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# Plant Breeding Technology Update

An historical review and comparison of two successful yet competing methods of plant breeding technology, both of which technically modify the genetic structure of plants, yet only one falls within the international community's definition of Genetically Modified. Authored by Mark Murphey Henry

Abundance. One word confirms that America is the most powerful force in the world community, home to the world's largest computer company and the largest agricultural companies. The American eagerness to become early adopters of technology gives Americans an overwhelming success in both business and agriculture advancements. From an agricultural perspective, this technology adoption is creating several international issues.

Recent surveys prove that the vast majority of Americans are not aware of the prevalence of genetically modified foods on the grocery store shelves because the FDA does not require a label for genetically modified foods ("GM"). Indeed, more than 70% of the processed foods served on America's tables contain

GM Crop components. However, as the world becomes a single commodity market, international tensions surrounding GM labeling issues squarely threaten American farmers' opportunity to export GM commodities. American scientists and farmers need to understand the international community's viewpoints in order to avoid a potential crisis over international markets prohibiting importation of GM food.

This brief article offers an historical perspective on the scientific advancements surrounding two types of plant technology, only one of which fits within an international definition of GM. The first technology critically analyzed is the gene insertion technology most

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closely associated with the products developed by Monsanto. The second technology does not readily insert foreign DNA into the plant genome; instead, the science concerns the TILLING scientific screening. TILLING is aligned with conventional plant breeding.

In order to provide overall perspective to these two different technologies, Section One is devoted to this historical perspective. Because the United States and international markets diverge on the requirements of GM food labeling, Section Two provides a societal context on the American consumer's lack of worry with the contents of a label on food. This stands in obvious contrast to the European market where citizens suffered through a massive Mad Cow epidemic of its meat supply. There is a reason for the American consumer's lack of worry; the United States does not affirmatively inform consumers of the existence of GM foods.

Section Three thus introduces the reader to U.S. administrative agencies responsible for oversight of GM foods and provides overview of the current labeling requirements for GM foods in the U.S. That is, because labels help dictate within the minds of consumers whether a food is safe for consumption, Section Three provides

the regulatory systems that explain why GM foods are not labeled in America.

So that scientists and farmers can plot a direction toward international exporting harmony, Section Four identifies the definition of GM for the international community as proclaimed by the Codex Alimentarius Commission (the "Codex"). It is with this definition that the agricultural community can identify relative risk associated with investing in technology that may ultimately be precluded from the international market.

Section Five ties the law to science by comparing two cutting edge methods of agricultural research technology in order to demonstrate how one form of scientific research falls within the Codex definition of GM and the other does not. This section describes in detail a current U.S. Patent relative to gene insertion technology in use today by Monsanto to establish exactly why Monsanto's Roundup Ready\* products unquestionably fall within the international community's definition of GM. In contrast to the Monsanto product is a rapidly growing company known as Anawah, Inc., self described as an alternative technology company that utilizes one or more sophisticated

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genetic screening mechanism to identify changes in plant genes. This second technology, known as the TILLING method, does not fit within any current definition of GM and, thus, products developed using this technology do not have immediate international marketing concerns.

### **SECTION ONE: Conventional plant breeding vs. Genetic Engineering**

For thousands of years agriculture evolved through the domestication of wild plants. Perhaps the best illustration is the evolution of corn (*zea mays*, or “maize”). The corn that is Iowa’s landscape traces its historical evolution back to a wild grass known as Teosinte. Native Americans domesticated and transformed Teosinte, a wild grass originally growing in Central America, into a plant that produced an edible harvest over several thousands of years. The process was relatively simple; Native Americans replanted only those Teosinte plants that demonstrated productivity and heartiness, thereby producing stronger and more productive crops.<sup>1</sup> Over these years, Native Americans had no formal scientific understanding of why these variations occurred naturally, much

less how to accelerate the process.

In 1865, Gregor Mendel published a paper that launched the body of science known today as modern genetics.<sup>2</sup> In his paper, Mendel explained how certain known plant characteristics, or “traits,” were predictably controlled by the dominant and recessive alleles associated with the genes of the respective parental plants.<sup>3</sup> Mendel is thus credited as the father of genetic research, and his research represents a brilliant design that introduced the scientific community to genetic traits. In his experiment, Mendel sought to control particular traits of peas that included the physical form of ripe seeds, differences in color of the seed, differences in the form of the ripe pods, and differences in color of unripe seed pods.

Mendel’s glimpse into the world of plant genetics gave scientists and plant breeders everything they needed to begin exploring the core scientific techniques of alternating cross-pollination and self-pollination, known today as “conventional plant breeding.”<sup>4</sup> In the early stages of development as a science, conventional plant breeding was limited only to those traits already present in nature. For example, the differences among the color of unripe seed pods was a function of naturally

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occurring genetic diversity. Plant breeders would search out plants from a number of different geographic locations in hope of finding plants of the same species expressing different seed color, form of ripe pods, and color of unripe seed pods.

The phenomenon of genetic variability explains why no two people are alike. In plants, genetic variability explains why two soybean plants differ in leaf size, flower color, and pod ripeness.<sup>5</sup> Genetic mutation drives genetic variability. Genetic mutation, whether occurring in nature or in a laboratory, is the random change to the sequence and physical arrangement of the genetic building blocks, and these changes occur within a gene or chromosome of an organism.<sup>6</sup> Cancer and Downs Syndrome are examples of deleterious genetic mutations, but there are many helpful genetic mutations.<sup>7</sup>

Genetic mutations occur randomly in nature and the true impact of that genetic mutation may be amplified or suppressed in the offspring by virtue of environmental pressures either in favor of or against the genetic mutation.<sup>8</sup> Using the corn plant as an example, a genetic mutation may create a stronger root system than its non-mutated corn plant counterpart.

The mutated corn with the stronger root system may thus be able to withstand environmental pressures more effectively. However, the mutation may not be fully appreciated until a severe environmental condition such as drought causes the non-mutated corn plant to perish while the mutated corn survives long enough to pass its beneficial genetic mutation into the next generation.

Genetic mutations that occur naturally are random events because the exact location of the genetic mutation is impossible to predict.<sup>9</sup> A mutation that confers a benefit to the organism is, in actuality, a tightly controlled event. There are at least two different types of overarching regulating mechanisms that control whether a genetic mutation will succeed, (1) internal genetic modulation and (2) external environmental pressure.<sup>10</sup> An organism's internal genetic modulation is what allows the organism to successfully survive a mutation and complete a life cycle. Following mutation, the overall integrity of the gene or chromosome must not be so fundamentally altered as to kill the organism. That is, in order for a mutation to confer a benefit to the organism, the overall internal genetic harmony must

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remain within normal tolerances for that organism. It is the corn plant's sophisticated internal regulatory modulating system that allowed it to survive for thousands of years. This genetic modulation keeps deleterious genetic mutations to a minimum. That is, if a genetic mutation were so drastic as to adversely impact the overall genetic health of the organism, then the mutation is not allowed to pass into the next generation because the organism cannot survive long enough to breed with other like organisms. If, however, the mutation confers benefit while at the same time not drastically disturbing the remaining genetic framework, then the mutation has at least the opportunity to transfer into the next generation.<sup>11</sup>

In the 1930s, a scientist named Muller discovered that the rate of genetic mutations can be accelerated or induced by treating an organism with ionizing radiation or with certain chemicals.<sup>12</sup> Following this discovery, scientists found several different ways to influence the rate of genetic mutation in plants by using X-rays, gamma rays, and chemicals known as "mutagens."<sup>13</sup> For nearly seventy (70) years, plant breeders have used mutagenesis to accelerate the rate at which genetic mutations to the crops were caused, identified and

subsequently incorporated into a consistent and stable plant variety. Essentially, scientific study using mutagens involved lots of hope on the part of the plant scientist that the exposure of the plant's germplasm to a particular mutagen or radioactive treatment would cause a phenotypic expression, known as an identifiable and useful genetic trait. While the use of mutagens in plant breeding constituted a substantial departure from the previous methods of randomly occurring natural mutations and conventional plant breeding, the broad use of mutagens was nevertheless viewed by the public without much skepticism or concern over public health.

In the 1970s, conventional plant breeding was again revolutionized as the scientific community began mapping genetic sequences of living organisms. Scientists used this mapping technique to navigate through genetic sequences to create a genetic roadmap of each plant. The next logical step is to use the roadmap to identify the genetic location of particular traits in plants. The use of mutagens and gene mapping are all part of "conventional plant breeding techniques" and that these techniques are accepted worldwide.<sup>14</sup>

In January 1983, three groups of

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scientists launched into an entirely different realm of genetic manipulation not previously believed possible. These groups combined genetic material from one organism with genetic material from another organism of an entirely different genetic classification. Bacteria genes were introduced into plants. Scientists used this technology to insert discrete portions of the genetic material derived from a bacteria into a plant in such a way so as to allow the subsequent generations to likewise contain the same bacterial genetic modification. The science was called “transgenics” and “genetic engineering.”

With this far-reaching scientific tool, plant breeders were completely liberated from traditional plant breeding science. Scientists could theoretically build to order certain traits into a plant. Likewise, using this technology in conjunction with gene mapping techniques, scientists could actually pinpoint where in the genetic sequence the bacterial genetic material was inserted. Early in this science, researchers believed that, for the first time in history, they were able to create one plant with all the useful genes from a wide variety of sources, including other plants, animals, bacteria, and fungi. This technology led to the practice known

today as “genetic engineering,” “bioengineering,” “genetically modified organism,” “living modified organism,” “genetic modification,” “GMO” or, for purposes of this article, “GM.”

Critics of GM science state that the insertion of genetic material from one organism to another is dangerous because the random insertion overrides all natural processes designed by nature to provide tolerances for acceptable genetic changes within a given organism’s genetic construct.<sup>15</sup> The label of “gene contamination” is used by critics of GM technology because studies reveal that the transgenic host has opportunity to breed with native species once released into the public, and the native population is thus irreversibly corrupted.<sup>16</sup>

### **SECTION TWO: The Public Perception of GM in America**

#### **American consumers lack knowledge about GM.**

An FDA consumer focus group found that consumers recognize GM as a new technology with tremendous upside, but that was the extent of most consumers’ knowledge. Over half of the food supply in the U.S. contains GM ingredients, but only

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fourteen percent (14%) of the population is aware of that fact; many people do not realize that they have consumed GM foods, and some consumers are disturbed at the lack of information regarding the ubiquity of GM food products.<sup>17</sup> According to at least one survey, consumers demand additional information on product labels regarding methods of crop production, including the use of chemicals and hybrid seed.<sup>18</sup> In a survey where consumers were asked if they thought GM foods were safe, half were unsure, and the other half was evenly split between safe and unsafe.<sup>19</sup> When the consumers were told that over half of our food came from GM sources, one in five consumers who answered that GM foods were unsafe retracted that answer, which leads to the conclusion that their real-life experiences minimized their ultimate concern for the safety of the GM products.<sup>20</sup>

### **The majority of Americans accept GM to be a safe and economic use of technology.**

People in the United States are more accepting of GM foods than in any other industrialized country, and citizens of developing countries are likewise supportive.<sup>21</sup> Leaders of the U.S. food industry embrace GM due to advantages such as increased yields

and greater nutritional value, and believe that GM foods will provide increasingly greater benefits to the industry itself in the future, especially when consumers realize the benefits of GM foods.<sup>22</sup> Farmers in America generally support the use of GM crops, including GM soybean, corn, canola and cotton crops that were introduced in the mid-1990's. As of 2003, U.S. farmers elected to plant GM crop seed for over eighty percent (80%) of soybeans, over seventy percent (70%) of cotton, and around forty percent (40%) of corn.<sup>23</sup>

In contrast, the discovery of Bovine Spongiform Encephalitis ("BSE") in foreign countries has led to an increased skepticism of processed foods in general, and it appears this caution extends to GM. Growers of organic foods are the most vocal opponents of GM. These organic producers attribute the rise in the sales of organic foods over the last decade to consumer wariness of GM.<sup>24</sup> Organic food proponents are concerned that traditional, non-modified seeds will become irreversibly contaminated by modified DNA.<sup>25</sup> Public concern over GM also exists due to ethical and emotional issues as GM relates to animals.<sup>26</sup> Consumers in European countries and Australia are extremely distrustful of GM foods and are

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closing their borders to GM food importation.<sup>27</sup>

### **History of GM products already released into the public.**

Today, GM foods account for greater than fifty percent (50%) of the foods on market shelves.<sup>28</sup> Other estimates predict that almost seventy percent (70%) of processed foods contain GM food components.<sup>29</sup> GM ingredients can be found in Frito-Lay Corn Chips, Kellogg's Corn Flakes, Quaker Chewy Granola Bars, Ball Park Franks, and Aunt Jemima Pancake mix.<sup>30</sup> The ingredients for these products come from approved GM crops, which include corn, cotton, potato, soybean, squash, and tomatoes.<sup>31</sup> An estimated 16% of corn and 63% of soybeans planted in the United States is GM.<sup>32</sup> Whether that GM corn is thereafter used to make high fructose corn syrup which is the staple sweetener to most products on grocery shelves today is not fully known.

Perhaps the most widely recognized failure of a GM product is the Starlink® corn affair, which occurred in 2000. Aventis CropScience inserted a pesticidal protein into corn that made Starlink® corn resistant to insects.<sup>33</sup> The Environmental Protection Agency certified Starlink® for industrial use and animal feed, but

not for human consumption.<sup>34</sup> Inevitably, the corn supply intended for human consumption became contaminated with Starlink®, and the discovery of Starlink® in food products ground the grain-handling infrastructure to a halt, requiring time-consuming testing of corn crops intended for human consumption. The sale of Starlink® to farmers without informing those farmers of restrictions against sale for human consumption of the crop compounded the problem.<sup>35</sup> The ramifications also included a depressed corn export market.<sup>36</sup> Iowa farmers filed a class-action lawsuit against Aventis seeking recovery for the damages caused to all corn farmers as a result of the contamination, and Aventis requested cancellation of its registration of Starlink® with the EPA.<sup>37</sup>

Other discontinued GM products include the FlavrSavr tomatoes, which were engineered to keep the tomatoes firm for a longer period of time than conventional tomatoes. The company producing the FlavrSavrs suffered from quality control problems and eventually discontinued the product.<sup>38</sup> A similar product, Zeneca tomato paste, was on the market for about three years but was discontinued due to the negative public perception of GM foods.<sup>39</sup>

Monsanto developed an insect and

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virus resistant potato dubbed NewLeaf that it marketed for five years. Several potential purchasers of the potatoes refused to buy them, and Monsanto discontinued the product line.<sup>40</sup> Bt 176 corn is possibly the only transgenic product to be discontinued due to its negative effect on the environment. The pollen of this GM corn is toxic to Monarch butterfly caterpillars.<sup>41</sup> Combined with the corn's poor late season insect resistance, the toxicity to caterpillars led to the discontinuation of Bt 176 corn in 2001.

DNA from GM crops has crossed over into, and is now found in, the majority of traditional seed supplies in the United States at levels of contamination estimated to be 0.05% to 1%.<sup>42</sup> This phenomenon, referred to as "pollen drift." Wind and insects carry the pollen from a GM crop to a conventional crop field and fertilize the conventional crop with the GM pollen. Pollen drift is a natural, expected event.

### **Should consumers demand increased regulation of GM foods?**

Based upon a variety of studies performed by the Food and Drug Administration, consumers have identified long-term effects on health as a main concern about GM foods.<sup>43</sup>

The FDA reports that the majority of consumers do not believe that the food industry adequately considers consumers' interests in making decisions about GM food, and that the adoption of GM crops mainly benefited those involved in the production and distribution of commodities.<sup>44</sup>

These surveys indicate that U.S. consumers dislike the inability to differentiate between conventional and GM foods, and they generally believe that GM foods should be labeled as such.<sup>45</sup> Based upon this evidence, consumers desire a choice in whether to purchase GM foods, and believe that if such foods are labeled then consumers can show their preference in the marketplace.<sup>46</sup> Consumers prefer labels that give them more information, such as why the food was genetically modified, *i.e.*, herbicide resistance, nutritional value, etc., but dismissed the idea of using a "warning label" on GM foods.<sup>47</sup> The studies and surveys discussed above demonstrate that the American public is generally unaware of the relative risks and benefits associated with GM crops.

The existing United States regulatory approach to GM is the reason why the American public has little idea of the prevalence of GM crops on the stores.

**SECTION THREE:  
The American regulatory approach to  
genetically modified foods.**

The U.S. Government agencies responsible for oversight of the products of agricultural modern biotechnology are the U.S.

Department of Agriculture's Animal and Plant Health Inspection (USDA-APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA). Depending on its characteristics, a GM food product may be subject to review by one or more of these agencies.<sup>48</sup> The Food Safety and Inspection Service, which is an agency under authority of the Assistant Secretary of Agriculture for Marketing and Inspection Services, is responsible for review of agricultural materials intended for food use.<sup>49</sup> Likewise, the FDA is involved for food labeling issues, and APHIS is involved when the microorganism involved is a plant pest, and animal pathogen, or a regulated article otherwise requires a permit.<sup>50</sup> Federal laws and regulations relating to control of agricultural inputs include the Federal Plant Pest Act, the Plant Quarantine Act, the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide,

and Rodenticide Act (FIFRA).

These three agencies essentially adopt the same core approach to GM: label or prohibit the GM crop only when it is proven unsafe. There is no affirmative approach in the existing regulatory system that requires GM products to be scientifically safe to eat.

**The Environmental Protection Agency ensures that GM crops intended to confer pest resistance do not adversely affect the environment.**

For purposes of review by the EPA, FIFRA defines a "pesticide" as (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer. If either a chemical or biological product falls within this definition, then it must be registered with the EPA.<sup>51</sup> An exception to FIFRA's registration requirement is for pesticides that the Administrator, under § 25(b) of FIFRA, has determined "to be of a character which is unnecessary to be subject to this Act."<sup>52</sup> These materials, known as "Minimum Risk Pesticides" are exempt from certain requirements of FIFRA, but may nonetheless still require special food tolerances if used

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on or around food, food crops, food contact surfaces, or animal feed.<sup>53</sup> Tolerances and exemptions for food are listed in Parts 180, 185, and 186 of Title 40 to the Code of Federal Regulations for each active ingredient and inert ingredient. Pesticides are exempted from the requirement of a tolerance in some cases because the pesticide is considered to be safe enough for use at any level.

The EPA regulates three major classes of biopesticides: biochemical pesticides, microbial pesticides, and plant-incorporated protectants (PIPs). Noting that “all plants produce some substances which act to repel insects or kill various pathogens such as bacteria and fungi,” the EPA published final rules exempting many PIPs from FIFRA requirements. Further, the EPA telegraphed its philosophy relative to PIPs by commenting how the use of PIPs greatly reduces the use of other organophosphate pesticides and thus reduces the introduction of other, more harmful toxic chemicals into the environment.<sup>54</sup>

The EPA maintains only a moderate level of scrutiny of PIPs by requiring certain data requirements for registration. These requirements require researchers to provide adequate product characterization, to implement satisfactory insect

resistance management practices, to conduct studies on mammalian toxicity, and to perform non-target organism hazard assessments. Several bioengineered plant products have received a Tolerance Exemption, meaning it is considered safe in food at any level.<sup>55</sup> The EPA also regulates certain GM technology under the Toxic Substances Control Act (TSCA).<sup>56</sup> Through TSCA, the EPA may potentially designate a GM product as a chemical and may possibly require safety data in the event of hazards or chemical exposures.<sup>57</sup>

The companies promoting the GM products have easily complied with the moderate level of EPA supervision, and many GM products already have Tolerance Exemptions, meaning they are safe in food at any level.

### **The United States Department of Agriculture ensures GM crops do not pose a threat to other aspects of the environment.**

The United States Department of Agriculture (USDA), acting through the Animal and Plant Health Inspection Service (APHIS), has authority under the Federal Plant Pest Act (FPPA) to determine whether a transgenic plant variety is likely to become a pest or have a

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negative agricultural or environmental effect by its introduction into the agricultural system.<sup>58</sup> While some GM crops may be grown in commercial quantities without APHIS's traditional notification process, APHIS generally performs an initial review prior to when the researcher imports, transports, or field tests a genetically modified plant if such plant is considered a "regulated article." A "regulated article" is any GM plant where a "plant pest" was involved in the modification process or where there is reason to believe the resulting GM Crop will be a plant pest. The term "plant pest" refers to insects, mites, bacteria, fungi, viruses, parasites or other substances capable of injuring plants.<sup>59</sup> Ordinarily though, as part of the notification process, a plant researcher may petition APHIS for non-regulated status. While the review by APHIS of these petitions for non-regulated status is not exhaustive, APHIS has authority to halt sale of crops where there is evidence that it is becoming a plant pest. Critics of the APHIS speak to the lack of resources available to the USDA in light of the dramatic increase in imports of perishable commodities and that APHIS has no authority to consider environmental risks such as risks to wildlife or ecosystems.<sup>60</sup> Participation

in this program is entirely voluntary. Few, if any GM crops have been termed a "plant pest." Furthermore, consumers do not see the products that are deemed a "plant pest," so this agency is not a solid source of potential GM labeling requirements.

### **The Food and Drug Administration ensures the safety and proper labeling of food.**

Under the Federal Food, Drug, and Cosmetics Act, the FDA has authority to determine the safety of foods or food additives and to set guidelines in the labeling of food.<sup>61</sup> Beginning in 1992, the FDA declared its optimism for biotechnology by claiming it would produce foods that are "tastier, more varied, more wholesome and that can be produced more efficiently."<sup>62</sup> Under current policy, foods from GM crops may legally go directly to market without pre-market approval from the FDA unless they fall within the definition of "food additives." In order for a GM crop to be considered a "food additive," the genetic modification must result in substances that significantly differ in structure, function or composition from substances currently found in the food supply.<sup>63</sup> Thus, when dealing with GM foods, the FDA only requires an affirmative label if the GM food has a significantly

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different nutritional property, includes an allergen that consumers would not expect to be present, or contains a toxic substance that is beyond acceptable limits. Genetically modified foods that are “substantially equivalent” to conventional counterparts are not subject to additional regulatory requirements or special labeling requirements.

In January 2001, the FDA signaled its scientific acceptance of bioengineering by proposing voluntary labeling guidance for foods developed using gene technology.<sup>64</sup> The FDA’s draft guidance was circulated for comment purposes only and binds no member in the GM food industry. Critically reviewed, the voluntary guidelines can be characterized as an opportunity for GM food producers to boast of the health reasons supporting the inclusion of bioengineered technology within their products.<sup>65</sup> Yet the voluntary guidelines do not serve to give the public notice of the fact that more than 70% of processed food on the grocery store shelves already contains genetically modified ingredients.<sup>66</sup> The FDA’s position appears to be much more in line with the corporate promoters to the technology instead of the U.S. consumers as recent surveys indicate that eighty percent (80%) of

consumers believe that all GM foods should be labeled.<sup>67</sup>

These voluntary guidelines do not help the organic farmers who wish to tout the non-GM nature of their products. The FDA expressly cautions against the use of the “GMO-FREE” label by stating that “[m]ost, if not all, cultivated food crops have been genetically modified,” (even naturally occurring genetic variance and mutation may nonetheless constitute a genetic modification.)<sup>68</sup>

The pre-marketing notification process used by the FDA to approve the use of genetically modified food is entirely voluntary. That is, researchers voluntarily provide to the FDA certain data relative to safety, nutrition, known toxicants, altered nutrient levels, new substances, and antibiotic resistance.<sup>69</sup> At the end of the review process, the FDA may notify the researcher whether the agency is satisfied with the data supplied by the researcher regarding food safety of the product. The FDA’s voluntary review process has been criticized due to its voluntary nature and because the FDA has no effective system of overseeing GM crops once released into the market.<sup>70</sup>

Approximately three years ago, the United States Government Accountability Office (GAO)

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reviewed the FDA's GM food safety procedures. The GAO issued a report that confirmed the FDA's process was adequate yet needing refinement.<sup>71</sup> The GAO observed that all foods pose inherent risks in the form of allergens and toxins, and the GAO concluded that these inherent risks were equal among GM foods and conventional foods.<sup>72</sup> The GAO report also acknowledges that various consumer groups, as well as some scientists from the European Union, have questioned the ethical or cultural appropriateness of genetically modifying foods but did not specifically identify nor address those complaints.

As described earlier in this article, the FDA's position relative to genetically modified foods has received criticism from the international community and is disharmonious with trends towards international views on GM food labeling. The American policy of not requiring labels on GM food differs not simply from undeveloped countries but also from other sophisticated trading countries including Japan and the European Union. Surprisingly, the FDA's guidelines on the labeling of organically grown products is premised upon international harmonization and makes express

reference to the Codex General Standard of the Labelling of Prepackaged Foods.<sup>73</sup> The stated goal behind the FDA's labeling requirements for purposes of sales of organic foods is to "provide international guidelines for organic food control systems in order to facilitate recognition of national systems as equivalent for the purposes of imports."<sup>74</sup>

As is more fully discussed below, the US government yields to the Codex on the issues surrounding proper labeling of organic foods, so it is appropriate to review the international weight given the Codex for purposes of forecasting the definition of GM as adopted by the international community at large in order to better determine what guidelines U.S. farmers may follow in the event foreign countries impose mandatory GM labeling requirements.

### **SECTION FOUR: The Codex Alimentarius Commission serves as an international source of definitions relative to international food labeling.**

The Codex Alimentarius Commission implements the Joint FAO/WHO Food Standards Programme, the purpose of which is to protect the health of consumers and to ensure

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fair practices in the food trade. The Codex Alimentarius is a collection of internationally adopted food standards presented in a uniform manner. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures to assist in achieving the purposes of the Codes Alimentarius.<sup>75</sup> Any formal publication by the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonization and, in doing so, to facilitate international trade.<sup>76</sup> The mission of the Codex is to create guidelines on food labeling that “facilitate the harmonization of requirements for organic products at the international level, and may also provide assistance to governments wishing to establish national regulations in this area.”<sup>77</sup>

**The Codex already establishes strict guidelines on organic food labeling.** Several years ago Codex published guidelines on the production and labeling of organically produced foods, and the guidelines offer a thorough statement of organic food production, preparation, inspection, certification, importing, labeling, and principles of production. The Codex organic labeling requirements apply to all unprocessed plants and plant products, including those processed plant products intended for human consumptions.<sup>78</sup> The requirements on labeling contain general provisions as well as specific requirements for products in transition from conventional to organic.<sup>79</sup> The Codex rules are specific enough such that, under Section 3.2, the labeling and claims of a product may refer to organic production only where the product was produced in accordance with a regimented guideline outlined in Annex 1 entitled “Principles of Organic Production.”<sup>80</sup> All tolled, there are ninety-one subparts to Annex 1 in which the Codex defines growing conditions of plants; handling of plant products; incorporation of fertilizer; authorization on types of microbes allowed for compost activation; identification of strict methodology in the control of pests; requirement to use untreated seeds;

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and the requirement to submit to a certifying agency. Not until an organic grower has passed each of these guidelines may she apply words to the product that “refer to organic production methods.”<sup>81</sup>

### **The Codex Committee on Food Labeling proposes a definition of Genetically Modified food that will influence future definitions of GM in the international community.**

In a Report to the Codex Alimentarius Commission in preparation for the Twenty-eighth Session occurring in Rome during July 2005, the Codex Committee on Food Labelling provided a “Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients (Para. 80, Appendix II).” In the current proposal, the Codex subcommittee adopts a highly specific definition of “Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering” to mean “food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained

through modern biotechnology.”<sup>82</sup> To complete the above definition, the Codex Committee also proposes the definition of “Genetically modified / engineered organism” to mean “an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.”<sup>83</sup> Lastly, the Codex proposes further definition of “Modern biotechnology” to mean the use of “in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome the natural physiological, reproductive or recombination barriers and that are not techniques in traditional breeding and selection.”<sup>84</sup>

According to the overall guidelines in this context, the definition of GM is intended to apply to the labeling of such food and food ingredients “when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology.”<sup>85</sup> While this standard is similar to the “substantial equivalent” phraseology in use today by the FDA, there is international pressure to implement a different strategy, one

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that could elevate the requirements for GM labeling. That is, the current labeling provisions do not stand as an express requirement by the international community to affirmatively require a label on all GM foods at this time. Instead, the Codex Committee on Food Labelling provides that the specific approach to labeling of food and food ingredients “could be used” in the event a food contains an allergen, may result in physiological disorders for certain sections of the population, or when other conditions are satisfied.<sup>86</sup> As recently as 2004, the Codex agreed that foods from GM crops have been evaluated according to existing procedures for risk assessment and have been deemed safe to eat.<sup>87</sup>

It is from this Codex GM definition that all future labeling requirements will most likely depend. Whether or not the Codex will adopt different labeling requirements is not a focus of this article; however, it is the understanding of the author that international pressure is in favor of mandatory labeling of GM foods.

### **SECTION FIVE:**

#### **A technology survey: Which scientific processes in use today may require a GM label if the Codex definition were mandated by the international community?**

In order to provide scientific context for the arguments and scientific positions swirling around the conventional vs. biotechnology debates, a few scientific definitions provide essential background. There are two main types of genetic structures referred to as nucleic acid, both deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). These are further composed of small subunits that are universally recognized and are often referred to by the single letter abbreviations A, C, G, T and U. DNA is composed of two long strings of nucleotides twisted around each other to form the spiral or helical structure. The twisted molecules are arranged in a particular manner, with specific nucleotides always found across from each other. The nucleotide containing adenine (A) always pairs with the nucleotide containing thymine (T). Likewise, guanine (G) always pairs with cytosine (C).

These core building blocks serve universally across all genetic boundaries, and the genetic variation as between plants and animals is

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really nothing more than a rearrangement of the core nucleotide sequences. In view of this fundamental commonality as between all things living, many scientists cannot fathom why there is any problem associated with commingling the gene sequences of plants, bacteria, viruses, and humans. After all, the only thing separating plants from animals is the length and sequencing of the core building blocks forming their respective DNA.

In laboratories around the world, herd of pigs are grown with partly human livers in the hopes of solving the organ-transplant shortage. Mice implanted with specialized cells are used for testing drugs or figuring out diseases afflicting humans.<sup>88</sup> Livestock could one day serve as a shopping selection for humans in need of tissue and organ transplants. In the future humans could walk the streets with pig kidneys just as there are human-to-human transplants of kidneys today.

In spite of all of the possible benefits, there are still ethical concerns. For example, the United States Patent Office refused a patent on a human-chimpanzee chimera, known as the “humanzee” in February, 2005.<sup>89</sup> These morality issues of scientific domination by humans is growing, not simply from

animal rights activists but also from ethicists and religious leaders. On March 17, 2005, Senator Sam Brownback (R-KS), introduced Senate Bill 659, entitled the Human Chimera Prohibition Act of 2005. The bill would prohibit any person from creating, or attempting to create a human chimera. A “human chimera” is broadly defined to include various methods of mixing non-human cells into human embryos. The bill includes both civil and criminal penalties.<sup>90</sup> Canada outlawed human chimeras due to the unknown possible consequences of bringing nonnative genetic material into the human genome. The same philosophy in outlawing human chimeras is likely a primary reason why the international community is questioning the long-term consequences of chimeric plants that are consumed, after all, by humans.

### **Two competing plant development technologies in view of the Codex definition of GM.**

Many different scientific techniques offer scientists various ways to bring new agricultural seed products to the marketplace. Whether or not the scientific technique will require a GM label depends upon the actual insertion of foreign genetic material into the host. For purposes of

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illustrating this key distinction, this article offers a comparison between competing plant technologies available to the scientific community.

Monsanto Company uses a first technology in connection with its Roundup Ready soybean in which a foreign bacterial genetic sequence is actually inserted into the soybean plant genome using a viral promoter. A growing company known as Anawah uses a second technology known as the TILLING method in which no foreign genetic sequences are inserted into the plant. Anawah relies upon induced mutation, which is more in line with conventional plant breeding techniques. Only Monsanto's use of gene insertion will trigger a GM label pursuant to the definition of GM by the Codex.

**Monsanto's use of the CaMV Promoter will require a label of GM by the Codex because it inserts foreign genetic material into the soybean genome.**

Through many years of lawsuits against farmers to enforce its patent rights, Monsanto Company became synonymous with biotechnology. Monsanto refers to its patented technology as "Roundup Ready." This technology involves the genetic engineering of plants to confer a survivability to a chemical that otherwise destroys plant tissue,

including weeds. That is, genetically engineered soybeans designed to survive a herbicide (Roundup\*) will live while the weeds perish. With this Roundup Ready\* technology, farmers conceivably save time and money cultivating the fields when compared to a traditional, conventional crop. The only thing physically capable of growing in the field is the soybean crop.

The Roundup Ready\* technology is described in U.S. Patent No. 5,352,605 (the '605 Patent), among others. The '605 Patent, captioned "Chimeric Genes for Transforming Plant Cells Using Viral Promoters" describes a "Chimera." This term is defined in botany as one single organism composed of two genetically different types of tissue.<sup>91</sup> In the '605 Patent, the inventors disclose how to "utilize promoter regions derived from viruses which are capable of infecting plant cells."<sup>92</sup> The main scientific advancement stems from the cauliflower mosaic virus promoter sequences (the CaMV Promoter), and today biotech scientists use this technology to incorporate genetic material into plants. The patent is filled with diagrams and discussion on how to cut apart the genetic sequences and how to infect a plant in order to permanently insert the two different CaMV promoter

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regions. The '605 Patent is lengthy, with twenty one (21) pages dedicated to discussion and diagrammatic illustration of two different genetic sequence insertions, the CaMV(19S) and the CaMV(35S) promoters. There is no mention to the words glyphosate or resistance to glyphosate. Instead, the patent refers to a petunia plant's genetically conferred resistance to kanamycin, an antibiotic that would otherwise destroy the plant but for the genetic modification.

The '605 Patent also mentions use of the promoter sequences in conjunction with bacterial plasmid hosts, so presumably Monsanto attempts to claim legal rights not to glyphosate resistance *per se*, but instead to the precursor tools necessary to the insertion of gene technology. That is, if the insertion of genetic material that confers resistance to glyphosate is utilized via the CaMV(19S) or the CaMV(35S) Promoter sequence technology, then Monsanto claims legal rights to such plant material. However, if the plant's resistance to glyphosate is conferred using different technology, then other companies can possibly compete. In view of recently published articles, it is clear that several companies including Stine Seeds, Inc. and Syngenta Seeds, Inc. actively search for glyphosate resistant soybeans that

fall beyond the legal claims of Monsanto's '605 Patent.<sup>93</sup> The patents recently issued to Stine Seed Farms, Inc. make no mention of the CaMV promoters.<sup>94</sup>

Gene insertion technology differs from conventional plant breeding in many ways. First, plants derived from gene insertion lack internal stability and consistency.<sup>95</sup> There may be a genome shift during the engineering process. In view of this random gene insertion, these plants do not have the native genetic modulation otherwise necessary to balance the effect of the insertion of the promoter sequences. That is, plants burdened with entirely separate gene sequences cannot accept such a drastic change using the existing framework of internal genetic modulation. Furthermore, the most radical problem of the genetic engineering of plants is in the technical difficulty of determining the location of the actual gene insertion into the plant's genetic sequence.<sup>96</sup> The random insertion of a foreign gene will affect various domestic gene activities, as inactivation of structural genes, promoters or enhancer sequences, all of which cause metabolic influences in the plant. The wholesale insertion of foreign bacterial or viral sequences into the plant's genetic structure is not an exact science, but this

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technology has undoubtedly revolutionized the American farming industry in the past ten (10) years.

**Anawah's use of their TILLING method, a high throughput targeted screening method for point induced mutations, will not require a label of GM by the Codex because it is most closely associated with conventional plant breeding.**

Anawah, Inc., a company self-described as a food and agricultural research and development company out of Seattle, Washington, is focusing intense effort at promoting a revolutionary way to capture mutations associated with plant breeding.<sup>97</sup> The technology is essentially a two part system, the first of which forces large volumes of plant genetic material to undergo point mutations.<sup>98</sup> The second component to the system is to quickly analyze each mutation using sensitive detection instruments to determine if the induced mutations will produce a plant with a desired commercial trait.<sup>99</sup> While the title to various papers and patent applications authored by Anawah, are lengthy and complex, the core technology is built upon conventional plant breeding technology as inspired by Muller in the 1930s through the use of mutagens to accelerate genetic

changes. Recall that in the 1970s, the plant breeding community used gene mapping to identify the location of the actual mutation.

One mutagen used by Anawah is ethyl methanesulfonate (EMS), which is a chemical mutagen that predictably forces C to T changes resulting in C/G to T/A transition mutations.<sup>100</sup> There is no reason to suggest that this list of chemical mutagens is limited to EMS. Once the plant genetic material is exposed to the mutagen, the plant's inherent genetic structure undergoes predictable changes, and the sequences are forcibly rearranged. The TILLING technology thus allows plant scientists to expose many thousands of individual plant genomes to a chemical mutagen and thereafter identify the extent and location of the induced mutations through a screening process.

TILLING methods literally permit a laboratory to induce millions of mutations and to identify and analyze each point mutation. The technology is built upon locus-to-phenotype reverse genetic screening.

Armed with comprehensive databases of the genetic code for a particular plant, scientists can identify genetic sequences that correspond to the phenotypic expression of a plant trait. Scientists using the TILLING

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method can quickly identify mutations that may have potential in the commercial marketplace. That is, when a genetic sequence has been associated with a certain trait, the functions of genes can be inferred using reverse genetic methods.<sup>101</sup> The instrument used in this process is described as a “sensitive mutation detection instrument.”<sup>102</sup> The scientific language surrounding this process is complex, but in essence the technology is reminiscent of a computer program designed to break a password or combination by testing every conceivable alpha-numeric combinations until one succeeds in producing a desired trait.

It appears only to be a matter of time before scientists will be able to forcibly mutate soybeans in such fashion as to form resistance to glyphosate herbicide in a manner that does not otherwise require a GM label.

### **Conclusion**

The American consumer remains in the dark as to the prevalence of GM foods on market store shelves because the United States, by and through its three different regulatory agencies, understands GM plants to be safe. Despite this staunch position by the United States regulatory agencies, early adopter agricultural

companies may wish to focus energy and study towards technology that does not fit within the predicted international definition of GM in the event foreign export markets increase requirements on GM labeling. The Codex is a solid source from which to predict the international community’s future viewpoints on GM food labeling, beginning first with the Codex definition of GM.

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