# Appendix 7: Monsanto's Success Requires Political Support

## HOW DID WE GET HERE?

Rhetoric from the United States government since the early 1990s proclaims that GM foods are no different from their natural counterparts that have existed for centuries. This is the basis of U.S. policy, including an aggressive promotion of GMOs by the State Department—as revealed by Wikileaks.

But the determination that GMOs were not different and therefore safe was entirely fictitious, and based on political sleight of hand.

The Food and Drug Administration (FDA) declared GMOs "Generally Recognized as Safe," or GRAS. This status allows a product to be commercialized without any additional testing. According to U.S. law, to be considered GRAS the substance must be the subject of a substantial amount of peer-reviewed published studies (or equivalent) and there must be overwhelming consensus among the scientific community that the product is safe. GM foods had neither. Nonetheless, in a precedent-setting move in 1992 that some experts contend was illegal, the FDA declared that GM crops are GRAS as long as their producers say they are. Thus, the FDA does not require *any* safety evaluations or labeling of GMOs. A company can even introduce a GM food to the market without telling the agency.

## POLITICS AS USUAL

Such a lenient approach was largely the result of the influence of large agricultural corporations. According to Henry Miller, who had a leading role in biotechnology issues at the FDA from 1979 to 1994, "In this area, the US government agencies have done exactly what big agribusiness has asked them to do and told them to do."[1] The agricultural biotech company with the greatest influence was clearly Monsanto. According to the *New York Times*, "What Monsanto wished for from Washington, Monsanto and, by extension, the biotechnology industry got. . . . When the company abruptly decided that it needed to throw off the regulations and speed its foods to market, the White House quickly ushered through an unusually generous policy of self-policing."[2]

This policy was heralded by Vice President Dan Quayle on May 26, 1992. He chaired the Council on Competitiveness, which had identified GM crops as an industry that could boost US exports. To take advantage, Quayle announced "reforms" to "speed up and simplify the process of bringing" GM products to market without "being hampered by unnecessary regulation."[3] Three days later, the FDA policy on non-regulation was unveiled.

The person who oversaw its development was the FDA's Deputy Commissioner for Policy, Michael Taylor, whose position had been created especially for him in 1991. Prior to that, Taylor was an outside attorney for both Monsanto and the Food Biotechnology Council. After working at the FDA, he became Monsanto's vice president. The Obama administration has put Taylor back into the FDA as the US Food Safety Czar.

### THE FDA COVERS UP HEALTH RISKS

Taylor's GMO policy needed to create the impression that unintended effects from GM crops were not an issue, otherwise their GRAS status would be undermined and they would need the extensive testing and labels that are normally required for food additives. But internal memos made public from a lawsuit showed that the overwhelming consensus among the agency scientists was that GM crops can have unpredictable, hard-to-detect side effects. Various departments and experts spelled these out in detail, listing allergies, toxins, nutritional effects, and new diseases as potential dangers. They urged superiors to require long-term safety studies.[4] In spite of the warnings, according to public interest attorney Steven Druker who studied the FDA's internal files, "References to the unintended negative effects of

bioengineering were progressively deleted from drafts of the policy statement (over the protests of agency scientists)."[5]

FDA microbiologist Louis Pribyl, PhD, wrote about the policy, "What has happened to the scientific elements of this document? Without a sound scientific base to rest on, this becomes a broad, general, 'What do I have to do to avoid trouble'-type document. . . . It will look like and probably be just a political document. . . . It reads very pro-industry, especially in the area of unintended effects."[6]

The scientists' concerns were not only ignored, their very existence was denied. The official FDA policy stated, "The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way."[7] In sharp contrast, an *internal* FDA report stated, "The processes of genetic engineering and traditional breeding are different and according to the technical experts in the agency, they lead to different risks."[8] The FDA's deceptive notion of no difference was coined "substantial equivalence" and formed the basis of the US government position on GMOs.

Many scientists and organizations have criticized the US position. The National Academy of Sciences and even the pro-GM Royal Society of London[9] describe the US system as inadequate and flawed. The editor of the prestigious journal *Lancet* said**,** "It is astounding that the US Food and Drug Administration has not changed their stance on genetically modified food adopted in 1992. . . . The policy is that genetically modified crops will receive the same consideration for potential health risks as any other new crop plant. This stance is taken despite good reasons to believe that specific risks may exist. . . . Governments should never have allowed these products into the food chain without insisting on rigorous testing for effects on health."[10] The Royal Society of Canada described substantial equivalence as "scientifically unjustifiable and inconsistent with precautionary regulation of the technology."

## POLITICAL COLLUSION SPREADS

Although other nations often do require submissions by the biotech industry for GMO approval, various analyses of approval committees in Europe, Brazil, India, and elsewhere reveal a disturbing trend: the majority of members have direct or indirect ties to the biotech industry. Furthermore, they consistently accept substandard evidence and unsupported claims of safety as justification for allowing GMOs onto the market.[11]

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1 Kurt Eichenwald, et al, New York Times, "Biotechnology Food: From the Lab to a Debacle," January 25, 2001 http://www.nytimes.com/2001/01/25/business/25FOOD.html?pagewanted=all

[2] Kurt Eichenwald, et al, New York Times, "Biotechnology Food: From the Lab to a Debacle," January 25, 2001 http://www.nytimes.com/2001/01/25/business/25FOOD.html?pagewanted=all

3 Dan Quayle, "Speech in the Indian Treaty Room of the Old Executive Office Building," May 26, 1992.

4 For copies of FDA memos, see The Alliance for Bio-Integrity, http://www.biointegrity.org/

5 Steven M. Druker, Alliance for Bio-Integrity, "The Illegality of FDA Policy on GE Foods," http://www.biointegrity.org/

6 Louis J. Pribyl, "Biotechnology Draft Document, 2/27/92," March 6, 1992, www.biointegrity.org http://www.biointegrity.org/

7 "Statement of Policy: Foods Derived from New Plant Varieties," Federal Register 57, no. 104 (May 29, 1992): 22991. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm

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8 Linda Kahl, Memo to James Maryanski about Federal Register Document "Statement of Policy: Foods from Genetically Modified Plants," Alliance for Bio-Integrity (January 8, 1992)
http://www.responsibletechnology.org/fraud/fda-quotes
9 See for example, "Good Enough to Eat?" New Scientist (February 9, 2002), 7.
http://www.newscientist.com/article/mg17323290.800-good-enough-to-eat.html
10 "Health Risks of Genetically Modified Foods," editorial, Lancet, 29 May 1999.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)77668-6/abstract
[11] See for example, Jeffrey M. Smith, Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods, Yes! Books, Fairfield, Iowa 2003, Part 2