

# HEALTH RISKS OF GENETICALLY MODIFIED FOOD: A NEED FOR UNBIASED RESEARCH INTO THE POTENTIAL HEALTH RISKS OF GENETICALLY ENGINEERED CROP PRODUCTS

## INTRODUCTION

Agriculture is the world's largest and oldest industry, and throughout history it has progressively undergone series of improvements through selectively cultivating those foods that are most hardy, tasty, or abundant in yield.<sup>1</sup> Increased yield has been achieved through the use of expensive nitrogen fertilizers, and the application of costly pesticides and herbicides for protection.<sup>2</sup> The need for production of food crops at a commercial level has led to the selection of superior and high yielding crops to the exclusion of other varieties.<sup>3</sup> Furthermore, production at a commercial level has resulted in a narrowed gene pool with increased uniform crop characteristics, and the possibility of increased disease epidemic in plants.<sup>4</sup> Genetic engineering of existing species is the current technological process for increasing the productivity and genetic diversity of the existing food base on which the human population depends.<sup>5</sup>

Genetic modification<sup>6</sup> of food crops through transgenic technology

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<sup>1</sup> Michelle J. Brace, *Regulation of Genetically Engineered Foods Under The Federal Foods, Drug, and Cosmetics*, 33 AM. U.L. REV. 899 n.2 (1984).

<sup>2</sup> *Id.* at 899.

<sup>3</sup> *Id.* at 900.

<sup>4</sup> *Id.*

<sup>5</sup> Steven H. Yoshida, *The Safety of Genetically Modified Soybeans: Evidence and Regulation*, 55 FOOD DRUG L.J. 193 (2000).

<sup>6</sup> Food and Drug Administration: *Foods Derived From New Plant Varieties*, 57 FR 22984 (1992)[hereinafter *New Plant Variety*]. The FDA defines "genetic modification" to mean the alteration of the genotype of a plant using any technique, new or traditional.

has resulted in profound improvements in the quality and abundance of food supplies.<sup>7</sup> This scientific break-through has led to production of food crops that are resistant to pests and diseases,<sup>8</sup> and could grow in various environmental conditions.<sup>9</sup> The products of these crops are capable of maintaining improved flavor, texture, shelf life, and protein content.<sup>10</sup> Furthermore, transgenic plants are expected to provide many other useful products such as edible vaccines.<sup>11</sup> These are expected to be of immense help to developing countries, where transportation and refrigeration problems, as well as the high cost of syringes and needles, make traditional forms of vaccination difficult.<sup>12</sup> On the other hand, the traditionally intensive agricultural method in which the world's food supply now depends, is in the long run, both unsustainable and potentially harmful.<sup>13</sup> It is unsustainable because it relies on the consumption of fossil fuels and consumes more energy than it produces.<sup>14</sup> Also, the traditionally intensive agriculture is harmful because the high use of nitrogen and phosphate fertilizers is potentially harmful to humans when their ions contaminate water supplies.<sup>15</sup> Therefore, any technology that may enable better yield should be welcomed.<sup>16</sup>

However, in spite of all of the benefits of genetically modified foods, consumer advocates, scientists, and consumers are highly skeptical of the technology and concerned about the potential health and environmental risks that could stem from these new food items.<sup>17</sup> Therefore, the question is whether the genetically engineered foods are substantially different from their non-genetically modified parent variety to the extent that a separate regulatory scheme is needed to monitor the production of these food types.<sup>18</sup> This comment argues that

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<sup>7</sup> Yoshida, *supra*, note 5.

<sup>8</sup> Sophia Kolehmainen, *Genetically Engineered Agriculture: Precaution Before Profit: An Overview of Issues In Genetically Engineered Food and Crops*, 20 VA. ENTLL.J. 267, 273 (2001).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 274.

<sup>11</sup> Yoshida, *supra* at 194.

<sup>12</sup> *Id.*

<sup>13</sup> Peter Lachmann, *Health Risks of Genetically modified Foods*, THE LANCET, July 3<sup>rd</sup>, 1999, at 69, available at <http://www.frg.eur.nl/personal/pieterman/GM> (last visited Nov. 11<sup>th</sup>, 2001).

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Alliance For Bio-Integrity v. Donna Shalala*, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).

<sup>18</sup> *See* Fed. Reg. 22984.

there are several demonstrable grounds for unbiased research into the health risks of genetically modified foods to determine adequate regulatory standards applicable to this area of emerging technology. Since manufacturers' aims are not always congruent with consumers' best interests and consumers are not always able to protect themselves adequately,<sup>19</sup> government regulation is preferable to marketplace or industrial self-regulation.<sup>20</sup> Should genetically modified foods have the potential to pose health and environmental risks to the public, governmental regulation may be necessary.<sup>21</sup>

#### I. BACKGROUND AND OVERVIEW OF THE FOOD ADDITIVES AMENDMENT

The safety of novel foods and food ingredients has always been of intense public concern. To protect the public, Congress, in 1906, enacted the original Food and Drugs Act, which prohibited interstate commerce of misbranded and adulterated foods, drinks, and drugs.<sup>22</sup> These laws were enacted in response to the shocking disclosure of unsanitary conditions in meat packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines.<sup>23</sup> The 1906 Act was amended in 1938 and became the Food, Drug and Cosmetics Act<sup>24</sup> (FD&C). The 1938 Act, like its 1906 predecessor, prohibited interstate commerce in misbranded and adulterated foods, drinks, and drugs.<sup>25</sup> However, the 1938 Act also extended the FDA's control to include products such as cosmetics and therapeutic devices.<sup>26</sup> Later, Congress, with the support of the food industry, enacted the 1958 Food Additives amendment to the Food, Drug and Cosmetics Act.<sup>27</sup> The Food Additives amendment is codified in section 409 of the Act (21 U.S.C. §348).<sup>28</sup> This act of Con-

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<sup>19</sup> Brace, *supra* note 1, at 901

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> FDA BACKGROUNDER: CURRENT AND USEFUL INFORMATION FROM THE FOOD & DRUG ADMINISTRATION: MILESTONE IN U.S. FOOD AND DRUG LAW HISTORY, May 3, 1999, available at [www.fda.gov/opacom/backgrounders/miles.html](http://www.fda.gov/opacom/backgrounders/miles.html) (last visited October 3, 2001).

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> Substances Generally Recognized as Safe, 62 Fed. Reg. 18938 (proposed April 17<sup>th</sup>, 1997)(to be Codified at 21 C.F.R. pt. 170).

<sup>28</sup> Food Additive Amendment Act of 1958, Pub. L. No. 85-929, 72 Stat. 1784

gress was enacted in response to the public's concern about the increased use of chemical additives in foods and cosmetics.<sup>29</sup> Section 409 of the Food Additives amendment to the FD&C provides that,

a food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402 (a), unless-(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or (2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used. . . .<sup>30</sup>

Therefore, any food additive use is unsafe unless the Administrator of the Food and Drug Administration has either granted an exemption covering it, or its use is within the limits of tolerance established by the Administrator.<sup>31</sup> The statute defines food additive to mean any substance, "the intended use of which will result or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of the food."<sup>32</sup> This definition includes packaging "which unavoidably, and often at barely detectable levels, contains chemical components that migrate into the food."<sup>33</sup> However, the statute excludes from the definition of food additives, substances that are generally recognized to be safe (hereinafter GRAS) under the condition of its intended use.<sup>34</sup> The statute, however, provides that a substance that becomes a component of food is not a food additive, if it is generally recognized for that particular use.<sup>35</sup> In general, the standard of safety is set by the specific scientific community who is knowledgeable about additives, and has common knowledge about the safety of the particular substance that may be directly or indirectly added to food.<sup>36</sup> "Unanimity among experts is not required."<sup>37</sup> However, the existence of a severe conflict among experts regarding the safety of a particular substance precludes a finding of general rec-

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(codified as 21 U.S.C. § 348). See 62 Fed. Reg. 18938.

<sup>29</sup> See 62 Fed. Reg. at 18942.

<sup>30</sup> 21 USCS § 348 (1958)

<sup>31</sup> *Continental Chemiste Corp. v. Ruckelshaus*, 461 F.2d 331, 339 (7th Cir. 1972.)

<sup>32</sup> 21 U.S.C. § 348 (1958)

<sup>33</sup> Lars Noah & Richard A. Merrill, *Starting From Scratch?: Reinventing The Food Additive Approval Process*, 78 B.U.L. REV. 329, 344 (1998).

<sup>34</sup> *Alliance For Bio-Integrity v. Donna Shalala*, 116 F. Supp. 2d 166, 177 (D.D.C. 2000)

<sup>35</sup> See 62 Fed. Reg. at 18939.

<sup>36</sup> See 62 Fed. Reg. at 18942.

<sup>37</sup> See 62 Fed. Reg. at 18939.

ognition.<sup>38</sup> Therefore, to establish such recognition, a manufacturer sponsoring the use of the substance bears the burden to show that the substance is GRAS.<sup>39</sup> Under the 1958 amendment, if a substance is GRAS for a particular use, it may be marketed for that use without agency review and approval.<sup>40</sup> Furthermore, this statute applies to a “substance whenever the manufacturers or food processors know or should have known would become a component or otherwise affect the characteristics of any food.”<sup>41</sup>

In its original regulatory framework of food additives based on GRAS, the FDA defined “safe” to require “convincing evidence, which establishes with reasonable certainty that no harm will result.”<sup>42</sup> However, in 1971, this regulation was relaxed to require only the proof of, “no significant risk of harm.”<sup>43</sup> Currently, the FDA defines “safe” to mean “that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended use.”<sup>44</sup> Nonetheless, on May 29, 1992, the FDA published a statement of policy,<sup>45</sup> announcing that the Agency would presume that foods produced through the recombinant deoxyribonucleic acid (rDNA) process were GRAS under the FD&C, and therefore, not subject to regulation as food additives.<sup>46</sup> The statutory definition of “food additive” makes it clear that it is the intended or expected introduction of a substance into food that makes the substance potentially subject to food additive regulation.<sup>47</sup> Thus, the encoded genetic materials and the expressed product or products derived from new plant varieties should be subject to food additive regulation, if such material or ex-

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<sup>38</sup> See *id.*

<sup>39</sup> See *id.*

<sup>40</sup> See *id.*

<sup>41</sup> Lars & Merrill, *supra* note 33, at 340.

<sup>42</sup> See 62 Fed. Reg. at 18944. See also Lar & Merrill, *supra*, note 33 at 388.

<sup>43</sup> Lars Noah & Richard A. Merrill, *supra* note 33, at 388.

<sup>44</sup> *Id.*

<sup>45</sup> See 57 Fed. Reg. 22984. (Summary: Food and Drug Administration is issuing a policy statement on foods derived from new plant varieties, including plants developed by recombinant deoxyribonucleic acid(DNA) technique. The policy statement is a clarification of the FDA's interpretation of the Federal Food, Drug, and Cosmetics Act, with respect to new technologies to produce foods, and reflects the FDA's current judgment based on new plant varieties now under development in agricultural research. This action was taken to ensure that relevant scientific, safety, and regulatory issues are resolved prior to the introduction of such products into the market).

<sup>46</sup> See 57 Fed. Reg. 22984.

<sup>47</sup> See *id.*

pressed product is not GRAS.<sup>48</sup>

## II. REACTIONS TO THE FDA'S POLICY STATEMENT

This FDA's Policy Statement was challenged in court by a group of concerned activists seeking greater federal regulation of genetically modified food.<sup>49</sup> The challenge was premised on the fear that these new breeds of genetically modified foods could contain unexpected toxins and allergens, and the existence of some religious prohibitions against the consumption of foods produced through rDNA technology.<sup>50</sup> The summary dismissal of this case upheld the FDA Policy Statement on the basis that the FDA was not arbitrary and capricious in its finding that genetically modified foods need not be labeled because they do not differ "materially" from non-modified foods.<sup>51</sup> Similarly in 1986, a non-profit organization brought suit in court, seeking to have the Coordinated Framework for Regulation of Biotechnology issued by the Office of Science and Technology Policy declared illegal and enjoined its operation.<sup>52</sup> The organization was also concerned with the various implications of certain technological developments involving biochemical and genetic engineering which it believed might adversely affect the environment and ultimately human and animal

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<sup>48</sup> *See id.*

<sup>49</sup> *Alliance For Bio-Integrity v. Donna Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000).

<sup>50</sup> *Id.* at p. 170.

<sup>51</sup> *Id.* at p. 181 (explaining that the Court dismissed the plaintiff's motion for summary judgment on the grounds that the FDA's 1992 Policy Statement did not violate the Administrative Procedure Act, the National Environmental Policy Act, or the procedures mandated by the FDCA and FDA regulations. It further held that the FDA was not arbitrary and capricious in its finding that genetically modified foods need not be labeled because they do not differ materially from non-modified foods under 21 U.S.C. §321(n). Similarly, the court found that the statement did not violate the first Amendment Free Exercise Clause or RFRA, 42 U.S.C. § 2000bb-1(b)).

<sup>52</sup> *Foundation On Economic Trends v. Johnson*, 661 F. Supp. 107, 108-109 (D.D.C. 1986) (explaining that the Framework was developed by the following Agencies, National Science Foundation, Department of Agriculture, Occupational Safety and Health Administration, Food and Drug Administration, National Institute of Health, and Environmental Protection Agency due to the confusion, controversy, indecision and delay in developing a coordinated approach to the regulatory issues that may arise from the introduction of genetically modified product into the environment. It was partly in recognition of this situation that the Agencies created the elaborate set of biotechnological definitions included in the Framework, in aid of communication, research project development and regulatory planning. However, the Plaintiffs asserted in part, that the definitions are incomplete and inexact, and thus will allow potentially dangerous genetically engineered products to be ignored or too casually regulated).

health.<sup>53</sup> This particular case was summarily dismissed on the basis that the plaintiffs did not meet the requirements of causation, redressability, and ripeness, and thus had no standing.<sup>54</sup> Also, a private organization which advocates limits on genetic engineering brought a suit seeking a ban on all releases of genetically engineered pesticides until the EPA has promulgated regulations requiring such persons to document their financial capability to “redress and abate any potential harms that may result from such releases.”<sup>55</sup> This case was dismissed because plaintiffs lacked standing to sue under Article III’s case and controversy requirement<sup>56</sup> and the ability to prove facts sufficient to show ripeness.<sup>57</sup> These cases represent the public’s position on the introduction of genetically engineered foods into commerce.<sup>58</sup>

### III. BT TOXIN FOUND IN TACO SHELL

Currently, a plaintiff group has filed a class action suit against Kraft Foods Inc., alleging that the company recklessly marketed and sold taco shells containing genetically engineered corn not approved for human consumption.<sup>59</sup> The group further alleged that the EPA’s current assessment of the allergenicity of the Bt Cry9C protein produced a preliminary result, which indicates the protein is heat stable and resistant to degradation in gastric juice.<sup>60</sup> These represent two strong characteristics of proteins that are food allergens.<sup>61</sup> The lawsuit indicated that at least one individual suffered severe abdominal cramping, headaches, and hives after eating the taco shells.<sup>62</sup> Furthermore, they claimed the doctor treating the individual attributed the illness to a severe allergic reaction.<sup>63</sup> Similarly, a class action suit was filed on behalf of Iowa farmers seeking recovery of economic losses resulting from the introduction of Aventis CropScience’s genetically engineered

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<sup>53</sup> *Id.* at 108.

<sup>54</sup> *Id.* at 110.

<sup>55</sup> *Foundation on Economic Trends v. Thomas*, 661 F. Supp. 713, 714 (D.D.C. 1986).

<sup>56</sup> *Id.* at 719.

<sup>57</sup> *Id.*

<sup>58</sup> *Alliance For Bio-Integrity v. Donna Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000).

<sup>59</sup> Michael Bologna, *Biotechnology: Class Action Filed Over Taco Shells Containing Genetically Engineered Corn*, BNA TOXIC LAW DAILY, October 19, 2000.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

corn into the market.<sup>64</sup> The lawsuit included farmers who did not grow Aventis's Starlink(TM) corn, but suffered significant economic losses as a result of public mistrust of corn grown in this country.<sup>65</sup> This mistrust was due to the detection of StarLink corn in the U.S. food supply, even though StarLink corn has not been approved for human consumption.<sup>66</sup> Aventis has asked EPA to cancel its registration of the product and has established a program to compensate growers and elevator owners for their losses.<sup>67</sup> In the same vein, Kraft Foods has recalled about three million boxes of tainted Taco Bell Home Originals, but maintains that the tainted taco shells do not pose a health threat.<sup>68</sup> The outcome of these two cases may lead to more stringent regulation by the FDA or a special legislative enactment by Congress that would address the potential health risks of genetically modified foods. Because of the current problems, people are concerned about the potential health risks posed by genetically modified foods. If nothing is done to change the public's perception, there may be a plethora of lawsuits filed as concerns over genetically engineered foods mount.<sup>69</sup>

#### IV. SUPPORT FOR A GENETICALLY ENGINEERED FOOD SAFETY ACT

One function of government is the regulation of technology in the interest of health, safety, and environmental protection.<sup>70</sup> Some effects of new technology "are visible and dramatic, but many are delayed and uncertain."<sup>71</sup> Therefore, an "assessment of such risk and the design of strategies to reduce them require the use of scientific and technical information."<sup>72</sup> There is a need to standardize and provide a guideline on the safety of foods, food products, and food additives because unlike medicine and medical devices, food ingredients are likely to be consumed by all segments of the population including children and the elderly, potentially for their entire lifetime.<sup>73</sup> Consumer advo-

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<sup>64</sup> Andrew M. Ballard, *Biotechnology: Farmers Sue Aventis Over Losses Incurred By Public Mistrust of GM Corn*, BNA TOXICS LAW DAILY, February 8, 2001; *See also*, *Sutter v. Aventis CropScience USA Holding Inc.*, 145 F. Supp. 2d. 1050, 1052 (2001).

<sup>65</sup> *See Ballard*, 145 F. Supp. 2d 1050.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> Bologna, *supra* note 59.

<sup>69</sup> *Id.*

<sup>70</sup> BARBOUR, IAN, *ETHICS IN AN AGE OF TECHNOLOGY: THE GIFFORD LECTURES* 214 (1st ed. 1993).

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> Lars & Merrill, *supra* note 33, at 387.

cates, some scientists, and members of Congress who are fearful of the environmental and health risks of genetically modified foods, premised their fear on the potential long-term effects of this new technology. To this effect, the Honorable John D. Dingell of Michigan while speaking on the environmental risks associated with biotechnology, acknowledged the need for more research into the transfer of genetic information between species of microorganisms utilized in food modification.<sup>74</sup> He also indicated the need for more studies on the role of genetic drift in evolution and adaptation.<sup>75</sup> These findings on the risks associated with the release of genetically engineered products were made public at the Ecologists' and Evolutionary Biologists' Workshop. The participants in this workshop unanimously determined that "products of biotechnology pose problems different from those of nonliving substances that are released into the environment because genetic materials have the capacity to replicate and these new organisms can increase in numbers and spread into new areas."<sup>76</sup> They also found that genetic materials developed to produce beneficial effects could be transmitted to other organisms by plasmids and viruses where they could produce adverse effects.<sup>77</sup> Similarly, Honorable Dennis J. Kucinich sponsored a bill to amend the FD&C with respect to the safety of genetically engineered foods.<sup>78</sup> This was based on the congressional finding that "genetic engineering is an artificial gene transfer process wholly different from traditional breeding," and that "genetically engineered foods present new issues of safety that have not been adequately studied."<sup>79</sup> He further observed that "federal agencies have failed to uphold the congressional intent of the Food Additives amendment of 1958 by allowing genetically engineered foods to be marketed, sold and otherwise used without requiring pre-market safety testing to address their unique characteristics."<sup>80</sup> The proposed amendment requires that genetically modified foods be regulated under the Food Additives amendment Act.<sup>81</sup> The proposed amendment requires that a petitioner re-

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<sup>74</sup> *Subcommittee on Oversight and Investigations: U.S. Ecologists and Evolutionary Biologists Look at the Environmental Risks Associated with Biotechnology*, 131 Cong. Rec. E 533 (1985) (statement of Hon. John D. Dingell of Michigan).

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> Genetically Engineered Food Safety Act, H. R. 3883, 106th Cong. 2nd Sess. (proposed March 9, 2000).

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

questing to introduce a product into commerce show the allergenic effect of any new protein, including a protein not naturally found in the food supply.<sup>82</sup> Another important addition to the FD&C includes an analysis for the presence of new toxins or an increased level of existing toxins.<sup>83</sup> The amendment allows the secretary to deny a petition for approval if the petitioner "fails to include full reports of investigations that used serum or skin tests (or other advanced techniques) on a sensitive population to determine whether such additive is commonly or severely allergenic."<sup>84</sup> Similarly, the secretary may not establish a regulation to approve for consumption, if a fair evaluation of the record submitted by the petitioner showed that selective markers (the additives) would remain in the food products when the food is marketed.<sup>85</sup> In the same vein, no regulation may be issued if the selective markers are found to inhibit the function of one or more antibiotics.<sup>86</sup> Finally, the amendment provides that any person engaging in the violation of the provision will be liable to the United States for a civil penalty in an amount not to exceed \$100,000.00 for each violation.<sup>87</sup> Hence, these legislators recognize that the 1958 Food Additives amendment is inadequate to ensure the safety of the food products from the genetically modified plant.

#### V. THE BASIC TECHNIQUES FOR GENETIC MODIFICATION AND ITS IMPLICATIONS

The question is whether the fear expressed by concerned members of the public is speculative. This question invites the need to take a closer look at the technique employed to effect genetic modification. Biotechnology, which began in the 1970s with the development of the recombinant deoxyribonucleic acid (rDNA) technique, beckoned in the modern genetic modification of food crops.<sup>88</sup> The technique requires that genetic engineers isolate the genetic and chemical basis of the quality they want the new plant to have.<sup>89</sup> Following the isolation, the scientist will use one of several complex methods to inject the foreign

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<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> Howard J. Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD DRUG L.J. 105, 106 (2000).

<sup>89</sup> Kolehmainen, *supra* note 8, at 270.

materials into the new plant.<sup>90</sup> This process is required to be specific, such that genetic materials will be inserted into the appropriate spot in order to aid functioning at the right time, in the appropriate sequence of development and level of expression, and without affecting any other processes of the living plant.<sup>91</sup> The advantage of the rDNA technique over the more conventional method of crossbreeding is that it allows rapid production of the precisely desired genetic combination.<sup>92</sup> The successful combination of the genetic material may result in the expression of proteins foreign to the recipient plant.<sup>93</sup> For instance, the gene derived from the bacteria *Bacillus thuringiensis* (Bt), when successfully inserted and expressed by a particular plant, induces the production of Bt toxin, a complex protein entirely foreign to the plant.<sup>94</sup> Also, genes that express antibiotic resistance and those that block or produce toxins can transfer their characteristics to the plant, these toxins and enzymes permeate the entire plant cells.<sup>95</sup> Consumers are concerned about how these toxins and enzymes could affect raw agricultural products because the sequences of the cloned toxin gene may modify the natural toxins.<sup>96</sup> Consumers are also concerned about any secondary effects of these toxins and enzymes, such as the inadvertent transfer of antibiotic resistance to dormant genes in the environment or in humans. Any possibility of this happening should be of grave concern to the medical community. Therefore, extensive research should be carried out in this area.

#### VI. CONFLICT AMONG EXPERTS REGARDING THE SAFETY OF THESE NEW FOOD PRODUCTS

The concern for the uncertainty of the health risks of genetically modified foods could be intensified by the conflicting information available on the issue. In 1999, scientists at Cornell University showed that monarch butterfly caterpillars could be killed if fed with milkweed

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<sup>90</sup> *Id.* at 271.

<sup>91</sup> *Id.* at 270.

<sup>92</sup> Beales, *supra* note 88, at 106.

<sup>93</sup> *Id.*

<sup>94</sup> *Allergens: Uncertainty About Allergic Responses To Bio-engineered Crops Debated at Meeting* (A Report by an advisory panel to the Environmental Protection Agency) TOXIC LAW DAILY, April 6, 2001.

<sup>95</sup> *Regulatory concern rises over food from genetically engineered plants*, BIOTECHNOLOGY NEWSWATCH, May 15, 1989, at 7.

<sup>96</sup> John Beringer, *Keeping Watch Over Genetically Modified Foods*, THE LANCET, February 20, 1999, at 605-606.

dusted with pollen from Bt engineered corn.<sup>97</sup> Furthermore, a study at Iowa State University showed that pollen levels normally observed on the leaves in and near cornfields could produce similar toxic effects.<sup>98</sup> However, the research's overall conclusion is that with the exception of corn with particularly high levels of the toxin in its pollen, caterpillars are not likely to be exposed to levels of pollen high enough to be harmful.<sup>99</sup> The papers also claim that the corn with high toxin in its pollen is being phased out. Based on the above, the Japanese Department of Agriculture, Forestry and Fisheries decided to revise the safety assessment guidelines for genetically engineered corn.<sup>100</sup> This new inspection guideline includes a requirement to check the amount of Bt corn pollen dispersed and measure the amount of harmful substances the pollen contains.<sup>101</sup>

On the other hand, new studies on the impact of genetically engineered corn on monarch butterflies shows that the corn has virtually no effect on these butterflies and claims that the earlier studies could have been flawed.<sup>102</sup> The studies claim that the pollen used in those early experiments appeared to be mixed with other parts of the genetically modified plants, and that it was those plant parts, not the pollen, that actually killed the caterpillars.<sup>103</sup> In 1995, before the approval of the first Bt corn, the Department of Agriculture conducted an environmental assessment which analyzed the data on the risks to insects beneficial to agriculture and other non-target insects, bobwhite quail, and certain species of butterflies.<sup>104</sup> The assessment also included tests to find out if endangered aquatic organisms were threatened when Bt corn pollen is blown into water.<sup>105</sup> The Department of Agriculture concluded that the data showed no significant potential to adversely affect organisms other than the targeted pests that destroy corn.<sup>106</sup> However, the finding of Bt toxin in taco shells marketed by Kraft Foods has

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<sup>97</sup> Andrew Pollack, *New Research Fuels Debate Over Genetic Food Altering*, N. Y. TIMES, September 9, 2001, at 25.

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> *Safety Rules For Modified Corn Revised*, THE YOMIURI SHIMBUN/DAILY YOMIURI, March 16, 2000.

<sup>101</sup> *Id.*

<sup>102</sup> Pollack, *supra* note 97.

<sup>103</sup> *Id.*

<sup>104</sup> Carl B. Fielbaum, *Health Risks of genetically Modified Foods*, THE LANCET, July 3, 1999 at 70.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

been of concern to consumers and farmers alike.<sup>107</sup> This conflicting information does not help consumer advocates and the public dispel their fears about the potential health risks of genetically modified foods, hence the need for unbiased research into this important technology.

Consumers' concern about genetically modified crops and foods derived from them stems from anxiety over the use of antibiotic-resistant genes in genetically modified plants as a marker of genetic transformation. For instance, the kanamycin resistance gene specifies the information for the production of the enzyme, aminoglycoside 3'-phosphotransferase II.<sup>108</sup> This enzyme modifies aminoglycoside antibiotic, which includes kanamycin, neomycin, and gentamicin, chemically inactivating the antibiotics and rendering the cells that produce the kanamycin resistant gene resistant to the antibiotic.<sup>109</sup> The importance of using this enzyme in genetic modification techniques is that plant cells that have received and expressed the kanamycin resistant gene survive and replicate on laboratory media in the presence of the antibiotic kanamycin.<sup>110</sup> While those that did not take up and express the resistant gene are killed by the antibiotic.<sup>111</sup> Therefore, by linking the selectable marker gene that specifies a desired trait, scientists can identify and select plants that have taken up the desired characteristics.<sup>112</sup> However, while the kanamycin gene is an important research tool, both the kanamycin resistant gene and its product, the kanamycin phosphotransferase II enzyme protein, are expected to be present in foods derived from such plants unless removed by some new technique.<sup>113</sup> Another major health risk concern is that associated with the use of "viral promoters" to help activate the foreign genes once they are inserted into the recipient plant.<sup>114</sup> Virtually all genetically engineered plants contain a viral promoter from cauliflower mosaic virus (CMV) to necessitate the initiation of protein expression in the recipient plant.<sup>115</sup> These viral promoters constitute a health risk because they can promote the expression of not only the inserted foreign genes, but

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<sup>107</sup> Bologna, *supra* note 59.

<sup>108</sup> See 57 Fed. Reg. 22984.

<sup>109</sup> See *id.*

<sup>110</sup> See *id.*

<sup>111</sup> See *id.*

<sup>112</sup> See *id.*

<sup>113</sup> See *id.*

<sup>114</sup> Kolehmainen, *supra* note 8, at 289-279.

<sup>115</sup> *Id.*

also of other genes within the recipient plant.<sup>116</sup> The fear is that this inappropriate over-expression of genes may result in cancer.<sup>117</sup> In addition, research has shown that plants genetically engineered for viral resistance could transfer genetic materials to other plant viruses, resulting in the formation of new plant pathogens.<sup>118</sup> In the study conducted at the Michigan State University, a genetically engineered modification of the plant *Nicotiana benthamiana* was performed by incorporating Cowpea Chlorotic Mottle Virus (CCMV) into the plant.<sup>119</sup> This experiment created viral mutants of the CCMV that lacked one-third of the protein coat gene because the genetically modified plant retained two-thirds of the virus' coat protein gene.<sup>120</sup> This new virus showed the ability to replicate inside the plant, but could not systematically infect it.<sup>121</sup> However, when individual plants were inoculated with the mutant virus, four of the 125 plants became systematically infected with the virus.<sup>122</sup> The researchers then concluded that the recombination of the viral protein coat could occur, thereby allowing the restoration of the complete protein coat gene and a return to systemic infectivity.<sup>123</sup> Hence, there is a fear of possible transfer of bacterial resistant genes and viral promoter genes to other organisms, resulting in the formation of new pathogens that may affect plants as well as humans.

Many scientists and consumer groups suspect the possibility that allergy-provoking genes can be transferred from one food to another. Such transfer was observed when a genetic material from Brazil nuts was added to soybeans to boost the beans' "nutritional" profile.<sup>124</sup> In a series of experiments performed by researchers from the University of Nebraska, they found that when they mix blood samples collected from people allergic to Brazil nuts with protein extracts from genetically engineered soybeans produced a severe allergic reaction.<sup>125</sup> This reaction is similar to that obtained when Brazil nut extract reacts with

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<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Can Viral Genes Be Transferred?*, APPLIED GENETICS NEWS, April, 1994.

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Genetically Altered States; Transfer of Allergy-Causing Agents Between Genetically Engineered Products*, TUFTS UNIVERSITY DIET & NUTRITION LETTER, May 1996, at 1.

<sup>125</sup> *Id.*

serum of individuals who are allergic to Brazil nuts.<sup>126</sup> Conversely, extracts from regular soybeans did not prompt any allergic response.<sup>127</sup> When the researchers performed skin-prick tests on people who are allergic to Brazil nuts; they displayed similar reactions to the new soybeans but not to the regular beans.<sup>128</sup> This led the researchers to conclude that the allergen in the Brazil nuts was transferred to the genetically altered soybeans.<sup>129</sup> Consequently, the manufacturers decided not to market the product to avoid the risk of accidentally mixing the new beans with regular soybeans.<sup>130</sup> This finding raises concern among consumers because the FDA protocol only applies to situations where companies are dealing with foods known to provoke allergic reactions and not to the unknown genetically altered food crops.<sup>131</sup>

#### VII. THE ADEQUACY OF CURRENT RISK ASSESSMENT FOR GENETICALLY MODIFIED FOODS

The risk assessment of genetically modified foods must be based on assessing the effect of these new products on the health of humans, animals, and plants. The area of concern is the adequacy of existing test methods and strategies for assessing the safety of genetically modified foods. Currently the FDA's guidelines on risk assessment for genetically modified foods are consistent with the concept of substantial equivalence which was developed by the Organization for Economic Cooperation and Development (OECD).<sup>132</sup> Substantial equivalence is based on the comparison of the phenotypic and compositional characteristics of the parent crop and the genetically modified crop.<sup>133</sup> The Food and Agriculture Organization, in conjunction with the World Health Organization (FAO/WHO), considered the safety assessment of the genetically modified foods under three categories:<sup>134</sup> (i) genetically modified crops that have the same composition as the parent crop, (ii) genetically modified crops that have the same composition as the par-

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<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.*

<sup>132</sup> See 62 Fed. Reg. 18945.

<sup>133</sup> Martens MA, *Safety Evaluation of Genetically Modified Foods*, INT. ARCH. OCUP. ENVIRON. HEALTH, June, 2000, at S14-8.

<sup>134</sup> *Id.*

ent crop with the exception of a well defined trait, and (iii) genetically modified crops that are different from the parent crop. The risk assessment of the first category only involves the molecular characterization<sup>135</sup> of the inserted genetic material, while the second category requires molecular characterization and assessment of the expressed protein.<sup>136</sup> However, the assessment of the last category is more extensive. It includes the evaluation of the molecular characterization, bio-availability, wholesomeness, and safety of the expressed proteins and their product.<sup>137</sup>

Under the substantial equivalence concept, toxicology analysis is performed by in-vitro analysis of the expressed proteins.<sup>138</sup> These proteins are assessed by their homology with known protein toxins, degradation in the gastrointestinal tracts, stability to food processing, and acute toxicity in rodents.<sup>139</sup> "The possible allergenicity of the expressed proteins are evaluated by comparing their amino acid sequence with that of known allergens and determination of their stability to digestion and food processing."<sup>140</sup> Finally, "if the source of the genetic insert is allergenic then the use of solid state immunoassay, skin prick tests, and even food challenge tests may be considered."<sup>141</sup> Furthermore, a substantial equivalence determination includes factors such as the type of food processing the food may undergo, the intended use of the food or food products, and the food's intended exposure.<sup>142</sup> This risk assessment standard embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner as its previously existing counterpart in terms of safety.<sup>143</sup>

Currently, critics argue that the substantial equivalent standard is inadequate for assessing the health risks posed by the second generation of genetically modified products.<sup>144</sup> Because the concept of substantial

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<sup>135</sup> *Id.* The molecular characterization of the genetic material includes the determination of the position, nature, stability, and the number of copies of the inserted DNA.

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> David L. Devernoe, *Note: Substantial Equivalence: A valid International Sanitary and Phytosanitary Risk Assessment Objectives for Genetically Modified Foods*, 51 CASE W. RES. 257 (2000).

<sup>143</sup> *Id.*

<sup>144</sup> Harry A. Kuiper, *Adequacy of methods for testing the safety of genetically modified foods*, THE LANCET, October 16, 1999, at 1315-1316.

equivalence entails the comparison of expressed protein only with known toxins, critics contend it should be replaced with a more practical approach that will actively investigate the safety and toxicity of all of these new proteins.<sup>145</sup> Risk assessment may be adjusted for the "second generation" of food plants that are modified to improve food-quality traits, increase the nutritional value of the protein, increase the concentration of novel carbohydrates, or to fortify foods with micronutrients or antioxidants.<sup>146</sup>

In the same vein, the critics propose that particular attention must be directed toward the detection and characterization of unintended effects of genetic modification because inferences of such effects can no longer be based solely on chemical analysis of single macronutrients, micronutrients, and known crop-specific antinutrients or toxins.<sup>147</sup> Since new methods have been developed to screen for potential alteration in the metabolism of modified organisms, "such as the analysis of gene expression by overall protein analysis, and by secondary metabolite profiling," risk assessment must encompass these new methods.<sup>148</sup> Further toxicological and nutritional studies may be needed depending on the outcome of the above studies.<sup>149</sup>

#### VIII. INADEQUACY OF THE 1958 REGULATORY FRAMEWORK

The present issue is whether the regulatory framework for foods and ingredients established before the advent of today's new technologies is adequate for ensuring the safety of the genetically modified foods. The 1992 FDA Policy Statement provides that genetically modified foods are generally recognized as safe (GRAS) and exempted from the FDA's pre-market review.<sup>150</sup> This policy grants the industry the power to self-regulate their activities because the FDA only relies on a voluntary, informal consultation process to regulate the genetically modified foods.<sup>151</sup> Furthermore, the FDA maintains that it does not know of any company that has failed to complete the consultation process before introducing a genetically modified crop into the marketplace.<sup>152</sup>

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<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> See Kuiper, *supra* note 144.

<sup>149</sup> *Id.*

<sup>150</sup> See 57 Fed. Reg. 22984.

<sup>151</sup> Lisa Seachrist, *FDA Continues Consideration of Genetically Modified Foods 1*, BIOWORLD TODAY, December 1, 1999.

<sup>152</sup> *Id.*

However, critics disagree with the FDA's position and claim the Agency has no way of knowing whether companies comply with the consultation requirement because of its voluntary nature.<sup>153</sup> One of the critics, the Director of the Food Policy Research Institute, observed that the mandatory system of regulation does not cost industries much money, and could even offer rewards in increasing public confidence in the process.<sup>154</sup> Similarly, the Executive Director of the Alliance for Bio-Integrity called for a more rigorous approval process<sup>155</sup> and for labeling all genetically modified foods, in addition to long-term animal and human feeding studies to ensure the products are safe before they reach the food supply.<sup>156</sup> These observations were made during public meetings held to provide the FDA with suggestions to bolster consumer confidence in biotechnology and provide greater understanding of how genetically modified foods are created, regulated, and labeled.<sup>157</sup> As a result of these public meetings, the FDA has now gone a step further from their 1992 stance, by proposing a new rule that will require biotechnology companies to notify the government before marketing modified foods and animal feeds.<sup>158</sup>

Although this new proposal for mandatory pre-market consultation by companies is applauded by various interest groups, some argue that there is a great need to educate the public about the science behind, and the benefits that will be achieved, through biotechnology.<sup>159</sup> They observed that to ensure that the public continues to support biotechnology, an educational effort must be put in place, through a co-operative effort among the business community, government, academia, and consumer groups.<sup>160</sup> The need for educating not only the consumers and investors from this country, but also those from abroad can never be overemphasized because no industry will survive without the support of venture capitalists.<sup>161</sup> The Bush administration has recognized a need for public education and science-based regulation and is determined to promote research by increasing the budget for the National

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<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

<sup>157</sup> Kim Coghill, *FDA Proposes Rules Requiring Notification On Genetically Modified Foods and Feeds*, BIOWORLD TODAY, January 18, 2001.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> Nuala Moran, *Bush On Videotape, Promises Broad-Based Biotech Support*, BIOWORLD TODAY, June 26, 2001.

Institute for Health.<sup>162</sup> The administration has also determined to “effectively engage with trading partners to win their acceptance of genetically modified foods.”<sup>163</sup> This is a move in the right direction because Japan has stated that mandatory safety testing will be required of all genetically modified crops coming into their country.<sup>164</sup> They also reported that non-genetically modified wheat would be replacing genetically modified corn and soybean in their food products.<sup>165</sup> Because Japan has been the single largest market for American corn producers,<sup>166</sup> the financial well-being of U.S. farmers may be jeopardized if their confidence in genetically modified food is not won.<sup>167</sup> Most importantly, it is not enough to declare a new technology safe and hope that the public will go along with it.<sup>168</sup> “If there is public concern over safety, the government and the scientific community must work together to address it.”<sup>169</sup> “The stakes are too great and public support is too vital to ignore.”<sup>170</sup> Furthermore, the scientific community and industry must realize that public perception will set the agenda for biotechnology regulation, research funding, and consumer support.<sup>171</sup> Therefore, science, industry, and legislators should work with the consumer to resolve these issues so that minimal risks will result from this important technology.<sup>172</sup>

## IX. CONCLUSION

Genetic modification of native crops to produce transgenic food products offers a great deal of benefit to farmers, manufacturers, and consumers alike. However, the casual handling of the potential health risks posed by the products of this technology is of major concern to

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<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> *Ag-BIO: Domestic Market Nixing Genetically Modified Food*, APPLIED GENETICS NEWS, May 1, 2000.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> Senator AL Gore, *The federal Biotechnology Policy: The Perils of Progress and The Risk of Uncertainty*, 20 U. MICH. J.L. REF. 965, 972 (1987). In his paper, the former vice president Al Gore, then a senator, urged the biotechnology industries to educate the people about the technology, and to not play down its risks in the hope that it will never materialize. He further observed that sooner or later an accident may happen, and it could devastate the industry if the public is unprepared and feels betrayed.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

consumers, both locally and abroad. The conflicting reports among scientists regarding the safety of this important technology and lack of effective public education helps fill the rumor mills with disjointed information that fuels fear in most consumers. Therefore, reinventing food regulations to meet the challenges of the new technology will require a critical assessment of the health risks of all protein expressed by the new plant varieties, so as to determine their GRAS status. Moreover, this will enable the regulatory agencies to design appropriate strategies to reduce the identified risks.

Most importantly, the government and the biotechnology industries should fund extensive and unbiased research into the health risks and benefits of the food products from the new plant variety. This will provide a reasonable basis for effective information for the constructive education of the public. Public education will in turn restore the confidence of the consumers in genetically modified foods. Finally, farmers and manufacturers may

down-play the need for extensive research into new technologies because of possible financial burdens. However, they stand to benefit immensely from the result if public confidence in genetically modified foods is restored.

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