a rationale, the agency cited the need to preserve the efficacy of foliar Bt sprays as well as the Bt crop.¹⁰² Soon

⁹⁸ SAP, *Final Report of FIFRA Scientific Advisory Panel, Subpanel on Bt Plant-Pesticides and Resistance Management* (1998).

⁹⁹ See UCS, *supra* note 70; see also Jeffrey Fox, *UCS Says EPA Bts Around the Bush*, 16 Nat. Biotech. 324 (1998).

¹⁰⁰ *Id.*

¹⁰¹ See Anonymous author, *EPA Urged to Move on Bt*, 16 Nat. Biotech. 499 (1998).

¹⁰² See EPA, *Pesticide Fact Sheet: Bt CryIA(b) Delta-Endotoxin and the Genetic Material Necessary for its Production in Corn: Update to Include Popcorn Use [Novartis/Mycogen]*, (1998); EPA, *Pesticide Fact Sheet: Bt Cry9C Protein and the Genetic Material Necessary for its Production in Corn: New Active Ingredient [for PGS-America]* (1998); see also K.R. Ostlie, W.D. Hutchinson, & R.L. Hellmich, *Bt Corn & European Corn Borer: Long-Term Success Through Resistance Management*, North Central Reg. Res. Project (NCR-602), Univ. of Minnesota (1997).

the larger refugia were being promoted by some companies, but advice varied among the four companies competing to sell Bt maize.¹⁰³

Eventually an expert panel convened, including academic scientists and all the companies, to devise a “science-based framework” for Bt IRM. Their majority view specified refugia sizes, in some cases larger than those in previously mandated plans.¹⁰⁴ Farmers would be required to sign contracts undertaking to follow the guidelines. These arrangements intended to avoid several problems: differences among the four companies, confusion among farmers, and mandatory EPA requirements which might be more stringent. For those reasons, the guidelines were endorsed by the National Corn Growers’ Association.¹⁰⁵

Soon the EPA and USDA together asked all registrants to update their IRM plants to “reflect the current state of the science.” Drawing upon the recent reports cited above, the agencies recommended specific refugia sizes. According to their retrospective explanation, “no scientific consensus existed to establish EPA-mandated structured refuge requirements” when registrations were originally granted in the mid-1990s.¹⁰⁶ Although still no consensus existed, by 1999 the EPA’s scientific rationale could find support in inter-agency agreements and industry guidelines.

Conclusions: Normalizing Novelty

A debate continues over whether biotechnological control will remedy — or perpetuate — the problems of intensive agricultural methods. Earlier symbolic terms, such as GMOs being “unnatural,” may have waned.¹⁰⁷ Yet agri-environmental values are still at issue, more subtly, in accounts of biotechnological novelty versus normality.

¹⁰³ See e.g. AgrEvo USA, *New StarLink: The Next Generation of Bt Corn* (1998); see also Novartis Interview, *supra* note 90.

¹⁰⁴ See International Life Sciences Institute, *An Evaluation of IRM in Bt Field Corn: A Science-Based Framework for Risk Assessment and Risk Management* (1999).

¹⁰⁵ See Andrea Foster, *Crop Developers Seek to Calm Concerns About Bt*, Chemical Week, (Jan. 20, 1999); Alan Dove, *Bt Resistance Plan Appraised*, 17 Nat. Biotech. 531 (1999).

¹⁰⁶ See EPA/USDA, Position Paper on IRM in Bt Crops, July (1999), <<http://www.epa.gov/pesticides/biopesticides/btworkshop826.htm>>.

¹⁰⁷ See e.g., Krinsky & Wrubel, *supra* note 16 at 219.

When the U.S. government put GMOs under “product-based” regulation, this framework presumed their normality within an intensive agricultural model. By contrast, critics emphasized that GMOs pose unknown novel risks and/or predictable harm, e.g., by analogy to the pesticides treadmill. They successfully pressed the EPA to regulate more categories of GMOs, even though the U.S. government framework restricted the formal channels available to NGOs for exercising influence. To issue new rules, the EPA had to devise scientific criteria for genetic novelty which poses a “risk” — a term which really meant a greater uncertainty about risk; only such novelty could warrant more stringent regulation of GMOs than their non-GM counterparts.

The EPA’s scientific rationale was criticized from various quarters. Some professional societies and academics opposed the new rules as “unscientific”. Large biotechnology companies basically supported them, while seeking to narrow the criteria for novelty. Industry more readily supported EPA rules, given that the Clinton Administration promoted GM products on grounds that they could reduce agrochemical usage and thus reduce overall environmental risk.

Having drafted new rules, the EPA devised additional criteria for predicting the environmental behaviour of GM products for commercial use. Concepts of novelty have influenced the burden of evidence. For a nitrogen-fixing microbe, the EPA asked whether its genetic characteristics could cause novel harm; such a question assigned a relatively greater burden of evidence for demonstrating risk. For a microbial pesticide, the company was persuaded to kill it before commercial sale, so that the EPA need not predict potential harm to non-target insects.

“Novelty” criteria also influence normative judgements about potential effects. For GM products which contain antibiotic-resistance marker genes, regulatory approval accepted the clinical loss of the corresponding antibiotic, as if such an effect were normal — despite dissent from advisors and even from some EPA staff. For GM crops which contain a Bt insecticidal gene, the EPA did not necessarily accept a genetic-pesticide treadmill as normal. Regulators and companies elaborated IRM methods which led the companies to become more accountable for preserving the pesticidal agent as a “public good” for

sustainable agriculture. Towards that aim, Bt crops underwent novel market-stage precautions which were eventually institutionalized as normal practice.

For all these issues, the EPA remained under pressure to cite “sound science” as the rationale for its policy. Consequently, disputes over scientific evidence served as surrogates for value conflicts, as in other regulatory sectors.¹⁰⁸ Despite the expert arguments, the EPA’s account of “sound science” gained political authority from a state-industry partnership and inter-agency agreements.

To summarize: Initially, EPA criteria for genetic novelty justify extra regulatory controls. In approving products, the EPA evaluates their potential effects — their predictability, manageability acceptability and normality — relative to a baseline which is influenced by public debate. In selectively normalizing biotechnological novelty, the regulatory procedure sets standards for a future environment.



¹⁰⁸ See Jasanoff *supra* note 10; Jasanoff, *supra* note 15.