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A Growing Controversy: Genetic Engineering in Agriculture

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A GROWING CONTROVERSY: GENETIC ENGINEERING IN AGRICULTURE

I. INTRODUCTION

Recent developments in biotechnology have raised concerns about the impact of genetic engineering on agriculture and the environment. Proponents claim these developments will make agriculture safer, more efficient and more profitable. Opponents argue, however, that long-term effects are not evident and that adopting the technology too quickly could unleash an irreversible series of environmental disasters. Complicating matters is the lack of a coherent governmental regulatory scheme. The uncertainty surrounding the issue will cause courts to allocate responsibility and provide guidance as technology continues to progress.

This Comment addresses the possible legal ramifications of recent developments in the field of genetic engineering and agriculture. Section II sets forth the background of genetic engineering and genetically modified crops. Section III addresses the legal issues concerning genetic engineering. Section IV discusses the current regulation of genetic engineering related to agriculture. Finally, Section V suggests that both regulatory and judicial oversight of genetic engineering is necessary to ensure that its future technological developments are safe.


2. See id. at 892-93 (noting advantages of GM crops).

3. See id. at 893-900 (examining drawbacks of GM crops).

4. See id. at 901-02 (highlighting deficiencies in regulatory structure).

5. See id. at 909-10 (citing challenges in establishing liability with regard to genetically modified crops).

6. See Rich, supra note 1, at 889 (addressing issues surrounding genetically modified crops).

7. For a discussion of the background of genetic engineering and agriculture, see infra notes 11-88 and accompanying text.

8. For a discussion of the legal issues involving genetic engineering and agriculture, see infra notes 89-140 and accompanying text.

9. For a discussion of the current regulatory scheme, see infra notes 141-204 and accompanying text.

10. For a discussion of the impact of genetic engineering, see infra notes 205-11 and accompanying text.
II. BACKGROUND OF GENETIC ENGINEERING

A. History

Genetic modification in agriculture has been practiced for centuries around the world. Traditionally, farmers saved the best seeds from one harvest for use in subsequent plantings. Since the 1500s, farmers have tried to develop plant varieties exhibiting the most hardy, productive and desirable traits. The first major development in the field of genetics occurred in the 1800s, with Gregor Mendel’s research. Mendel first discovered that genetic traits are passed on in a predictable manner, and thus opened the door to the modern era of genetic research.

All major crops have evolved through the process of selective breeding, a slow and imperfect procedure. Today, advanced technology allows a specific gene trait to be taken from one organism and inserted into a completely unrelated organism. The new DNA technology provides more precision in producing offspring with the desired trait than the traditional method of breeding the entire organism. Genetic engineering enhances the resistance of food crops to certain pests and herbicides, increases their nutritional value and lengthens their shelf lives.

Genetically engineered organisms, also labeled as "transgenic" or "genetically modified" (GM), are now widespread, and Americans unknowingly consume them on a daily basis. Since the introduction of the first genetically engineered food item in 1994, the Flavr Savr Tomato, over fifty transgenic crops have been commercialized in the United States. It is estimated that “[seventy percent] of food on grocery shelves contains ingredients from

12. See id. (explaining traditional farming practices).
13. See id. at 2174-75 (describing how crops were developed through traditional breeding techniques).
14. See id. (citing major breakthrough of Mendel’s research).
15. See id. (noting lasting impact of Mendel’s discovery).
16. See Mandel, supra note 11, at 2175 (addressing development of conventional crops).
17. See id. (highlighting precision of genetic engineering).
18. See id. (noting benefits of new technology).
20. See Mandel, supra note 11, at 2176 (describing prevalence of GM products).
21. Id. at 2176-77 (highlighting number of genetically engineered crops).
genetically modified crops." In the United States alone, farmers grew over 110 million acres of GM crops in 2004, an increase of eleven percent from 2003 harvests. Genetic engineering is the fastest growing agricultural development in history, increasing by millions of acres every year and constantly expanding to include new products.

B. Common GM Products

Most GM products are currently altered to be pest and herbicide resistant. The high-tech genetic engineering industry focuses primarily on large commercial crops such as corn, cotton, canola and soybeans. For example, "Bt" corn is a common crop which expresses Bt, Bacillus thuringiensis, a bacterium that is toxic to insects. Conventionally, farmers sprayed Bt on crops to prevent insect infestation. Now, the crop has been modified to produce the bacterium itself, eliminating the need for sprayings while providing constant protection. Bt no longer wears off the plant, and it also protects the plant internally from pests such as the bollworm and corn borer. On the market for almost a decade, Bt corn now commands nearly one-third of the United States' market share.

Another common GM crop is the "Roundup Ready" soybean. Herbicide does not affect these plants, which increases crop yields because weeds are easily eliminated from the crop. The use of these plants is widespread, accounting for eighty-five percent of all soybean plantings in the United States in 2004.

22. See id. at 2177 (noting quantity of GM food consumed in United States as estimated by Grocery Manufacturers of America).
24. See id. (acknowledging rapid growth rate of GM technology since its inception).
25. See Mandel, supra note 11, at 2178 (mentioning most common GM traits).
27. See Kunich, supra note 19, at 811 (discussing Bt crops).
28. See id. (highlighting previous pesticide use).
29. See id. at 810-11 (discussing how Bt crops reduce need for pesticides).
30. See id. at 811 (explaining protection provided by Bt crops). The Department of Agriculture estimates that corn pests cause nearly a billion-dollar loss to United States farming revenues each year. See Palmer, supra note 23, at 25.
31. See Kunich, supra note 19, at 811 (noting popularity of Bt crops).
32. See id. (describing Roundup Ready soybeans).
33. See id. (explaining how Roundup Ready crops work).
34. See Palmer, supra note 23, at 22 (providing statistical information showing percentage of genetically modified crops grown in United States).
Aside from the high-tech manipulation occurring in Bt and pest-protected crops, virtually all fruits and vegetables on the market have been genetically manipulated in some way to affect their size or taste in order to increase their marketability. Nearly all potatoes, tomatoes, corn, oats and rice are hybrids resulting from cross-fertilization between species. Additionally, all “seedless” varieties of fruit, such as grapes and watermelons, are a result of genetic modification.

C. Benefits of Genetic Engineering

Genetic engineering allows modern farmers to produce higher crop yields more efficiently. GM plants require less irrigation, as well as fewer herbicides and pesticides. For example, crop loss from plant pests totals billions of dollars annually. Utilizing pest-protected crops, like Bt corn, can greatly mitigate this loss. Not only is the quality of the crop improved while costs are reduced, but farmers no longer need to worry about pesticide application and exposure. GM crops have decreased the use of pesticides by several million pounds. Bt cotton alone has reduced pesticide use by eighty percent since 1998. This benefit has been most striking in China, where up to one thousand people died each year from the mishandling of pesticides before the introduction of Bt crops. As a further benefit, farmers can target the pest protection provided by modified crops also account for forty-five percent of all corn and seventy-six percent of all cotton grown in the United States. Id. at 27.

35. See id. at 23 (noting widespread use of genetic engineering in agricultural products for human consumption).

36. See id. at 25 (discussing types of crops subject to engineering).

37. See id. (providing examples of man-made varieties of seedless fruits). Other man-made varieties of fruits and vegetables include red grapefruits, black currants, pumpkins and pea pods that remain closed. See id.

38. See Mandel, supra note 11, at 2180-82 (describing agricultural benefits of GM products).


40. See Mandel, supra note 11, at 2180 (noting costs caused by pest destruction). About $14 billion in crops are lost in the United States each year due to plant pests. See id.

41. See id. (describing economy of planting modified crops).

42. See id. at 2180-81 (acknowledging benefits of reduced pesticide use). Crops designed to be tolerant of certain herbicides allow growers to use specific herbicides without worrying about harming the crop itself. See id.

43. See Kunich, supra note 19, at 813 (highlighting Bt crops’ decreased need for pesticides).

44. See Harry Cline, Farmers Told to Take Up Battling Against Anti-biotech Groups, WESTERN FARM PRESS, Oct. 2, 2004, at 19 (providing statistics on decreased pesticide use).

45. See id. (discussing health and production benefits of Bt crops worldwide).
by GM crops to specific insects, whereas traditional pesticides kill all insects, including those that are not harmful to crops.\textsuperscript{46} Herbicide-tolerant crops also result in higher yields and lower production costs.\textsuperscript{47} Although GM seeds can cost up to fifty percent more than conventional seeds, the increased profits from higher yields and reduced growing costs from the use of fewer pesticides offset the initial cost.\textsuperscript{48}

Greater agricultural efficiency can help combat world hunger and provide for the steadily increasing world population.\textsuperscript{49} Current statistics show that “[t]he world today produces twice as much grain as it did in 1960, on only a third more land, yet the harvest still falls short of demand, and an estimated 840 million people, or [thirteen percent] of the world population, are still malnourished, most of them in developing nations.”\textsuperscript{50} In addition to being more efficient, GM crops can also have more nutritional value.\textsuperscript{51} These crops frequently contain higher levels of vitamins and minerals.\textsuperscript{52} Monsanto Corporation, one of the leaders in the GM industry, has developed “golden rice” for distribution in developing countries.\textsuperscript{53} Golden rice is modified to contain high levels of beta carotene, which alleviates the health problems resulting from vitamin A deficiencies.\textsuperscript{54} Considering the world population is expected to swell to ten billion people by 2050, GM crops can play an integral part in reducing world hunger and problems associated with malnutrition.\textsuperscript{55}

As technology progresses, even greater benefits may result from genetic engineering.\textsuperscript{56} Dubbed “next-generation biotechnology,” the possibilities include using plants to grow industrial chemical compounds, absorb toxic pollution or produce pharmaceuticals

\textsuperscript{46} See Mandel, supra note 11, at 2184-85 (noting pest protected crops are more selective than traditional pesticides).

\textsuperscript{47} See id. at 2181 (mentioning additional benefits of Roundup Ready crops).

\textsuperscript{48} See Palmer, supra note 23, at 22 (acknowledging farmers willingness to pay premium prices for biotechnology).

\textsuperscript{49} See Mandel, supra note 11, at 2182 (explaining need for increased crop efficiency). Increased yields and lower costs should make food less expensive, which should in turn help reduce hunger problems. Id.

\textsuperscript{50} Palmer, supra note 23, at 22 (noting insufficiency of current world food supply).

\textsuperscript{51} See Mandel, supra note 11, at 2183 (describing health benefits of GM crops).

\textsuperscript{52} See id. (noting potential impact of GM crops on world hunger).

\textsuperscript{53} See id. (providing example of nutritional modification).

\textsuperscript{54} See id. (discussing benefits of “golden rice”).

\textsuperscript{55} See Palmer, supra note 23, at 22 (acknowledging increased world food demand in future).

\textsuperscript{56} See Mandel, supra note 11, at 2186-87 (mentioning biotechnology can reach other areas).
and vaccines. \(^{57}\) In the future, it may even be possible to "grow" plastics and petroleum. \(^{58}\)

D. Risks of Genetic Engineering

Although there is no direct, documented evidence that GM products have harmful effects on humans, the public still has reservations about GM technology. \(^{59}\) The United States is generally more accepting of genetically engineered food products than other countries, albeit due to consumer ignorance. \(^{60}\) In the United States, most GM crops are used for animal feed, clothing or as ingredients in processed food, rather than for direct consumption. \(^{61}\) These crops gained widespread use before consumer awareness was heightened. \(^{62}\) In contrast, Europe has banned modified crops, and many European consumers support a mandatory labeling requirement. \(^{63}\) The concern about genetic modification stems from the unknown long-term effects on both human health and the environment. \(^{64}\) In the face of such uncertainty, many opponents of genetic engineering advocate a cautious approach to this new technology. \(^{65}\)

Many people are particularly concerned about the potential adverse effects of genetic engineering on the environment and ecosystems. \(^{66}\) The concern results from the engineering of GM crops that are designed to carry a superior trait, as compared to a "natural" plant. \(^{67}\) Theoretically, seeds or pollen containing the superior

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57. See id. (describing future possibilities of genetic engineering in agriculture).

58. See Palmer, supra note 23, at 22 (addressing future developments in biotechnology); see also Mandel, supra note 11, at 2187 (proposing possibility of replacing traditional plastics with plant-made, biodegradable polymers).

59. See Mandel, supra note 11, at 2190 (mentioning there are no reported cases of negative health reactions). The United States Food and Drug Administration has not found "a single adverse reaction to any biotech food." See Palmer, supra note 23, at 22.

60. See Kunich, supra note 19, at 813-14 (finding United States citizens generally more accepting of GM products than Europeans).


62. See id. (providing status of GM products).

63. See Kunich, supra note 19, at 814 (noting European labeling requirement).

64. See id. at 816 (acknowledging popular concerns about genetic engineering).

65. See id. at 817 (advocating conservative adoption of biotechnology).

66. See Mandel, supra note 11, at 2194 (highlighting environmental concerns of genetic modification).

67. See Kunich, supra note 19, at 818 (describing process and potential effects of cross-pollination).
trait can transfer to other wild plants with unknown results. The wild plants now containing the GM trait could then spread, upsetting the fragile balance of ecosystems along the way.

The consequences of this type of gene transfer are unknown and could range from harmless to large-scale ecological disaster. The National Research Council stated, "[t]he introduction of any type of biological novelty can have unpredicted effects on the recipient community and ecosystem." For example, if the wind or insects transferred the gene for herbicide resistance from a crop in one field to weeds in a nearby field, the resulting weeds would also become resistant to the herbicide. This situation is not entirely hypothetical. In 2004, the Environmental Protection Agency (EPA) reported that a strain of Roundup resistant grass demonstrated the potential to pollinate conventional grass up to thirteen miles away. If the Roundup resistance trait spread to wild grasses, it could result in weeds that would be resistant to the most widely used weed killer. This would make the hybrid weeds much more difficult to control and would increase the likelihood that they would dominate other native species. In response, GM proponents argue that gene flow has always occurred without devastating consequences. They also claim that allowing sufficient buffers between closely related crops would reduce the chances of cross-pollination, thus minimizing any danger.

Special concerns arise if GM plants were to invade the habitat of threatened or endangered species. Such fragile species would be unable to preserve their place in the ecosystem when confronted by a superior and advantageous organism. As a consequence,

68. See id. (discussing possibility of unintended gene flow).
69. See id. (noting how quickly modified genes could escape into wild).
70. See id. at 819 (addressing undetermined environmental impacts from gene flow).
71. See Mandel, supra note 11, at 2194-95 (providing possible negative impacts of genetic engineering).
72. See Kunich, supra note 19, at 818-19 (explaining danger of gene flow).
74. See id. (mentioning concerns about genetically engineered crops).
75. See id. (discussing danger of gene flow to wild plants).
76. See Kunich, supra note 19, at 819 (addressing possible consequences of pollen drift).
77. See Pollack, supra note 73, at 12 (responding to concerns about pollen drift).
78. See id. at 13 (acknowledging mitigation of pollen drift).
79. See Kunich, supra note 19, at 819 (discussing concern of gene flow involving sensitive species).
80. See id. (explaining dangers of gene flow in fragile environments).
many wild plant species and the animals that depend on them could become extinct.\textsuperscript{81} "Gene flow" also affects members of the same species by slowly eliminating the genetic variations that occur naturally.\textsuperscript{82} Because GM strains tend to be stronger, they can overcome native species, reducing biodiversity.\textsuperscript{83} Less biodiversity results in less flexibility in an ecosystem, which makes entire species vulnerable to crop failure.\textsuperscript{84}

Similarly, pest-protected plants may be hazardous to the environment because the pesticide they produce is constantly present.\textsuperscript{85} This increases the chances that the targeted insects will evolve to overcome the pesticide.\textsuperscript{86} As a result, stronger, more toxic pest protection will be required.\textsuperscript{87} Admittedly, this risk is not limited to GM plants, but is present with natural plants and traditional pesticides as well.\textsuperscript{88}

### III. Legal Issues Concerning Genetic Engineering

The legal issues surrounding GM crops are numerous: liability for contamination of conventional crops, intellectual property liability for misuse of patented GM organisms and contract law issues related to license agreements, to name a few.\textsuperscript{89} Because genetic engineering is a new and developing field in both technology and law, society has yet to resolve these unique legal issues.\textsuperscript{90} A few noteworthy cases, however, indicate the path future courts might take.\textsuperscript{91}

\begin{itemize}
  \item \textsuperscript{81} See Mandel, \textit{supra} note 11, at 2196 (discussing possibility of negative environmental impacts).
  \item \textsuperscript{82} See Kunich, \textit{supra} note 19, at 819-20 (noting gene flow is not restricted to affecting wild species).
  \item \textsuperscript{83} See id. (providing effect of gene flow on related species).
  \item \textsuperscript{84} See id. at 820 (highlighting dangers of reduced biodiversity).
  \item \textsuperscript{85} See Mandel, \textit{supra} note 11, at 2197 (acknowledging pest protected plants constantly express their pesticides).
  \item \textsuperscript{86} See id. at 2197-98 (mentioning possibility of increased insect tolerance to pesticides).
  \item \textsuperscript{87} See id. at 2198 (addressing possible adverse consequence of crops genetically engineered to express pesticides).
  \item \textsuperscript{88} See id. (noting increased insect tolerance is possible with any pesticide use).
  \item \textsuperscript{90} See id. at 611-12 (explaining specific legal issues concerning GM crops).
  \item \textsuperscript{91} See, e.g., id. at 616 (discussing Monsanto Co. v. Davis, 97 S.W.3d 642 (Tex. Ct. App. 2002)).
\end{itemize}
A. Negligence

Farmers of organic, or non-GM crops, have sought damages from GM crop producers when their non-GM crops became contaminated through pollen drift. As a result of the pollen drift, the non-GM farmer must take expensive remediation measures and cannot command as high a price in the market as a result of the contamination. Although it is possible to recover in tort for any physical property damage, the economic loss doctrine prevents farmers from collecting for purely economic damages.

In Monsanto Co. v. Davis, a group of farmers who bought Bt seeds from Monsanto, a large company holding the patents to Bt cotton, sought class action certification of their claims for fraud, negligence and negligent misrepresentation. Despite Monsanto's representations that Bt cotton was immune to infestation, in 1996 bollworms destroyed nearly one million acres of Bt cotton. The farmers claimed they relied on the representations of the company regarding the performance of the seeds they purchased. The trial court initially certified the class, but the Texas Court of Appeals reversed the decision because certain plaintiffs had a distinctive defense which destroyed the typicality requirement necessary for class certification. Although the suit did not proceed, it indicated future liability issues surrounding genetically engineered crops.

The District Court for the Northern District of Illinois also addressed negligence in the context of GM organisms in the case of In re StarLink Corn Products Liability Litigation. In Starlink, non-GM farmers claimed damages resulting from the mishandling of GM
corn seed, which cross-pollinated and commingled with the farmers' conventional crops. EPA approved StarLink corn only for use in animal feed because of concerns about the pesticide it was engineered to produce. Because EPA did not authorize StarLink corn for human consumption, its maker, Aventis and any licensees had to take precautions to avoid contamination of the human corn supply. EPA also required Aventis to instruct farmers on proper segregation and buffering methods and to obtain a signed contract from all farmers planting StarLink corn. These use restrictions were not strictly followed, and, as a result, StarLink corn entered the human food supply.

The results of the StarLink contamination were widespread. In 2000, StarLink corn was discovered in Kraft Foods’ Taco Bell brand taco shells, resulting in a recall of two-and-a-half million boxes of shells costing Kraft millions of dollars. Eventually, manufacturers had to recall over three hundred human food products as a result of StarLink corn contamination. Grain elevators and transporters had to perform expensive testing on all corn shipments to detect contamination. In addition, as a result of contamination worries, South Korea, Japan and other countries have eliminated or substantially limited their imports of American corn. The full cost of StarLink contamination could total over one billion dollars.

In the course of litigation, the plaintiff farmers contended that the label on StarLink corn was defective because certain StarLink

102. See id. at 835 (stating basis of plaintiffs’ suit).
103. See id. at 834 (noting StarLink corn's limited approval due to possible allergic reactions and explaining how Starlink corn could contaminate regular corn supply).
104. See id. (explaining StarLink corn was unfit for human consumption because EPA regulated it as pesticide).
105. See id. (stating use contracts were required from all farmers to prevent contamination).
106. See StarLink, 212 F. Supp. 2d at 834-35 (discussing contamination of United States corn supply).
107. See Mandel, supra note 11, at 2203 n.200 (noting it could take up to four years for contaminated corn to work itself out of food supply).
108. See id. at 2204 (providing data on profit losses resulting from StarLink Corn recall).
109. See id. (noting large number of products ultimately contained contaminated corn).
110. See id. at 2205 (discussing effects of contamination on third parties).
111. See StarLink, 212 F. Supp. 2d at 835 (mentioning impact of contamination on foreign trade).
112. See Mandel, supra note 11, at 2205 (noting StarLink litigation resulted in multimillion-dollar settlement with affected farmers).
seeds were sold either without a label giving notice of the use restrictions or were sold without the accompanying Grower Agreement. In response to this claim, the District Court for the Northern District of Illinois held that the plaintiffs' claims were not preempted by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), even though EPA imposed the label requirement under FIFRA. The court further concluded that states could require pesticide manufacturers to notify third parties of the restrictions placed on the pesticide. In this case, grain elevator operators and other handlers should have been notified that StarLink corn was not fit for human consumption and should have been stored apart from conventional corn.

The plaintiffs further alleged that StarLink corn was a defective product. In response, the court concluded that the product was not defective, but rather the warnings attached to the product were inadequate. Because EPA set the labeling requirements under FIFRA, however, federal law preempted the claim.

Next, the District Court for the Northern District of Illinois discussed the economic loss doctrine and determined that the plaintiffs had a viable claim as long as they alleged tangible harm to their actual crops, not just an economic loss. Once specific harm was alleged, the plaintiffs could recover for economic loss. Finally, the court held that the contamination of the plaintiffs' crops did

113. See StarLink, 212 F. Supp. 2d at 836 (presenting plaintiffs' defective warning argument). The Growers Agreement set forth field management requirements and stated the limits on StarLink corn use. Id. at 834.

114. See id. at 836 (holding FIFRA did not preempt defect argument). FIFRA regulates the use, sale and labeling of pesticides. Id. at 835. For a further discussion of FIFRA, see infra note 164 and accompanying text.

115. See StarLink, 212 F. Supp. 2d at 837 (noting warning could have been more comprehensive and states may require warnings be apparent to parties beyond initial purchaser).

116. See id. (explaining better warning could have mitigated contamination).

117. See id. (addressing plaintiffs' final argument).

118. See id. at 837-38 (holding product was not defective). The court held that under FIFRA, claims about defective labeling were not preempted but claims that warnings were inadequate were preempted. Id.

119. See id. at 838 (concluding claims based on label adequacy were preempted). FIFRA prohibits states from imposing labeling requirements beyond those required by EPA. Id. at 835-36. Because EPA determined the label on the StarLink corn to be adequate, FIFRA preempted any claims that the label was inadequate. Id. at 836.

120. See StarLink, 212 F. Supp. 2d at 842-43 (applying economic loss doctrine to facts of case).

121. See id. at 843 (concluding plaintiffs could recover if they could demonstrate specific harm).
not amount to conversion because conversion requires intent, whereas the commingling in this case resulted from negligence.\textsuperscript{122}

B. Intellectual Property

Patent law allows GM seed producers to obtain a general utility patent on their products.\textsuperscript{123} Most seed producers require purchasers to sign a Grower’s Agreement or a Technology Use Agreement, stating the farmer will not save, resell or replant the GM seed.\textsuperscript{124} Consequently, farmers can be sued for misappropriation of technology if they save seed from one harvest for replanting the following year.\textsuperscript{125}

In \textit{Monsanto v. Trantham},\textsuperscript{126} the defendant farmer, Trantham, purchased both Roundup Ready soybeans and Roundup Ready cottonseed without signing the Technology Agreement.\textsuperscript{127} Trantham subsequently saved the seeds and replanted them the following year.\textsuperscript{128} Plaintiff Monsanto sued Trantham for patent infringement, and Trantham countersued on the grounds of monopolization, attempted monopolization and conspiracy to monopolize.\textsuperscript{129} In ruling on the plaintiff’s motion for summary judgment, the District Court for the Western District of Tennessee dismissed Trantham’s monopolization claim because he could not meet either prong of the monopolization test: relevant market share and willful monopolization.\textsuperscript{130}

The court also dismissed Trantham’s attempted monopolization claim because he could not prove Monsanto had a “dangerous probability of success” in monopolizing.\textsuperscript{131} Additionally, the court dismissed Trantham’s conspiracy to monopolize claim for lack of

\textsuperscript{122.} See id. at 844 (finding conversion claim meritless).
\textsuperscript{123.} See McEowen, \textit{supra} note 89, at 643 (noting GM technology can be patented). Utility patents apply to any new process, machine, manufacture, composition or any new improvements and protect the patent holder for twenty years. \textit{Id.} at 634.
\textsuperscript{124.} See id. at 643 (addressing common contracts seed producers require farmers to sign). The farmer is required to sign the Agreement at the time the seeds are purchased. \textit{Id.}
\textsuperscript{125.} See id. (describing liability resulting from saving patented seeds).
\textsuperscript{126.} 156 F. Supp. 2d 855 (W.D. Tenn. 2001).
\textsuperscript{127.} See id. at 859 (presenting factual background of case).
\textsuperscript{128.} See id. (continuing presentation of facts).
\textsuperscript{129.} See id. at 861 (stating plaintiff’s and defendant’s claims).
\textsuperscript{130.} See id. at 863-64 (dismissing monopolization claim). The relevant market includes the products that consumers can substitute for the monopolizing product. \textit{Id.} at 861-62.
\textsuperscript{131.} See \textit{Trantham}, 156 F. Supp. 2d at 864 (dismissing attempted monopolization claim).
evidence establishing a conspiracy. Finally, the court concluded that Trantham was liable for patent infringement based on evidence gathered from his fields, which showed that his crops were grown from GM seed produced by Monsanto.

In another infringement case, *Monsanto v. McFarling*, the defendant farmer, McFarling, purchased two seasons worth of Roundup Ready soybeans and signed the Technology Agreement that accompanied the seed bags. The Technology Agreement specifically stated the seeds were "for planting a commercial crop only in a single season." Monsanto sued McFarling for patent infringement and obtained a preliminary injunction after McFarling replanted the patented seeds in subsequent seasons. McFarling challenged the Technology Agreement as an illegal restraint on trade and sought to have the preliminary injunction against him reversed. The Court of Appeals for the Federal Circuit concluded that McFarling was not restrained or obligated to continue purchasing seeds from Monsanto, but he was constrained by the Technology Agreement for the seeds already purchased which included the restrictions on saving or replanting seeds. The court concluded the trial court did not abuse its discretion by granting the preliminary injunction to prevent McFarling from planting and harvesting crops from his saved seeds.

**IV. CURRENT REGULATION OF GENETIC ENGINEERING**

"The primary purpose of any regulatory system is to protect against harm . . . . At the same time, a regulatory system should provide a clear pathway to the market for safe and useful products." No single federal agency has ultimate regulatory authority over genetically modified products. Current regulation is piece-

132. See id. at 865 (dismissing conspiracy to monopolize claim).
133. See id. at 872 (holding defendant liable for patent infringement).
134. 302 F.3d 1291 (Fed. Cir. 2002).
135. See id. at 1293 (providing factual background).
136. See id. (stating provisions of use agreements required from farmers).
137. See id. (mentioning plaintiff's claim against defendant).
138. See id. at 1297 (stating defendant's counterclaims).
139. See *Mcfarling*, 302 F.3d at 1298 (concluding technology agreements bound defendant).
140. See id. at 1299-1300 (upholding preliminary injunction).
meal at best, with numerous gaps and overlaps. Such uncoordinated oversight only intensifies the safety concerns about genetic modification in the eyes of GM opponents. Uncertain regulation is also difficult for proponents of GM products, who must attempt to comply with numerous statutes and costly regulations.

Genetic engineering presents unique problems to any regulatory scheme because no particular statute addresses the issue and does not clearly fit under existing statutes. Three separate agencies administer the statutes currently applied to genetic engineering: EPA, the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). All three agencies can simultaneously regulate a single GM product, increasing costs and resulting in confusion about which agency has primary authority.

A. EPA Oversight

EPA's mandate is to protect both the environment and human health. EPA has extended its authority granted under existing statutes to include oversight of GM products. In the context of GM organisms, EPA exercises its authority under the Toxic Substances Control Act and FIFRA.

1. Toxic Substances Control Act

The Toxic Substances Control Act (TSCA) originally applied to the manufacture of industrial chemicals. Placing GM products within the TSCA framework is a difficult task because

143. See id. (explaining numerous problems exist with current regulatory structure).
144. See id. (acknowledging lack of confidence in government oversight of genetically engineered products).
145. See id. (noting high costs of inefficient regulation).
146. See id. (highlighting lack of precision in regulation).
147. See Kunich, supra note 19, at 824 (stating which agencies exercise regulatory power over GM crops).
148. See Liebert, supra note 141, at 568 (highlighting problems in current regulatory structure).
150. See id. (noting EPA exercises jurisdiction over genetically engineered products).
151. See id. (providing statutes under which EPA regulates GM products).
153. See Matton & Thomas, supra note 149, at 291 (providing original purpose of TSCA).
nothing within TSCA’s language specifically mentions genetic engineering.\textsuperscript{154} Further, TSCA, enacted in 1976, is too outdated to effectively deal with the current state of biotechnology.\textsuperscript{155} Faced with the technological advancements inherent in GM products, EPA has extended its regulatory authority under TSCA to apply to all commercial microorganisms, including GM organisms.\textsuperscript{156} Under TSCA, GM organisms are treated as new chemicals which must be reviewed and approved by EPA prior to marketing.\textsuperscript{157}

TSCA has been ineffective in the context of GM products.\textsuperscript{158} TSCA focuses primarily on gathering information on chemicals before they can be used commercially.\textsuperscript{159} As applied to genetic engineering, TSCA can only mandate testing and information collection, and does not grant EPA authority over any GM products already in the environment.\textsuperscript{160} EPA can only require further testing if the chemical substance presents an “unreasonable risk” to health and the environment.\textsuperscript{161} Additionally, EPA does not have authority to impose liability on growers who do not comply with the restrictions placed on GM plants.\textsuperscript{162}

2. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA\textsuperscript{163} grants EPA authority to regulate pesticides and requires that all pesticides be registered prior to use.\textsuperscript{164} Because FIFRA defines “pesticide” in broad terms, EPA has extended FIFRA to cover GM products expressing pesticide traits, such as Bt crops.\textsuperscript{165} Consequently, pest-protected GM organisms must be registered before they can be marketed.\textsuperscript{166} To satisfy registration requirements, there must be adequate data to assure the plants will

\textsuperscript{154} See Kunich, supra note 19, at 826 (mentioning that TSCA does not specifically apply to GM crops).
\textsuperscript{155} See id. (discussing advancement of biotechnology beyond scope of TSCA).
\textsuperscript{156} See Matton & Thomas, supra note 149, at 291 (describing EPA’s authority to regulate genetically engineered plants).
\textsuperscript{157} See id. at 292-93 (discussing EPA’s approach to regulating GM plants).
\textsuperscript{158} See Kunich, supra note 19, at 827 (noting TSCA regulation of GM products has had problems).
\textsuperscript{159} See id. (stating primary aim of TSCA).
\textsuperscript{160} See id. (noting TSCA’s limitations regarding review of GM products).
\textsuperscript{161} See id. at 829 (acknowledging EPA must have reasonable basis for its determination of “unreasonable risk”).
\textsuperscript{162} See Liebert, supra note 141, at 569 (noting EPA’s limited authority under FIFRA).
\textsuperscript{164} See Kunich, supra note 19, at 831 (describing purpose of FIFRA).
\textsuperscript{165} See id. (discussing EPA’s extension of FIFRA).
\textsuperscript{166} See id. at 832 (stating result of FIFRA’s application to GM products).
not adversely affect the environment.\textsuperscript{167} FIFRA does exempt some pest-protected plants from regulation, but unless the GM plant fits within such an exception, complying with the data and testing requirements will be costly for any new product.\textsuperscript{168} As a practical matter, FIFRA does not adequately address the concerns raised by genetic engineering because it only applies to a narrow class of GM organisms – those intended to act as pesticides.\textsuperscript{169} Furthermore, neither FIFRA nor TSCA require public notification when a genetically modified organism is being planted or tested.\textsuperscript{170}

B. USDA Regulation

USDA regulates GM products used in food or food-related products.\textsuperscript{171} USDA has authority under several federal statutes, such as the Plant Protection Act,\textsuperscript{172} the Meat Inspection Act,\textsuperscript{173} the Poultry Products Inspection Act,\textsuperscript{174} the Egg Products Inspection Act,\textsuperscript{175} the Virus-Serum Toxin Act\textsuperscript{176} and the National Environmental Policy Act\textsuperscript{177} to regulate these GM products.\textsuperscript{178} USDA also operates through a sub-agency, the Animal and Plant Health Inspection Service (APHIS).\textsuperscript{179} APHIS is primarily responsible for monitoring the release of GM plants into the environment, such as when the plants are field tested or planted as crops.\textsuperscript{180}

APHIS regulates “the movement of plants . . . developed through genetic engineering” if they present “a risk of plant pest

\textsuperscript{167} See id. (providing EPA’s requirements for pesticide registration).
\textsuperscript{168} See id. at 833-34 (noting that complying with registration requirements places high burden on producer).
\textsuperscript{169} See Kunich, supra note 19, at 834 (highlighting limitations of FIFRA’s application to GM organisms).
\textsuperscript{170} See id. at 837 (noting lack of public participation in EPA regulation).
\textsuperscript{171} See Matton & Thomas, supra note 149, at 289 (discussing scope of USDA regulation).
\textsuperscript{174} See id. §§ 451-471 (creating regulation of poultry products for consumers’ health).
\textsuperscript{175} See id. §§ 1031-1056 (regulating egg products for public health).
\textsuperscript{176} See id. §§ 151-159 (finding transportation or sale of harmful virus or toxin to be unlawful).
\textsuperscript{178} See Matton & Thomas, supra note 149, at 289 (noting statutes granting USDA authority).
\textsuperscript{179} See id. at 290 (mentioning that USDA acts through APHIS).
\textsuperscript{180} See id. (describing role of APHIS).
introduction, spread or establishment." 181 Regulations define a “plant pest” as an organism or substance “which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof.” 182 Such broad definitions allow APHIS to reach GM organisms as plant pests, regardless of the type of plant or the type of modification made to the plant. 183

Prior to the release of any GM organism, the developer must notify the government and apply for a permit. 184 Once the developer applies for the permit, APHIS must determine whether to classify the GM product as either “regulated” or “non-regulated.” 185 If APHIS classifies the product as “non-regulated,” producers can commercialize it without further governmental oversight. 186 APHIS grants non-regulated status when it determines that a new plant would be as safe as traditional varieties if released. 187 If APHIS deems the product “regulated,” it must go through a much more extensive APHIS review process. 188

There are some downsides to APHIS regulation, however. 189 APHIS can only examine the risks posed by the plants themselves, and it does not consider possible effects on overall ecosystems. 190 Also, once APHIS designates a GM organism as non-regulated, it loses any subsequent jurisdiction over the product and cannot impose any conditions on its release. 191 Since the inception of the permit program in 1987, APHIS has allowed over four thousand exemptions from its permit requirements, having concluded that the exempted organisms did not pose a threat as plant pests. 192

181. See Kunich, supra note 19, at 838 (highlighting USDA’s authority under APHIS).
182. See id. at 838-39 (providing definition of “plant pest”).
183. See id. (discussing effect of APHIS interpretation).
184. See Matton & Thomas, supra note 149, at 290 (explaining pre-release permit requirement).
185. See id. (mentioning APHIS classifications).
186. See id. (providing result of “non-regulated” status).
187. See Kunich, supra note 19, at 839-40 (addressing APHIS process of reaching “non-regulated” determination).
188. See Matton & Thomas, supra note 149, at 290 (explaining result of “regulated” status).
189. See Liebert, supra note 141, at 569 (discussing drawbacks of USDA oversight).
190. See id. (highlighting limits of APHIS authority in addressing large-scale issues).
191. See id. (providing limits of APHIS jurisdiction).
192. See Kunich, supra note 19, at 838-39 (noting number of exceptions granted by APHIS).
C. FDA Regulation

FDA is responsible for ensuring the safety of GM products placed on the market, deriving its authority from the Federal Food, Drug, and Cosmetic Act \(^{193}\) and the Public Health Service Act. \(^{194}\) FDA's primary focus is on the human health implications of GM products, rather than potential environmental impacts. \(^{195}\) FDA has exclusive authority to regulate all food products, as well as all food components and additives produced in the United States. \(^{196}\) FDA regulates GM products as food additives. \(^{197}\) Substances "generally recognized as safe" (GRAS), however, are not considered food additives and are exempt from the FDA's pre-market approval program. \(^{198}\) So long as the GM product is substantially similar to the non-modified product, the engineered product can be classified as GRAS. \(^{199}\) Thus, nearly all GM products enter the market without formal FDA approval because of their GRAS classification. \(^{200}\)

FDA's policy remains that GM products should not be subject to special regulation unless they express attributes uncharacteristic of traditional products. \(^{201}\) Consequently, unlike Europe, GM products in the United States do not require special labeling unless they are either unlike their natural counterparts or require special instructions, such as to avoid allergic reactions, for example. \(^{202}\) In response to the growing public concern over genetic engineering, FDA has proposed new regulations that would require applicants to submit specific information to aid the determination of whether new GM products pose any threats to safety. \(^{203}\)


\(^{194}\) See 42 U.S.C. § 201 (2000); see also Kunich, supra note 19, at 842 (describing source of FDA's authority).

\(^{195}\) See Kunich, supra note 19, at 842-43 (discussing FDA's regulatory priorities).

\(^{196}\) See Matton & Thomas, supra note 149, at 305 (reviewing FDA's scope of authority).


\(^{198}\) See id. (noting FDA's GRAS exception).

\(^{199}\) See id. at 61 (discussing GM product classification).

\(^{200}\) See id. (explaining FDA's formal approval process).

\(^{201}\) See Kunich, supra note 19, at 843 (providing FDA's approach to GM product regulation).

\(^{202}\) See id. at 843-44 (noting lack of mandatory labeling requirement in United States); see also id. at 847 (acknowledging compulsory labeling of genetically engineered food products in European countries).

\(^{203}\) See id. at 845 (discussing reforms to FDA regulation of genetically modified foods).
intends to implement a voluntary labeling system to help consumers identify GM products.204

V. CONCLUSION

As technology progresses and the possibilities of genetic engineering distance new products even farther from their conventional counterparts, it will become critical that the new products are reviewed in a coordinated and consistent manner.205 The public must be confident that a thorough review of potential effects on both human health and the environment has occurred before new products are placed on the market.206 The full potential of biotech advancements cannot be realized without some assurance of safety.207

Genetic engineering has the potential to both completely revolutionize agriculture and solve the shortages in the world’s food supply.208 Genetic engineering, however, also has the potential to cause far-reaching environmental damage if it is allowed to progress unchecked.209 Maintaining this delicate balance between technology and environmental stability requires a combination of cautious acceptance and proper regulation.210 The only certain conclusion is that both regulatory agencies and the judiciary must stay apprised of new biotech developments to ensure that society enjoys greater benefits than burdens as a result of the technology.211

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204. See id. (mentioning introduction of new labeling program).
205. See Mandel, supra note 11, at 2232-33 (noting proper role of regulation in biotech development).
206. See id. at 2246-47 (discussing proposed regulatory changes).
207. See id. (highlighting necessary reforms).
208. See Kunich, supra note 19, at 869 (discussing significance of genetic engineering).
209. See id. at 816-17, 821-22 (mentioning possible harms of biotechnology and genetic engineering).
210. See id. at 823 (acknowledging need for proper regulation).
211. See id. at 836 (noting costs and benefits of genetic engineering must be balanced).