Balancing Risk and Reward in Regulating the Use of Genetically Modified Organisms as a Food Source

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I. Introduction

Advances in the field of biotechnology over the past 30 years have led to a powerful new ability to modify and manipulate the genetic material of almost any organism on Earth.[1] This advance has had huge implications for scientific progress, and has enabled substantial progress in multiple fields including biomedical research and agriculture.[2] However, this progress has not been seamless as many have opposed the unregulated creation of new organisms due to environmental and ethical concerns.[3] In recent years, this debate has centered on the use of newly created crop plants which have been genetically engineered to have new advantageous characteristics, but which raise concerns about potential adverse effects on human health, agriculture, and the environment.[4] A recent survey found that approximately 75% of Americans favored use of modified foods.[5] Currently, federal regulation of this field is carried out jointly by the Food and Drug Administration ("FDA"), the Environmental Protection Agency ("EPA") and

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[1] *See* Serge Hardy, Vincent Legagneux, Yann Audic & Luc Paillard, *Reverse Genetics in Eukaryotes*, 102(10) BIOLOGY OF THE CELL 561, 561 (2010).
[2] *Id.*
[3] *See, e.g.*, Greenpeace, *Say No to Genetic Engineering*, http://www.greenpeace.org/international/en/campaigns/agriculture/problem/genetic-engineering/ (expressing concerns regarding the unforeseen effects on human health, the effects of altered organisms on the environment, and the perceived impropriety of "playing god" by creating new organisms and introducing them into the environment).
[4] *See generally GM Crops: The Arguments Pro and Con*, AMERICAN RADIOWORKS, http://americanradioworks.publicradio.org/features/gmos_india/pro_con.html (discussing the main arguments for and against genetically modified foods).
[5] Int'l Food Info. Council Found., *2010 Consumer Perceptions of Food Technology Survey*, FOOD INSIGHT, http://www.foodinsight.org/Resources/Detail.aspx?topic=2010_Consumer_Perceptions_of_Food_Technology_Survey. Surveyed Americans would be somewhat or very likely to buy genetically modified food that provides more healthful fats (76%), allowed reduced use of pesticides (77%), contained less trans fats (74%), used less resources to grow (73%), or tasted better (67%). *Id.*

the United States Department of Agriculture ("USDA").[6] Many view this system as either inefficient or inadequate and have therefore mounted efforts to supplement the federal regulations at the local and state level.[7] This article examines those efforts, their effectiveness, and the future outlook of attempts to implement additional state regulation.

II. Genetically Modified Organisms: Use and Concerns

The advent of genetic engineering was the 1973 announcement that scientists had successfully transferred specific genetic material from one organism to another.[8] This discovery prompted many to become concerned about the possibility of accidental and dangerous transfer of DNA to humans, a concern that even resulted in scientists self-imposing a brief moratorium on genetics research.[9] While these concerns about the techniques involved proved unfounded and genetic manipulation is the basis for much scientific research today, a general apprehension with the genetically modified organisms ("GMOs") themselves has persisted in various forms to the present day.[10] For instance, the potential for "designer babies" with selected genetic traits and the ability to create genetically tailored crops are both subjects of much debate in today's society.[11]

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[6] Government Accountability Office, *Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced* 7, GAO-02-566 (2002) [hereinafter GAO], http://www.gao.gov/new.items/d02566.pdf.
[7] *See* Greenpeace, *supra* note 3.
[8] Stanley N. Cohen, Annie C.Y. Chang, Herbert W. Boyer & Robert B. Helling, *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70(11) PROC. NAT'L ACAD. SCI. 3240, 3240 (1973).
[9] Paul Berg, David Baltimore, Sydney Brenner, Richard O. Roblin III & Maxine F. Singer, *Summary statement of the Asilomar Conference on recombinant DNA molecules*, 72(6) PROC. NAT'L ACAD. SCI. 1981 (1975).
[10] *See* Hardy, *supra* note 1, at 561.
[11] *See* Greenpeace, *supra* note 3; Nicholas Agar, *Designer Babies: Ethical Considerations*, http://www.actionbioscience.org/biotech/agar.html (2006).

The use of GMO food crops is a particularly contentious aspect of the GMO debate.[12] Large biotechnology companies such as Monsanto and Syngenta have specialized in altering crops to be either more productive or have desirable traits that aren't normally found in those organisms, patenting those organisms, and selling them to farmers.[13] One example is the insertion of a gene that is normally found in the bacteria *Bacillus thuringiensis* into crop plants such as cotton and corn.[14] This exchange allows the crop plants ("BT-cotton" and "BT-corn") to produce an insecticidal protein that kills any insects that feed on them, a very desirable trait that allows farmers to avoid application of expensive and dangerous pesticides on their fields.[15] Other examples of genetic modification of plants include the introduction of viral resistance, herbicide resistance, altered growth characteristics, and increased vitamin production.[16] It should be noted that the creation of GMOs is not limited to plants, as genetic modification of salmon has led to a new species that matures quicker and grows larger than wild salmon.[17]

Proponents of GMOs argue that such modifications offer many advantages to society that outweigh potential risks, and that the risks can be managed by careful study of new products.[18] The potential benefits include the ability to alter plants to grow faster, have less waste per acre, require less maintenance to grow, have more nutrients and vitamins, or perhaps even taste

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[12] *See* Greenpeace, *supra* note 3.
[13] *See Monsanto at a Glance*, MONSANTO, http://www.monsanto.com/whoweare/Pages/default.aspx; *Products and Innovation*, SYNGENTA, http://www.syngenta.com/global/corporate/en/products-and-innovation/Pages/products-and-innovation.aspx.
[14] *See* GAO, *supra* note 6, at 5; *infra* Figure 1.
[15] *See generally* Ric Bessin, *BT-Corn: What It Is And How It Works*, UNIVERSITY OF KENTUCKY ENTOMOLOGY, http://www.ca.uky.edu/entomology/entfacts/ef130.asp (explaining in general terms how the BT delta endotoxin functions to convey insecticidal properties to the plants that produce it).
[16] *See generally* Jeff Schahczenski & Katherine Adam, *Transgenic Crops* (2006), http://attra.ncat.org/attra-pub/PDF/geneticeng.pdf (providing a comprehensive overview of genetically modified crops available and used as of 2006).
[17] *See* Martin D. Smith, Frank Asche, Atle G. Guttormsen & Jonathan B. Wiener, *Genetically Modified Salmon and Full Impact Assessment*, 330 SCIENCE 1052, 1052 (2010).
[18] *E.g.*, COMMITTEE ON IDENTIFYING AND ASSESSING UNINTENDED EFFECTS OF GENETICALLY ENGINEERED FOODS ON HUMAN HEALTH, SAFETY OF GENETICALLY ENGINEERED FOODS 175-88 (2004) [hereinafter COMMITTEE], *available at* http://www.nap.edu/catalog.php?record_id=10977#toc.

better.[19] All of these factors should lead to increased food availability, decreased food cost, and increased societal food security.[20] Furthermore, some studies have shown that GMO crops have a decreased environmental impact, particularly the BT crops that don't require pesticide use.[21] These proponents view the industry as an advanced form of the selective crop breeding that has been ongoing for millennia, and believe that our society should encourage such innovation rather than restrict its progress.[22]

Opponents of GMOs, on the other hand, have a number of concerns including the potential environmental impact of these organisms.[23] A number of studies have demonstrated that it is possible for genetic material from GMOs to be transferred to closely related wild species through interbreeding as pollen from the crops drifts on the wind.[24] This "genetic pollution" could have unknown adverse effects on those wild plants and on the ecosystem in general.[25] One example of such a transfer has been observed, albeit at a low rate, from genetically modified corn to the related Mexican landrace varieties of maize.[26] There is significant concern that such transfers to maize or other species could lead to loss of environmental diversity, creation of herbicide resistant weeds, or have unexpected environmental effects.[27] An example of such an unintended environmental effect is seen in the increased prominence of secondary pests that normally aren't prevalent, but become common in BT cotton

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[19] *Id. at* 17
[20] *Id. at* 17
[21] *See* Terry Raney, *Economic Impact of Transgenic Crops in Developing Countries* , 17 CURRENT OP. BIOTECH. 1, 2 (2006).
[22] *See* COMMITTEE, *supra* note 18, at 17.
[23] *See* Greenpeace *supra* note 3.
[24] *See* David Quist & Ignacio H. Chapela, *Transgenic DNA Introgressed Into Traditional Maize Landraces in Oaxaca, Mexico*, 414 Nature 541, 542 (2001); George A. Dyer et al., *Dispersal of Transgenes through Maize Seed Systems in Mexico*, 4(5) PLOS ONE 5734, 5734 (2009).
[25] Dyer et al., *supra* note 24.
[26] *Id.*
[27] *Id.* at 5735.

fields.[28] This increased prevalence of secondary pests is likely due to the lessened pesticide application, and partially negates the main advantage of BT cotton.[29] This concern is magnified by the fact that a long-term effect of the proliferation of BT-resistant crops is a strong selection pressure for BT-resistant insects to develop.[30] These BT-resistant insects would be difficult to control and could make the BT crops irrelevant since they would no longer have the insect resistance that is their primary benefit.[31]

Critics also point to what they consider insufficient safety testing for GMOs before they are introduced into the food supply.[32] The primary concern with the existing regulatory system is the perceived impropriety of the agencies ceding a large portion of the testing to the companies who make and market the foods.[33] Critics consider this a rubber-stamping process that may placate the consumer, but does little to rigorously test the environmental and safety concerns that the critics have regarding GMOs.[34] The FDA does not conduct its own tests of genetically modified ("GM")-food, but rather reviews reports submitted to them from the developers of the engineered food.[35] A review by the U.S. Government Accountability Office ("GAO") concluded that this method is adequate since they "pose the same types of inherent risks to human health as conventional foods," and stated that most scientists feel that long-term testing is unnecessary as there is nothing to suggest that there are long-term risks.[36] This conclusion still leaves many uncomfortable, however, and critics suggest that the FDA could do more random repeat testing

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[28] *See* Bhaskar Goswami, *India: Bt Cotton Devastated By Secondary Pests*, GRAIN (Jan. 9, 2007), http://www.grain.org/btcotton/?id=398.
[29] *Id.*
[30] Bruce E. Tabashnik, Aaron J. Gassmann, David W. Crowder & Yves Carriére, *Insect Resistance to Bt Crops: Evidence Versus Theory*, 26 NATURE BIOTECHNOLOGY 199, 199 (2008).
[31] *Id.*
[32] *E.g.*, Brian Tokar, *Deficiencies in Federal Regulatory Oversight of Genetically Engineered Crops*, ENVIRONMENTAL COMMONS (2006), http://environmentalcommons.org/RegulatoryDeficiencies.html.
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *See* GAO, *supra* note 6 at 2.

and increase the transparency of the testing process.[37] While GMOs have been on the market for over 15 years and there have been no reported adverse effects,[38] many remain concerned that there could be long-term consequences or that new crops may not be as benign.[39] One concern that has been repeatedly stated is a fear that glyphosate (an herbicide marketed as Roundup) applied to glyphosate-resistant GMOs could lead to a buildup of harmful chemicals in the food products from the treated plants, or in plants subsequently planted in the same areas.[40] To combat the public anxiety over concerns such as these, the government has implemented a system to approve and regulate GMO use in the United States.[41]

III. The Federal GMO Regulatory System

In 1986, the White House published a policy statement entitled "Coordinated Framework for Regulation of Biotechnology," which laid out a system for reviewing and approving new GMOs.[42] This system was provides regulatory authority to three agencies: the FDA, the EPA and the USDA.[43] The USDA bears the main responsibility for regulating the environmental impact of GMOs on natural habitats or agriculture in general.[44] It accomplishes this by requiring permits for the testing of new organisms, reviewing those tests as they occur, and then certifying the organism for use in the marketplace.[45] The EPA regulates only those GMOs that have been

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[37] *See* Tokar, *supra* note 32.
[38] *See* Suzie Key, Julian K-C Ma & Pascal M.W. Drake, *Genetically Modified Plants and Human Health*, 101 JOURNAL OF THE ROYAL SOCIETY OF MEDICINE 290, 292 (2008).
[39] *E.g.* Organic Consumers Association, *Genetic Engineering and Biotechnology*, ORGANIC CONSUMERS ASSOCIATION, http://www.organicconsumers.org/gelink.cfm.
[40] *See* Ken Roseboro, *Monsanto's Glyphosate Problems: Scientist Warns of Dire Consequences with Widespread Use*, ORGANIC CONSUMERS ASSOCIATION, http://www.organicconsumers.org/articles/article_21039.cfm (June 14, 2010).
[41] Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology: Announcement of Policy; Notice for Public Comment, 51 Fed. Reg. 23302 (Jun. 26, 1986).
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*

engineered to be pest-resistant, and subjects those plants to the regulations on sale and use of pesticide chemicals.[46] Finally, the FDA is primarily concerned with the safety of the US food supply, and therefore can control what GM foods are allowed into the market.[47]

Those who oppose the use of GMO's as a food source often challenge decisions made as part of this federal regulatory system, which has resulted in a number of high profile court decisions.[48] For instance, the Supreme Court recently held that an injunction completely banning the planting of Monsanto's Roundup-resistant alfalfa was inappropriate, but confirmed the need for completing an Environmental Impact Statement ("EIS") before deregulation of planting GM-alfalfa, or any other GM crop.[49] Another recent case in federal District Court held that a USDA decision to allow widespread GM sugar beet use was not valid, also for a lack of an EIS.[50] Finally, there has been a large outcry over the likely approval of genetically engineered salmon by the FDA for use as a food source.[51] While the agency issued a preliminary report finding no significant risk of health or environmental harm, there seems to be a high likelihood of a court challenge to that decision.[52] These controversies illustrate the intense debate occurring over the increasing prevalence of GM foods at the federal level, but it is important to note that the fight is occurring on the state level as well.

IV. Development of State Level Regulation of GMOs

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[46] *Id.*
[47] *Id.*
[48] *E.g.* Monsanto Co. v. Geertson Seed Farms, 130 U.S. 2743 (2010); Ctr. for Food Safety v. Vilsack, 2010 U.S. Dist. LEXIS 92369 (N.D. Cal. Aug. 13, 2010).
[49] Monsanto Co. v. Geertson Seed Farms, 130 U.S. 2743, 2748 (2010).
[50] Ctr. for Food Safety, 2010 U.S. Dist. LEXIS at 23.
[51] *See* Smith *supra* note 17, at 1053
[52] *Id.*

GMO critics have advocated using state regulatory agencies as a supplemental regulatory system which could bolster the efforts of federal agencies.[53] One of the first and most well regarded efforts to set up such as system was the Genetically Engineered Organisms Act passed in North Carolina in 1989.[54] This act invested the North Carolina Department of Agriculture ("NCDA") with ultimate authority to regulate the release and commercial use of genetically modified organisms.[55] The NCDA's authority was designed to allow for public input through hearings and pressure on public officials, and was supposed to provide another layer of control.[56] While the Act was initially held up as a good example of how GMO regulation should be approached in the future, the change seemed to make little difference in the prevalence and use of GMOs in North Carolina.[57] The Act contained a sunset provision,[58] and it was allowed to expire after a five-year trial period.[59] Even though this effort was not ultimately successful, there have been continuing attempts to promote greater GMO regulation on the state level.[60]

Many states have subsequently passed laws requiring the registration of GMOs or mandating that farmers must have permits to be allowed to plant such crops.[61] Once again using North Carolina as an example, the legislature provided in §130A-479 of the Public Heath Law that the Department of Public Health "shall establish and administer a program for the

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[53] *See* Tokar, *supra* note 32.
[54] Genetically Engineered Organisms Act, N.C. Gen. Stat. Ann. §§ 106-765 to 106-777 (1989).
[55] *Id.*
[56] *Id.*
[57] Michelle Thom, *Genetic Engineering Regulations*, http://user.uni-frankfurt.de/~ecstein/gen/iatp/ipr-info12 (last visited Jan. 2, 2011).
[58] *See* Genetically Engineered Organisms Act, N.C. Gen. Stat. Ann. §§ 106-765 to 106-777 (1989).
[59] *See* Thom, *supra* note 57.
[60] *See generally* MICHAEL R. TAYLOR, JODY S. TICK & DIANE M. SHERMAN, TENDING THE FIELDS: STATE & FEDERAL ROLES IN THE OVERSIGHT OF GENETICALLY MODIFIED CROPS, *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Tending_Fields_Biotech1204.pdf (a comprehensive report funded by the Pew Charitable Trust that details a number of strategies states have taken to regulate agricultural biotechnology).
[61] *See Biotechnology Statutes Chart*, NATIONAL CONFERENCE OF STATE LEGISLATURES, http://www.ncsl.org/default.aspx?tabid=12467 (last updated Jan., 2009).

registration of biological agents."[62] This program is meant to be a method of identifying, tracking, and controlling the use of biological agents within the state, where "biological agents" includes GMOs.[63] Such legislation became more common over the last 10 years, and as of January, 2009, 14 states required registration or a permit to use such GMOs.[64] While such requirements do not limit the use of GMOs beyond the federal restrictions that already exist, they do point to a trend of states wanting to assert their authority over the industry.[65]

While no states have considered GMOs a significant enough risk to restrict their general use beyond that done by federal agencies, a few local municipalities have done so.[66] For instance, in 2004 three counties in California (Mendicino, Marin, and Trinity) passed ballot initiatives to ban the cultivation of genetically modified crops.[67] This tactic has not become widespread, perhaps since many consider it to be overly broad with a significant chance to stunt research efforts in the biotechnology field.[68] The biotechnology industry itself saw the passage of such bans as a large threat, and went on the offensive to prevent further initiatives and statutes from coming into being.[69] To protect themselves, they lobbied state legislatures to consider "preemption" bills, with language investing the sole power to regulate GMOs in the state government.[70] These bills therefore prevent any municipalities or counties from implementing regulatory efforts on their own, and make GMO regulation consistent across the state.[71] Fifteen

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[62] Biological Agents Registry, N.C. Gen. Stat. Ann. § 130A 479 (2010).
[63] *Id.*
[64] *See Biotechnology Statutes Chart*, *supra* note 60.
[65] *See* Tokar, *supra* note 32.
[66] *See Banning GMOs*, VOICE OF THE ENVIRONMENT, http://voiceoftheenvironment.org/gmos/ (last visited Jan. 2, 2011).
[67] *Id.*
[68] See California Biomedical Research Association, *Genetically Modified Organisms and Biomedical Research*, http://www.ca-biomed.org/pdf/media-kit/fact-sheets/FS-GMO.pdf.
[69] *Seed Law Preemption Background: Industry Aims to Strip Local Control of Food Supply*, ENVIRONMENTAL COMMONS, http://environmentalcommons.org/seedlawbackgrounder.pdf.
[70] *Id.*
[71] *Id.*

states have passed preemption bills[72], while a number of others (including North Carolina) considered them but ultimately failed to pass them.[73] After this surge of legislation which occurred mostly in 2006-2007, efforts seemed to have slowed on both sides of the debate, with few localities considering legislation to regulate GMOs in broad terms.

The most recent trend is for states to consider the GMO debate in relation to local issues that carry more weight with the electorate.[74] By doing so, the concerns over the safety of GM food become more concrete, thereby providing the impetus to take action and to prevent harm.[75] For instance, Minnesota has passed legislation which provides for regulation of GM wild rice, despite the fact that the product does not even exist yet.[76] Wild rice is a native crop in Minnesota, has large significance to the Native American population there, and is a commercially important crop for the state.[77] Minnesota therefore had a large incentive to protect wild rice from possible dangers, and it now requires the presentation of an environmental impact statement to the state Environmental Quality Board before that Board can grant permits for use of GM rice.[78] The legislature further instructed the Minnesota Department of Natural Resources to perform a study to determine the potential risks of GM rice crops.[79] Another example of a crop having significance to a state is seen with the recent efforts in Hawaii to regulate the creation and use of GM coffee and taro crops.[80] These crops are commercially and culturally

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[72] *Id.*
[73] Britt Bailey, *Seed & Plant Preemption Bills Fail in 2006 Legislatures*, ENVIRONMENTAL COMMONS, http://environmentalcommons.org/preemption-bills-fail-2006.pdf (last updated Dec., 2006).
[74] *E.g.* Rachel Durkee Walker & Jill Doerfler, *Wild Rice: The Minnesota Legislature, a Distinctive Crop, GMOs, and Ojibwe Perspectives*, 32 HAMLINE L. REV. 499, 502 (2009).
[75] *Id.*
[76] *Id.* at 501.
[77] *Id. at* 503.
[78] *Id. at* 501
[79] *Id.*
[80] *See* Joan Conrow, *A seed of doubt*, HONOLULU WEEKLY, Apr. 8, 2009, http://honoluluweekly.com/cover/2009/04/a-seed-of-doubt/.

important to the state.[81] The Hawaii state legislature has considered bills to introduce a 10 year moratorium on GM taro and coffee research, but has also debated a preemption bill to prevent local action on the use and regulation of these crops.[82] With the issue very much still up for debate, Hawaii is one of the states with an active legal debate over the safety of GM food. Hawaii may also assume a particular importance since it is the state where the largest number of field trials of GM plants is performed.[83] Debates such as those in Minnesota and Hawaii are the center of action for the current GMO debate, and should provide valuable insight on the direction the country is taking with regard to GM foods.

V. Conclusion

This brief overview of state and local efforts to regulate GMOs reveals the active debate in this country over the proper usage of newly developing biotechnologies in conjunction with food products. While the federal government bears primary responsibility for the approval and use of these products, it is clear that many do not feel that the federal regulatory system is adequate. The state and local debates are a sign of that discomfort, and perhaps will serve as testing grounds for different mechanisms to regulate the use and availability of GM foods. The local efforts, therefore, will bear watching as a sign of what the future will hold for GM food crops in the United States.

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[81] *Id.*
[82] *Fall 2009 Hawai'i GMO Legislative Update*, ENVIRONMENTAL COMMONS, http://environmentalcommons.org/Hawaii-GMO-update-2009.html.
[83] Robynne Boyd, *Genetically Modified Hawaii*, SCIENTIFIC AMERICAN, Dec. 8, 2008, http://www.scientificamerican.com/article.cfm?id=genetically-modified-hawaii.

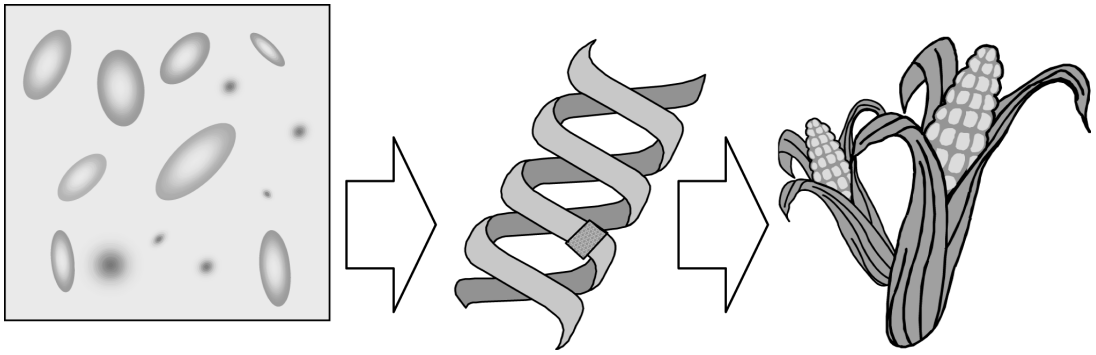

Figure 1: BT-corn creation and use. Graphic Courtesy of US Government Accountability Office.