

TRANSCRIPT: PUBLIC REGULATION OF BIOTECHNOLOGY (OR NOT)

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The United States Department of Agriculture (USDA) is taking steps that will contract the scope of its regulation of biotechnology. Here, biotechnology refers to genetic engineering (GE), a technology which debuted in the early 1970s based on scientific experiments showing that genetic segments can be cut out of and spliced into genetic material almost at will.¹ Because genetic material determines biological traits, the technology empowers scientists to create organisms with combinations of traits not found in nature. Because genetic material is the same across the spectrum of living organisms, genetic engineering can be applied to modify virtually any organism with DNA coming from any organism and, in some cases, with completely synthesized DNA. Biotechnology has been recognized as a special technology—both in terms of its risks and its potential benefits—almost from the beginning.

Several years after the very first experiments with cut-and splice techniques, scientists withdrew to a resort on the coast of California—Asilomar—and decided, for the first time, that the scientific community should restrict its use of a new technology.² These conversations resulted in containment requirements imposed on scientists as conditions to government funding. However, it was soon clear that this technology was not going to remain a set of research tools; rather it would become the basis of new industries.³ That meant biotechnology was going to need regulation in the commercial sphere.

The Reagan Administration coordinated a framework for biotechnology in the early '80s.⁴ Let me say that again: This was a major

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1. JOHN. C. AVISE, THE HOPE, HYPE, AND REALITY OF GENETIC ENGINEERING: REMARKABLE STORIES FROM AGRICULTURE, INDUSTRY, MEDICINE, AND THE ENVIRONMENT 13 (2004); Susan Wright, *The Social Warp of Science: Writing the History of Genetic Engineering Policy*, 18 SCI. TECH. & HUMAN VALUES 79, 79 (1993), available at http://deepblue.lib.umich.edu/bitstream/handle/2027.42/68761/10.1177_016224399301800105.pdf?sequence=2.

2. Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 71 PROC. NAT'L. ACAD. SCI. 1981, 1981–82 (1975), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC432675/pdf/pnas00049-0007.pdf>; Wright, *supra* note 1.

3. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 736–37 (2003), available at <http://lawdigitalcommons.bc.edu/bclr/vol44/iss3/2>.

4. *Id.* at 738.

regulatory initiative that came out of the *Reagan* Administration. I was there at the time and can tell you that the Reagan Administration was not responding to the concerns of the environmental community on this—or almost any—issue. In this case, the regulatory framework was driven by the government, big science, and big industry to facilitate acceptance of the technology. The regulatory framework was different from other environmental legislation, much of which was driven by public outrage over concrete harms—burning lakes or clouds over Los Angeles—which people could observe.⁵ Biotechnology was regulated even before it was commercialized—not on the basis of demonstrated harm, but on the basis of potential risk.

The regulatory initiative—perhaps not surprisingly, considering its genesis—proceeded with one cardinal rule: There would be no new legislation.⁶ The Reagan Administration did not take biotechnology regulation to Capitol Hill. It elected to handle it through administrative agencies, implementing existing authorities—stretching them if necessary—with new rules and guidances. And this approach succeeded. United States regulation of biotechnology was then, and is now, based on old statutes adapted to a new technology.

One can question this approach. In the 1980s, Congress did consider a new comprehensive statute that would regulate all products of biotechnology. But that approach proved to be a heavy lift. The breadth of biotechnology products—everything from research mice to tomatoes to corn crops to fish and trees—challenged the practicality of a single statute. On the other hand, the set of existing authorities failed to cover many of the predictable products of biotechnology. Basically, the agencies were told to look through the statutes they administered to see which of them could be applied to products of the new technology. If existing statutes were inadequate, then the agencies were simply out of luck. They could not go to Congress for better regulatory authority. The approach put enormous pressure on agencies to stretch regulatory authority to regulate biotechnology.

At the time the framework was developed, GE products that were foods, drugs, or cosmetics fell comfortably within the Federal Food Drug

5. *See, e.g.*, *Solid Waste Agency of N. Cook Cnty v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 174–75 (2001) (Stevens, J., dissenting) (observing that Congress responded to the 1969 Cuyahoga River fire, and to other “dramatic event[s]” like it, by enacting the Clean Water Act).

6. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23, 302–03 (June 26, 1986); Gary Marchant, Douglas Sylvester & Kenneth W. Abbot, *Nanotechnology Regulation: The United States Approach*, in *NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY* 189, 190 (Graeme Hodge et al. eds., 2007).

and Cosmetic Act (FDCA).⁷ And GE pesticides were adequately governed under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁸ But commercial microorganisms that were not pesticides were largely unregulated. Similarly, there was no clear authority to oversee new genetically engineered crops, trees, or animals. Genetically engineered crops and farm animals, which were discussed early on as major applications of the technology, were big holes in the statutory scheme. The animal hole was filled by declaring that the genetic material contained within genetically engineered animals is a drug and is thus subject to the drug provisions of the FDCA.⁹ The Toxic Substances Control Act (TSCA), originally designed for chemicals, was extended to cover commercial applications of microorganisms.¹⁰ In the case of crops, the Plant Pest Act (replaced in 2000 by the Plant Protection Act)¹¹ was adapted—some would say contorted—into a program that required premarket reviews of GE crops.¹²

One of the issues at play in adapting existing authorities is the strength of oversight. In general, a premarket permit system based on required data submissions offers the strongest oversight. The drug provisions of the FDCA are an example. Less protective—but also less burdensome—approaches provide the government notice and an opportunity to act before products go on the market without imposing specific data requirements. TSCA is an example. Even less burdensome are authorities that empower agencies to only respond after a product already on the market causes harm. The food provisions of the FDCA are examples of this type of regulation.¹³ In general, the regulatory efforts extending authorities to biotechnology

7. 21 U.S.C. §§ 301–399f (2006).

8. 7 U.S.C. §§ 136–67 (2006).

9. FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 6–7 (2009) [hereinafter REGULATION OF GENETICALLY ENGINEERED ANIMALS], available at <http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm113903.pdf>.

10. Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act, 62 Fed. Reg. 17,910, 17,910 (Apr. 11, 1997) (codified at 40 C.F.R. pts. 700, 720, 721, 723, and 725).

11. Plant Protection Act, Pub. L. No. 106-224, 114 Stat. 438 (2000) (codified as amended at 7 U.S.C. §§7701–86 (2006)).

12. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests, 52 Fed. Reg. 22,892, 22,892 (June 16, 1987) (codified at 7 C.F.R. pts. 330 and 340 (2012)).

13. See, e.g., 21 U.S.C. § 350f(d) (requiring persons responsible for food products to notify the Food and Drug Administration when they determine that an article of food is likely to be adulterated); *id.* § 350l (authorizing the Secretary of Health and Human Services to recall adulterated or misbranded foods).

moved in the direction of premarket permit programs based on data submissions.

Why should society regulate this new technology? So far, there do not appear to be any harmful effects associated exclusively with products of genetic engineering. The risks that inhere in the technology result from the new combinations of traits it produces.¹⁴ Such combinations can produce harmful effects, such as allergic reactions, which are not unique to biotechnology but are serious nonetheless. In general, biotechnology products appear to pose the same kinds of threats as the products of other technologies: Harms to human and animal health and perturbations in the environment. But there may be risks associated with the products that have not yet been identified. At this early stage, the relative risk of biotechnology compared to similar technologies is an open question. Science has not identified any specific harm that is exclusive to GE products; nor can science declare all biotechnology products to be safe. Since the risks of the technology derive from new combinations of traits, risk evaluation must look at each combination individually. The safety of a virus-tolerant squash says nothing about the safety of an herbicide-tolerant canola. Blanket statements about the safety or risks of biotechnology products are scientifically unjustified.

The understanding that some—but not all—products of biotechnology could cause harm raises the question of how to regulate the technology. One approach is to review all products produced by genetic engineering or similarly advanced molecular techniques until we better understand them. Subjecting GE products to greater scrutiny than conventional technologies runs the risk of stigmatizing the new technology but also confers a government imprimatur that could build confidence in the marketplace. Process-based definitions are relatively easy to incorporate into jurisdictional provisions in regulations. Alternatively, regulators could come up with characteristics of concern, say toxicity, and regulate all the products that have one of those characteristics, regardless of how they were produced. Such an approach is technology-neutral and avoids stigma. On the other hand, it is difficult to determine beforehand that a product might have a particular characteristic and needs review. Also, broad product-based schemes can subject many conventional products to new oversight.

Many days and pages were devoted to what came to be known as the process vs. product debate. But now the debate is over, and it is clear that

14. Desiree Hautea, *Chapter 3: Risk Analysis for GMOs: Concepts, Methods and Issues*, in *BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS: BASIC CONCEPTS, METHODS AND ISSUES* 107, 107, 137 (M. Khalequzzaman A. Chowdhury et al. eds., 2009), available at <http://www.fao.org/docrep/012/i1252e/i1252e.pdf>.

the winner is process-based regulation. Virtually all of the regulations and guidances that extend existing regulatory authority to GE organisms do so on the basis of the process by which organisms are produced. The regulations create a premarket review system under the Plant Protection Act and cover only GE organisms;¹⁵ conventionally bred crops are not reviewed. The voluntary pre-market program overseeing GE foods under the food laws applies only to GE foods.¹⁶ The Food and Drug Administration does not look at conventional foods before they go on the market. The guidance subjecting animals to the drug laws applies only to GE animals.¹⁷ And TSCA, in its extension to microorganisms, applies only to GE microorganisms—not to all microorganisms.¹⁸ In choosing process-based regulation, the U.S. has aligned itself with the rest of the world.

Now I would like to return to the “Grand Contortion” of what is now the Plant Protection Act, which refashioned a quarantine statute that governs *pests of plants*¹⁹ into a permit-based system used to regulate the plants, primarily crops themselves. This was no mean trick. The Plant Protection Act regulates plant pests, such as a locust looking to dine on a wheat plant.

The appealing feature of the Plant Pest Act was a permit provision governing the movement of plant pests around the United States. The USDA’s challenge was to define genetically engineered crops in such a way

15. 7 C.F.R. § 340.1. This regulation defines “regulated article” as:

Any organism which has been altered or produced through *genetic engineering*, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest.

Id. (emphasis added). Section 340.0 imposes restrictions on the introduction of “regulated articles.” *Id.* § 340.0.

16. FOOD & DRUG ADMIN., DEP’T OF HEALTH & HUMAN SERVS., VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING; AVAILABILITY 1 (Draft, 2001), available at <http://www.fda.gov/ohrms/dockets/98fr/cf00123.pdf>.

17. REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 9.

18. Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act, 62 Fed. Reg. at 17,913 (“[M]icroorganisms resulting from deliberate combinations of genetic material from organisms classified in different genera constitute ‘new’ microorganisms subject to [premanufacture] reporting requirements.”). “EPA terms [new] microorganisms intergeneric. . . . The term ‘intergeneric microorganism’ includes a microorganism which contains a mobile genetic element which was originally isolated from a microorganism in a genus different from the recipient microorganism.” *Id.*

19. *See, e.g.*, 7 U.S.C. § 7715 (authorizing the Secretary of Agriculture to, *inter alia*, quarantine “any plant, biological control organism, plant product, article, or means of conveyance that the Secretary has reason to believe is infested with the plant pest or noxious weed”).

that they could be subjected to this permit requirement. Plant pests are defined in the Plant Protection Act as, among other things, nonhuman animals, parasitic plants, and microorganisms, such as viruses.²⁰ The definition does not encompass non-parasitic plants, including most crops, because crops are what the statute aims to protect. In addition to belonging to particular biological classes, the statute requires that a plant pest *can*—not *may*—directly injure a plant.²¹

The regulations applying the Plant Protection Act to genetically engineered crops met that challenge by defining new regulable entities—so-called regulated articles—that would include GE crops. Under the regulation, regulated articles are defined to include organisms that have been altered or produced by GE techniques—again, this is a process-based definition—that the USDA determines is a plant pest or has reason to believe is a plant pest.²² How could crops be considered plant pests? The regulation set up a two-part definition based on the origin of the genetic material used in genetic engineering and the biological function of the donor organisms as plant pests. Under the regulation, a plant is considered a regulated article if the organism from which the new genetic material was taken, the recipient organism into which the material was placed (in most cases, the crop), or the vector (a molecular entity used to ferry genes from donors to recipients) came from a taxonomic class of organisms that contains plant pests.²³

In the early days of crop engineering, scientists commonly used a small piece of mobile DNA found in the bacteria within the genus *Agrobacterium* as a vector to move genetic material into crops.²⁴ *Agrobacterium* causes crown gall tumors and, as a microorganism that harms plants, clearly meets the definition of a plant pest. Its widespread use in plant biotechnology meant that most genetically engineered crops could meet the first part of the definition of a regulated article based on the source of the DNA. In fact, the *Agrobacterium* vector that is used in genetic engineering is disabled and cannot cause tumors. So it can be argued that such a vector does not meet the definition of a plant pest because it cannot harm plants and therefore cannot be regulated under the Plant Protection Act regulations.

20. *Id.* § 7702(14).

21. *Id.* (defining “plant pest” as “any living stage of any of the [listed categories of organisms] that *can* directly or indirectly injure, cause damage to, or cause disease in any plant or plant product” (emphasis added)).

22. 7 C.F.R. § 340.1; *see supra* note 15.

23. *Id.*

24. Emily Montgomery, *Genetically Modified Plants and Regulatory Loopholes and Weaknesses under the Plant Protection Act*, 37 VT. L. REV. 351, 351 (2012).

Over the years, very little attention was paid to whether crops met the legal definition of a plant pest. Industry would have been the party to raise the concerns, but it did not, apparently because it welcomed an imprimatur from the government for its products and because the burdens of the USDA system were relatively light. Despite the availability of arguments that most of its products were beyond the scope of the Plant Protection Act regulation, the biotechnology industry has routinely submitted its products to USDA for review. The agency has conducted analyses of these products, framed in terms of whether a GE product is a plant pest, even though for example a conversion of a corn or soybean plant into a plant pest was never a realistic scientific concern. The Agency also conducted analyses under the National Environmental Policy Act (NEPA), which allowed it to look at a broader range of environmental effects beyond harm to plants.

The industry, however, always had the jurisdictional card to play whenever it wished. At any time, a company could have asserted that its product did not meet the definition of plant pest and could not be regulated under the Plant Protection Act. But industry did not make such claims until recently. In July 2011, the USDA agreed with an assertion by Scotts Miracle-Gro that its product, a genetically engineered version of Kentucky bluegrass, was not a regulated article under 7 CFR part 340 because it “does not contain plant pest sequences and no plant pest was used to create” it.²⁵ Furthermore, USDA said that other products that are not plant pests or not made using plant pests would likewise fall outside of the USDA’s regulatory authority.²⁶

Those genetically engineered products outside of the USDA’s regulatory authority can be created and marketed without notification to the USDA and without being subjected to agency review. As more and more products are being engineered without *Agrobacterium* and companies are becoming more willing to challenge Plant Protection jurisdiction on other grounds, more products will fall outside of the USDA’s regulatory purview—a result that the USDA seems to accept.

By acknowledging the limitations of the Plant Protection Act’s jurisdiction and apparently encouraging companies to circumvent those limitations and avoid regulation, the USDA is curtailing the scope of its oversight of genetically engineered crops. That will lead to two sets of GE crops: regulated and unregulated. The public will know some products; others will be hidden from view.

25. Animal and Plant Health Inspection Serv., USDA, Questions and Answers: Kentucky Bluegrass (2011), available at http://www.aphis.usda.gov/brs/aphisdocs/scotts_kbg_q&a.pdf.

26. *Id.*

The different treatment of regulated and unregulated products will not be based on scientifically credible differences in risk but on a legal fiction necessary to adapt the eminently unsuitable Plant Protection Act to the task of regulating the nation's commodity crops. This irrational result could have been avoided had we taken a different path at the dawn of the biotechnology era and crafted new regulatory programs specifically tailored to the products of biotechnology.