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Genetically Engineered Produce Travels North America Under NAFTA: An Issue Ripe For Consideration

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GENETICALLY ENGINEERED PRODUCE TRAVELS NORTH AMERICA UNDER NAFTA: AN ISSUE RIPE FOR CONSIDERATION

I. INTRODUCTION

If it is not nice to fool mother nature, then perhaps it verges on criminal to dissect and recombine the fruits of her labor under the guise of improving them. We have the technology. We can build a better tomato. We can make it bigger, redder, meatier, and tastier. Best of all, we can make it last longer.[1] The Six Million Dollar Man pales in comparison to our technology to rebuild produce.

This summer, Amelia bought several lovely looking nectarines at her local grocery. They were not yet ripe. With decided anticipation, she set them aside and awaited the moment of consumption.

Amelia checked the nectarines frequently. With each passing day, she contemplated the usual change in color and texture which would indicate that the long-awaited moment of consumption had finally arrived. Much to her dismay, the nectarines remained unchanged, hard and bitter to taste. They crunched like ripe apples when she bit into them. Amelia became despondent when, after two weeks, the nectarines cultivated mold before they even developed a soft spot. Alas, this fruit would never be fit for consumption.

Amelia was a bit bewildered. She briefly entertained the possibility that she had mistaken a new imported tropical fruit for the simple nectarine. Regrettably, the fruit were indeed nectarines. Amelia speculated that these particular nectarines might have been on steroids. Perhaps they were just supposed to stay fresh longer or look better longer.[2] All Amelia knew was that she had to throw away three large nectarines.

Unbeknownst to Amelia, the nectarines may have been a product of genetic engineering, the latest in a long line of endeavors we humans have undertaken to improve upon perfection. You too may have pumped-up produce lurking about your refrigerator or fruit bowl.

This Comment will explore genetically altered crops and produce. It will outline the potential for future regulation under the North American Free Trade Agreement pursuant to existing United States regulations and applicable international standards.[3]

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1. Monsanto Agricultural Co. has engineered a tomato that will remain firm and red 137 days after harvest. MAARTEN J. CHRISPEELS & DAVID E. SADAVA, PLANTS, GENES, AND AGRICULTURE 412 (1994).

2. They were lovely to look at and delightful to hold but the only thing ripe about these nectarines was the mold.

3. This Comment concentrates specifically on Chapter 7 of the North American Free Trade Agreement, Agriculture and Sanitary and Phytosanitary Measures. A comprehensive discussion of the North American Free Trade Agreement is beyond the scope of this Comment.

For a discussion of NAFTA pursuant to the framework of the General Agreement on Tariffs and Trade (GATT), *see* David R. Purnell, *1993 International Trade Update: The GATT and NAFTA*, 73 NEB L. REV. 211 (1994).

II. BACKGROUND

A. Genetic Engineering

1. History

Never content to leave well enough alone, for centuries[4] we human beings have aspired to alter mother earth to suit our every whim and fancy, right down to the fruits of her soil. Recent biotechnology processes are the modern counterparts of crop domestication, which dates back over 10,000 years.[5] The more modern techniques of selective breeding and cross breeding have developed as a direct result of this early domestication process. While the characteristics of plants gradually changed because of domestication,[6] the work of Gregor Mendel ultimately shed some insight on how specific characteristics passed from generation to generation.[7]

Gregor Mendel, a Moldavian monk, crossbred peas in his spare time.[8] Mendel discovered the rules of heredity based upon his experiments cross breeding pea seeds.[9] It was not until the 1940s, however, that Oswald Avery, a Canadian doctor, established that factors determining heredity are located on the deoxyribonucleic acid (DNA).[10] Scientists unraveled the basics of the genetic code of DNA by the mid-1960s,[11] a discovery which sparked the development of recombinant DNA technology[12] in the early 1970s.[13] Most genetic engineering techniques now involve recombinant DNA technology.[14]

Genetic engineering uses the same molecular-based concepts as the more conventional breeding processes of selective breeding and cross breeding.[15] Conventional breeding processes are slow and confined to organisms compatible to sexual cross breeding.[16] Genetic engineering, on the other hand, allows genetic material to be pinpointed and manipulated in order to enhance desir-

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4. Domestication of animals and agricultural practices date back to the dawn of civilization. CHRISPEELS & SADAVA, *supra* note 1, at 58.

5. APPLICATION OF BIOTECHNOLOGY: ENVIRONMENTAL AND POLICY ISSUES 3 (John R. Fowle III ed., 1987) [hereinafter APPLICATION OF BIOTECHNOLOGY]. *See also* JEFFREY N. GIBBS ET AL., BIOTECHNOLOGY & THE ENVIRONMENT: INTERNATIONAL REGULATION 2 (1987), J.R.S. FINCHAM & J.R. RAVETZ, GENETICALLY ENGINEERED ORGANISMS 2 (1990).

6. CHRISPEELS & SADAVA, *supra* note 1, at 58.

7. HENK HOBBELINK, BIOTECHNOLOGY AND THE FUTURE OF WORLD AGRICULTURE 20 (1991).

8. CHRISPEELS & SADAVA, *supra* note 1, at 242.

9. The experiments conducted by Gregor Mendel involved crossbreeding two varieties of pea plants: one with round and one with wrinkled seeds. CHRISPEELS & SADAVA, *supra* note 1, at 242. Mendel observed that when he crossbred the round and wrinkled peas, the first generation of the cross consisted entirely of round peas. The next generation of peas, grown from the seeds of the first, however, consisted of 75% round and 25% wrinkled peas. None of the peas were in between; i.e. a little round and a little wrinkled. In this way, Mendel was able to determine that characteristics are transmitted to the next generation as discrete units, now known as genes. CHRISPEELS & SADAVA, *supra* note 1, at 243. His observations were published in 1865 in a local journal but went unnoticed for some 35 years. CHRISPEELS & SADAVA, *supra* note 1, at 242.

10. HOBBELINK, *supra* note 7, at 20.

11. HOBBELINK, *supra* note 7, at 21.

12. Recombinant DNA technology is also known as gene cloning. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 55.

13. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 55.

14. WILLIAM BAINS, BIOTECHNOLOGY FROM A TO Z 153 (1993).

15. CHRISPEELS & SADAVA, *supra* note 1, at 260.

16. UNDERSTANDING GENETIC ENGINEERING 9 (J. C. Murrell & L. M. Roberts eds., 1989).

able qualities.[17] It enables the precise transfer of genetic material from one distinct organism to another.[18] Recombining DNA from distinctly different organisms, a process known as recombinant DNA technology, is currently at the center of the controversy surrounding biotechnology products.[19]

The potential for utilizing gene-transfer techniques to improve food crops is an area of special focus for the agricultural industry.[20] The field of agriculture stands to reap substantial benefits if application of genetic engineering processes to food crops is successful.[21] The goal of this effort is to engineer specific traits into a variety of crop plants to improve the efficiency of farming, increase crop yield and quality, and reduce stress on the environment.[22]

Feeding the world's ever-growing population of human beings is a daunting task.[23] Modern farming practices favor planting single, high-yielding crop varieties, a practice known as monoculture.[24] Because genetic uniformity makes the crop vulnerable to attack from pests or diseases, monoculture can have potentially disastrous effects.[25] Genetic engineering has the potential to mitigate the effects of monoculture.[26]

One major concern of farmers and consumers is the amount of herbicides and pesticides used in farming.[27] Using biotechnology to develop herbicide- and pest-resistant crop plants has the potential for substantially reducing the amount of herbicides and pesticides used on crops and for increasing yields.[28] Using genetically engineered herbicide-resistant plants in conjunction with

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17. Anastasia Schepers, R.S., M.D., *Biotechnology: Rewards, Hazards of Fooling With Mother Nature*, 17 ENVTL. NUTRITION, Aug. 1994, at 1.

The accuracy of genetic engineering makes it possible to add or subtract certain traits from the cells of an organism. GEORGE J. BANWART, BASIC FOOD MICROBIOLOGY 435 (1989).

18. CHRISPEELS & SADAVA, *supra* note 1, at 400. Genes are discrete units which transmit traits or characteristics from one generation to the next. CHRISPEELS & SADAVA, *supra* note 1, at 243. Genes are made of DNA and have the necessary information to synthesize protein. CHRISPEELS & SADAVA, *supra* note 1, at 247, 249. Genes are located on filamentous structures in the cell of the nucleus called chromosomes. CHRISPEELS & SADAVA, *supra* note 1, at 246.

Through a process called "gene splicing", desired traits are isolated along the DNA strand and spliced out. AGRICULTURAL BIOETHICS: IMPLICATIONS OF AGRICULTURAL BIOTECHNOLOGY 5 (Steven M. Gendel et al. eds., 1990) [hereinafter AGRICULTURAL BIOETHICS]. Because DNA strands from all organisms have the same structure, they can be cut into segments. The cut segments can then be linked together in new and different ways. Linking together or "recombining" DNA segments from different source organisms is known as "recombinant DNA technology." DNA from any source can be introduced into any host. The only limitation of the technique is the amount of genetic information that can be stably inherited or expressed. *Id. See generally* CHRISPEELS & SADAVA, *supra* note 1, at 259 for a more thorough discussion of the molecular basis of plant breeding and genetic engineering.

19. Schepers, *supra* note 17, at 1.

20. *See generally* R. WALDEN, GENETIC TRANSFORMATION IN PLANTS 101 (1989). Genetically engineered plants are sometimes referred to as transgenic plants. BAINS, *supra* note 14, at 153.

21. *See generally* WALDEN, *supra* note 20, at 101.

22. WALDEN, *supra* note 20, at 101.

Using recombinant DNA technology to introduce new genetic information into organisms differs from traditional plant breeding methods in three ways: (1) the source of the genes; (2) the means of transferring DNA; and (3) the precision of the transfer of DNA. ENGINEERED ORGANISMS IN THE ENVIRONMENT: SCIENTIFIC ISSUES 49-50 (Harlyn O. Halvorson et al eds., 1985) [hereinafter ENGINEERED ORGANISMS].

23. CHRISPEELS & SADAVA, *supra* note 1, at 1.

24. Patricia Orwen, *Global Indigestion: The Green Revolution Put the World's Food on Your Plate. But it's Backfired. We May be Running out of Food When We Need it the Most*, TORONTO STAR, Mar. 20, 1994, at E1.

25. *Id.*

The Irish potato famine was the result of the practice of monoculture. *Id.*

Monoculture also results in a higher prevalence of heartier weeds. CHRISPEELS & SADAVA, *supra* note 1, at 328. There are 13 characteristics which make a plant a weed. While crop plants share only five or six of these characteristics, serious weed crops have 11 or 12. CHRISPEELS & SADAVA, *supra* note 1, at 423.

Rotating crops is the present method used to mitigate the effects of monoculture. CHRISPEELS & SADAVA, *supra* note 1, at 328.

26. CHRISPEELS & SADAVA, *supra* note 1, at 328.

27. CHRISPEELS & SADAVA, *supra* note 1, at 355.

28. Schepers, *supra* note 17, at 4.

improved herbicides will be less detrimental to the environment and may improve the efficiency of farming.[29]

Many crops are genetically engineered to resist plant viruses which might otherwise devastate these plants.[30] Genetically engineered crops, therefore, have less viral contamination than unmodified plants.[31] This healthy improvement increases both crop yield and crop quality.[32] Thus, splicing animal and other genes into the breeding stock of crops accomplishes multiple goals: it makes food crops resistant to insects and to poisons sprayed on weeds; it improves the taste and nutritional value of food crops; and it increases their shelf life.[33] Scientific forecasters predict an eruption of biotechnology products by the year 2000.[34]

2. *Deliberate Release*

Human beings have a long history of introducing foreign species into new environments.[35] Technology development has a history abounding with examples of well-intended introductions of new technologies followed by unexpected adverse consequences.[36] Their examples serve as reminders that absolute security cannot coincide with biological innovation.[37] The biological and ecological

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29. Karen Goldman Herman, Comment, *Issues in the Regulation of Bioengineered Food*, 7 HIGH. TECH. L. J. 107, 110 (1992). *But see* CHRISPEELS AND SADAVA, *supra* note 1, at 423 (stating that introducing herbicide resistant genes in plants poses the problem of potentially causing crop plants to become weeds).

30. Herman, *supra* note 29, at 110.

Crops that are genetically engineered to resist plant viruses include tomatoes, potatoes, alfalfa, cucumbers, corn, and soybeans. Herman, *supra* note 29, at 110.

Scientists vaccinate the plants by introducing a gene that produces part of the protein that surrounds all viruses. That way, the plants develop resistance, and the immunity becomes part of the plant's genetic makeup. *OK For Genetically Altered Produce Doesn't Squash Critics*, CHI. TRIB., Dec. 25, 1994, at 7.

31. Herman, *supra* note 29, at 110. *But see* Schepers, *supra* note 19, at 4 (stating that inserting genes to boost a plant's resistance may produce altered forms of the virus at a higher rate than predicted by experts, thus actually damaging crops and reducing yield).

32. Herman, *supra* note 29, at 110.

33. Richard Kahlenberg, *Federal Government Allows 'Frankenfood', Genetically Altered Produce, to be Marketed Without Usual Safety Testing*, L.A. TIMES, July 9, 1992, at J14.

34. Schepers, *supra* note 17, at 4.

Tomatoes are apparently a favored subject of genetic engineers. For example, the Zeneca tomato will have more pectin and a naturally thicker consistency, making it ideal for use in processed tomato products. Schepers, *supra* note 17, at 4.

Ripening tomatoes produce ethylene, which starts and accelerates the ripening process. CHRISPEELS & SADAVA, *supra* note 1, at 411. To prolong shelf life, tomatoes are now picked green, transported, and gassed with ethylene to begin the ripening process. Tomatoes are tastier, however, if they are left on the vine longer. Genetically engineering tomatoes to alter their ripening process allows them to be left on the vine longer and eliminates the need to gas them with ethylene. CHRISPEELS & SADAVA, *supra* note 1, at 411.

Antisense RNA, which eliminates particular gene functions, is being used in tomatoes to retard softening and subsequent spoilage that normally accompanies ripening. Herman, *supra* note 29, at 109. This modification also allows tomatoes to be machine-picked without bruising them, thus improving the efficiency of farming. Herman, *supra* note 29, at 109. While this genetic alteration may have improved the efficiency of the agricultural industry, consumers will not be reaping the benefits of a lower priced tomato. Damon Darlin, *I Say Tomato, You Say Vinesweet: DNA Plant Technology Corp. Competes With Calgene Inc. to Produce a Genetically-Engineered Tomato*, FORBES, Oct. 11, 1993, at 88. For example, the "Vinesweet," a genetically engineered tomato, will cost approximately double the price of gassed green tomatoes. *Id.*

A subsidiary of Monsanto is developing a potato with higher starch content which will absorb less oil when the potato is fried. Schepers, *supra* note 17, at 4.

35. FINCHAM & RAVETZ, *supra* note 5, at 2.

36. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 125.

The dust bowl of the American Midwest in the 1930s is an example of how the introduction of agriculture has destroyed ecosystems. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 4.

The use of DDT is also an excellent example of technology gone awry. *See* STEVEN C. WITT, BIOTECHNOLOGY, MICROBES AND THE ENVIRONMENT 13 (1990) The following quotation appeared in the June 30, 1947 issue of Time Magazine: "The great expectations held for DDT have been realized. During 1946, exhaustive scientific tests have shown that, when properly used, DDT kills a host of destructive insect pests, and is a benefactor of all humanity." *Id.* (quoting an advertisement for DDT appearing in the June 30, 1947 edition of Time Magazine). A cartoon depicting an apple, potato, cow, chicken, dog and woman standing together singing "DDT is good for me-e-e!" accompanied the quotation. *Id.*

37. FINCHAM & RAVETZ, *supra* note 5, at 3.

sciences cannot predict, much less guarantee, that any particular new introduction will be harmless.[38]

Introducing genetically engineered agricultural organisms into the environment is known as deliberate release.[39] Containment is the main concern associated with deliberate release.[40] The precision upon which genetic engineering principles are based becomes less reliable when the process moves from the safety of a laboratory to a natural environment.[41] The greatest controversy surrounding deliberate release centers on a desire to have the scientific community prove that deliberate release will not harm humans or the environment.[42]

The size of a proposed release is a factor that significantly affects the likelihood of containing the release.[43] Deliberate release is done with the expectation that the organisms will grow and reproduce.[44] Containment of large-scale deliberate release is more problematic due to unintentional spread.[45] Because populations of the genetically engineered organisms will become larger, the likelihood that genetically engineered traits will escape containment and disperse is larger.[46] The only certainty associated with deliberate release is that escape into the environment is a inevitable.[47]

The environment into which the organisms disperse is of major significance in determining the effects of such dispersal.[48] Introducing foreign species into new environments can have potentially disastrous effects.[49] Care should therefore be exercised to insure that genetically engineered organisms are released into environments that closely parallel the native environment of the host species.[50]

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38. FINCHAM & RAVETZ, *supra* note 5, at 3.

39 BUREAU OF NATIONAL AFFAIRS, SPECIAL REPORT #2, U.S. BIOTECHNOLOGY: A LEGISLATIVE AND REGULATORY ROADMAP 3 (1989) [hereinafter BNA SPECIAL REPORT #2].

40. *Id.* at 4. *See also* APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 126.

41. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 99.

42. BNA SPECIAL REPORT #2, *supra* note 39, at 4.

Releasing genetically engineered organisms into the environment is also called intentional release. AGRICULTURAL BIOETHICS, *supra* note 18, at 4.

Scientists concur that deliberate release does pose the possibility of risk. They disagree, however, over the probability of damage occurring. No scientific evidence regarding the effect of deliberate release presently exist. AGRICULTURAL BIOETHICS, *supra* note 18, at 7. Scientists, therefore, can only speculate about the effects of deliberate release. AGRICULTURAL BIOETHICS, *supra* note 18, at 5.

43. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 127.

44. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 127.

45. WITT, *supra* note 36, at 81. Unintentional spread refers to the unknown of where a genetically engineered organism may eventually wind up. WITT, *supra* note 36, at 81.

46. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 127.

47. FINCHAM & RAVETZ, *supra* note 5, at 130.

The perceived risk is real and unbounded and perceptions of the risk can be as important as the real risk itself. WITT, *supra* note 36, at 88.

48. ENGINEERED ORGANISMS, *supra* note 22, at 83. *See also* FINCHAM & RAVETZ, *supra* note 5, at 5.

49. ENGINEERED ORGANISMS, *supra* note 22, at 83. *See also* FINCHAM & RAVETZ, *supra* note 5, at 5.

The water-hyacinth is an excellent example of the detrimental effects of removing a plant from its indigenous area and transplanting it. ASSESSING ECOLOGICAL RISKS OF BIOTECHNOLOGY 9 (Lev R. Ginzburg ed., 1991) [hereinafter ASSESSING ECOLOGICAL RISKS]. The water-hyacinth, native to South America, was brought to New Orleans in 1884 to decorate tables at the Cotton Exposition. *Id.* An individual attending the Exposition brought some of the plants home and put them in his pond near Palatka, Florida. *Id.* The water-hyacinth eventually escaped into the St. Johns River causing navigational problems of such severity that Florida was forced to institute removal programs. *Id.* By the mid-1970s, a dense mat of water-hyacinth covered 90,000 acres of Florida's lakes and streams, destroying native aquatic plants and reducing fish, turtle, alligator and waterfowl populations. *Id.*

See also supra note 36 regarding the Midwest dust bowl resulting from agricultural practices.

50. ENGINEERED ORGANISMS, *supra* note 22, at 83. *See also* FINCHAM & RAVETZ, *supra* note 5, at 5.

This provides at least a minimum assurance that natural enemies of the host organism may serve as a natural checks and balance system of the dispersing organism. ENGINEERED ORGANISMS, *supra* note 22, at 83.

3. Health Risks of Genetically Engineered Foods

Biotechnology promises to benefit and to improve the human condition.[51] Accompanying the potential benefits, however, are risks of undesirable side effects on human health.[52] Because genes encode proteins, many foods derived from genetically engineered crops will contain new proteins.[53] New proteins in food spawned by genetic engineering pose concerns about the safety of ingesting these foods.[54]

Plants naturally produce a number of toxins and most foods derived from plants contain levels of natural toxins considered safe.[55] Genetically engineered plants may produce new proteins which may increase the level of these naturally occurring toxins or produce new toxins altogether.[56] The foods from these plants may, therefore, be so toxic as to be harmful to human health.[57]

Increased levels of toxins in genetically engineered foods is only one of the problems that may arise.[58] The level and form of important proteins in genetically engineered foods may also differ significantly from those found in non-engineered foods.[59] These changes, coupled with increases in levels of other constituents that affect the protein's absorption, may disrupt the way protein is processed in the human body.[60] There is also a potential for allergic reactions to genetically engineered foods that have been altered with the genes of a known allergin.[61]

B. Regulation of Genetically Engineered Produce in the United States

The United States domestic regulatory policy uses a risk-based and policy-based approach to genetic engineering.[62] Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), established in 1985, details the policies for federal regulation of biotechnology.[63] Pursuant to the Coordi-

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51. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 125.
The benefits of biotechnology for the human race include important advances in pharmaceutical production, food processing, agricultural production, and environmental management. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 125-26.

52. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 126.

53. *Familiar Anti-Biotech Arguments Brandished at APHA Session*, FOOD LABELING NEWS, Nov. 10, 1994, at 13 (quoting Rebecca Goldburg of the Environmental Defense Fund) [hereinafter *Familiar Anti-Biotech Arguments*].
Increased toxicity is only one of the three primary safety issues associated with the addition of new proteins to food. *Id.* at 14. The remaining primary safety issues relate to the allergenicity of new proteins and the unexpected effects of genetic engineering. *Id.*

54. *Id.* at 14 (quoting Rebecca Goldburg of the Environmental Defense Fund).

55. Schepers, *supra* note 17, at 4.
Toxins are poisonous substances with a protein structure secreted by certain organisms which are capable of causing a pathological condition when introduced into the human body. THE AMERICAN HERITAGE DICTIONARY 1283 (2d College ed. 1985). Something that is toxic is therefore harmful, destructive or deadly. *Id.* at 1282.

56. *Familiar Anti-Biotech Arguments*, *supra* note 53, at 13; Schepers, *supra* note 17, at 4.

57. Schepers, *supra* note 17, at 4.
Plant breeders claim that they will be able to identify and eliminate plants with unacceptably high levels of natural toxins. Schepers, *supra* note 17, at 4.

58. Schepers, *supra* note 17, at 4.

59. Schepers, *supra* note 17, at 4.

60. Schepers, *supra* note 17, at 4.
The term "bioavailability" refers to the way in which nutrients are processed in the body. Schepers, *supra* note 17, at 4.

61. Schepers, *supra* note 17, at 4.
For example, many people are allergic to peanuts. Transferring a peanut gene into corn could make the new variety of corn allergenic to people allergic to peanuts. Schepers, *supra* note 17, at 4.

62. 49 Fed. Reg. 50,856, 50,857 (1984) (proposed Dec. 31, 1984). United States policy aims toward assuring food safety while not unduly burdening the biotechnology industry. 49 Fed. Reg. 50,857.

63. 50 Fed. Reg. 47,174 (1985) (proposed Nov. 14, 1985).

nated Framework, each federal agency retains jurisdiction over biotechnology applications within their traditional domains.[64]

The Food and Drug Administration (FDA) has the primary responsibility for the safety, wholesomeness, and nutritional quality of food[65] and is, therefore, the main enforcer of regulations concerning food.[66] The FDA enforces the Food, Drug and Cosmetic Act (FDCA),[67] administers the Fair Packaging and Labeling Act as related to foods and household products,[68] and regulates the production, storage, and labeling of all foods, except red meats and poultry.[69] Most of the FDA activities are devoted to food safety; the remainder of its activities concern economic aspects of regulation.[70] The "Statement of Policy: Food Derived From New Plant Varieties" (Statement), issued in 1992, outlines the FDA position on the regulation of genetically engineered food.[71]

The FDA relies almost exclusively on the provisions of the FDCA pertaining to adulterated foods[72] to ensure the safety of whole foods.[73] In the Statement, the FDA stated that it would continue to use the existing standards for adulterated food as the primary legal tool for ensuring the safety of whole foods derived from transgenic plants.[74]

The FDCA prescribes different standards to determine whether a food is adulterated.[75] Food is adulterated pursuant to the FDCA if it "bears or contains any poisonous or deleterious substance."[76] The source of the toxicant,[77] however, is of primary importance in determining FDA regulatory action.[78] FDA regulatory action extends to toxicants occurring naturally in the food, if the FDA can show that the quantity of the toxicant would "ordinarily render the food injurious to health."[79]

The FDA applies a different standard when regulating substances that have been added to food.[80] The FDA considers a substance to be an additive

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64. 50 Fed. Reg. 47,181-95.

65. BANWART, *supra* note 17, at 713.
Statutes dictate the responsibilities of the FDA. 49 Fed. Reg. 50,858.

66. BANWART, *supra* note 17, at 713.

67. BANWART, *supra* note 17, at 713.

68. BANWART, *supra* note 17, at 713.

69. The USDA regulates red meats, poultry, and eggs. BANWART, *supra* note 17, at 713.

70. The food safety programs include control of food sanitation, chemical contaminants, mycotoxins, food and color additives, and nutrition. The economic aspects include food standards and the control of unfair competition because of economic cheating. BANWART, *supra* note 17, at 713.

71. 57 Fed. Reg. 22,984 (1992) (proposed May 24, 1992).

72. 21 U.S.C. § 342 (1988).

73. 57 Fed. Reg. 22,988.

74. 59 Fed. Reg. 26,700 (1994) (to be codified at 21 C.F.R. pts. 173 & 573) (proposed May 23, 1994).
The FDCA prohibits introducing or receiving adulterated food into interstate commerce and outlines enforcement measures for the FDA. 21 U.S.C. § 331(a)-(c) (1988). The full range of enforcement mechanisms available to the FDA include injunction, criminal prosecution, and seizure. 21 U.S.C. §§ 332-334 (1988).

75. 21 U.S.C. § 342 (1988).

76. 21 U.S.C. § 341(a)(1) (1988).
The FDCA also defines a food as adulterated if the food is missing any valuable constituent. 21 U.S.C. § 342(b)(1) (1988).

77. Toxicants are poisonous substances. THE AMERICAN HERITAGE DICTIONARY 1282 (2d College ed. 1985). *See also supra* note 55.

78. 21 U.S.C. § 342 (1988).

79. This is the "ordinarily render injurious" standard. 21 U.S.C. § 342(a)(1) (1988). *See also* INTERNATIONAL FOOD REGULATION HANDBOOK: POLICY, SCIENCE, LAW 20 (Roger D. Middlekauff & Phillippe Shubik eds., 1989) [hereinafter INTERNATIONAL FOOD HANDBOOK].
Most cases of toxins that occur naturally in food and that render food ordinarily injurious to health, however, are well known and carefully avoided by food producers. 57 Fed. Reg. 22,988.

80. 21 U.S.C. § 342(a) (1988).

within the meaning of the FDCA if that substance is not an inherent constituent of food or if the level of the substance in food has been increased by human intervention.[81] The FDA regulates substances that have been added to food if it can show that the added substance "may render the food injurious to health."[82] A food with an added substance is considered adulterated under the "may render injurious" standard if there is a "reasonable possibility" that consumption of the food will be injurious to health.[83] The "may render injurious" standard can be applied to toxicants occurring naturally in food if the level of the toxicant is increased in the new plant variety as a result of traditional plant breeding techniques or through human intervention.[84] The FDA establishes tolerance levels for undesired and unintended contaminants in food and takes enforcement action if such levels are exceeded.[85]

Because most plant-derived foods predate the establishment of federal food laws, the FDA accepts the safety of most plant-derived foods based on extensive consumer use and years of experience.[86] The FDA is satisfied that established practices employed by plant breeders in selecting and developing new varieties of plants have proven to be reliable for ensuring food safety.[87] It has not, therefore, found it necessary to conduct routine safety reviews of either transgenic plants or the whole foods derived from these plants.[88] Developers of new plant varieties through genetic engineering are responsible for ensuring the genetic stability of the new transgenic plants.[89] Factors that maximize stability include inserting genes at a single site on the DNA and introducing a minimum number of copies of genetic material.[90] Although genetically engineered food may contain new or different proteins than the parent foods from which they are derived, the FDA will not regulate these proteins unless they are "toxicologically different from other . . . enzymes in the food supply."[91]

Under the FDCA, the FDA also regulates food additives.[92] To determine whether a substance is a food additive, the FDA employs a two-step process.[93] First, the FDA includes as a food additive any substance with an intended use that results in its becoming a component of food.[94] Then, the FDA excludes from this definition those substances that are generally recognized as safe

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81. 57 Fed. Reg. 22,989.

82. This is the "may render injurious" standard. 21 U.S.C. § 341 (a)(1) (1988). *See also* 57 Fed. Reg. 22,988; INTERNATIONAL FOOD HANDBOOK, *supra* note 79, at 20.

The "may render injurious" standard is more stringent than the "ordinarily render injurious" standard used for toxicants naturally occurring in food. 57 Fed. Reg. 22,988.

83. United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914).

84. 57 Fed. Reg. 22,989.

85. 57 Fed. Reg. 22,989.

86. 57 Fed. Reg. 22,988.

87. 57 Fed. Reg. 22,988.

88. 57 Fed. Reg. 22,988.

89. 59 Fed. Reg. 26,701.

90. 59 Fed. Reg. 26,701. *See also* 57 Fed. Reg. 23,004.

91. 59 Fed. Reg. 26,703. Whole foods normally contain thousands of different proteins, and proteins, as a class, are rarely toxic. 59 Fed. Reg. 26,703. Proteins are enzymes and all plants and animals in the food chain contain enzymes. 59 Fed. Reg. 26,703.

92. 21 U.S.C. § 348 (1988).

93. 57 Fed. Reg. 22,989.

94. 57 Fed. Reg. 22,989; 21 U.S.C. § 348 (1988).

(GRAS).[95] Therefore, a food additive is any non-GRAS substance that becomes a component of food.[96]

In determining food safety for additives, all that FDA guidelines require is "proof of a reasonable certainty that no harm will result from the proposed use of an additive."[97] A food additive is, therefore, considered safe if "there is reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[98] Once the FDA promulgates regulations specifying the conditions under which the additive may be safely used, the use in conformity with such regulations does not require further pre-market clearance.[99]

The FDA currently does not consider DNA transferred through the process of genetic engineering to be an ingredient which must be regulated under the Amendment.[100] Because DNA is present in all living organisms and is efficiently digested by human beings, the FDA considers it to be a GRAS substance.[101] The FDA, therefore, does not require pre-market approval before DNA is transferred through the process of genetic engineering.[102] Although products rendered through the process of genetic engineering are generally considered GRAS, the FDA will intervene if the genetically engineered food is modified to such an extent that it differs significantly from the parent food.[103]

The FDA does not require all genetically engineered products to be labeled as such.[104] Normally, the FDA requires foods fabricated from two or more ingredients to bear a label containing the common or usual name of each ingredient.[105] Substances that "are inherent components of food" are not considered to be ingredients "that must be disclosed in the food's label" by the FDA.[106] The FDA considers DNA to be an inherent component of food.[107] This is based upon the FDA's recognition that "DNA is present in . . . all living organisms, including

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95. 57 Fed. Reg. 22,989.

GRAS substances are (1) a substance whose safety has been established by a long history of food use or (2) a substance that does not raise a safety concern worthy of pre-market evaluation by the FDA based upon the nature of the substance and the information generally available to scientists about the substance. 57 Fed. Reg. 22,989.

96. 21 U.S.C. § 348 (1988).

97. 59 Fed. Reg. 26,701.

"Proof beyond any possible doubt that no harm will result under any conceivable circumstance" is not required. 59 Fed. Reg. 26,701.

98. 59 Fed. Reg. 26,701.

99. 57 Fed. Reg. 22,989.

Food additives not subject to such regulation are deemed unsafe as a matter of law and the foods containing them considered adulterated under the FDCA. 57 Fed. Reg. 22,989.

100. 57 Fed. Reg. 22,990.

101. 59 Fed. Reg. 26,701.

102. 59 Fed. Reg. 26,701.

103. 57 Fed. Reg. 22,990.

In such case, the FDA recommends either a new common or usual name for the food or labeling the food to reveal the alteration to the consumer. *International Impact on Biotech Labeling Pointed Up at Codex Session*, FOOD LABELING NEWS, Nov. 10, 1994, at 8 [hereinafter *International Impact*].

104. 59 Fed. Reg. 26,709.

The FDA favors limiting labeling of biotechnology products to rare circumstances to be determined on a case-by-case basis. *See generally International Impact*, *supra* note 103, at 4.

105. 59 Fed. Reg. 26,709.

According to the FDA an ingredient is "a substance used to fabricate (i.e., manufacture or produce) a food." 59 Fed. Reg. 26,709.

The FDA excuses compliance with the labeling requirement if it is impracticable or results in deception or unfair competition. 59 Fed. Reg. 26,709.

106. 59 Fed. Reg. 26,709.

107. 59 Fed. Reg. 26,701.

every plant and animal used for food by humans or animals."[108]

The United States Department of Agriculture (USDA) and Environmental Protection Agency (EPA) have primary jurisdiction over deliberate release of genetically engineered organisms.[109] The Animal and Plant Health Inspection Service (APHIS) is the regulatory agency of the USDA.[110] APHIS uses the Plant Quarantine Act and the Federal Plant Pest Act (FPPA) to regulate genetically engineered plants and organisms.[111] Both laws authorize APHIS to "prevent the introduction, dissemination, or establishment of organisms that can damage plants."[112] The FPPA regulates importation and movement of plant pests.[113] The definition of plant pest under the FPPA includes "any infectious substance that can directly or indirectly cause disease or injury to plants or plant parts."[114] Because of the uncertainty associated with deliberate release, the USDA recently established a research grant program to assist United States federal regulatory authorities in making science-based decisions about the safety of introducing genetically altered plants into the environment.[115]

C. *The North American Free Trade Agreement*

Effective January 1, 1994, Canada, Mexico and the United States formed an economic alliance under the North American Free Trade Agreement (NAFTA).[116] NAFTA is predominantly a trade and tariff agreement which "lays the foundation for a continental common market."[117] NAFTA governs trade for a wide variety of goods and provides for the elimination of tariffs between the

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108. 59 Fed. Reg. 26,701.

The FDA advocates labeling if the transgenic food contains an allergin consumers would not normally expect to be associated with that food. *International Impact*, *supra* note 103, at 8.

109. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 6.

Statutes define the responsibilities of the USDA and FDA. 49 Fed. Reg. 50,856, 50,858 (1984).

110. BNA SPECIAL REPORT #2, *supra* note 39, at 29.

111. BNA SPECIAL REPORT #2, *supra* note 39, at 29.

112. BNA SPECIAL REPORT #2, *supra* note 39, at 29.

113. 57 Fed. Reg 6,753, 6,754 (1992).

114. BNA SPECIAL REPORT #2, *supra* note 39, at 30.

115. The grant program is also seeking assistance in determining the safety of introducing genetically modified animals and microorganisms into the environment. 59 Fed. Reg. 59,348 (1994).

One-point-seven million dollars is available in 1995 to support the program. The USDA is accepting proposals from both public and private research or educational institutions or organizations. The research grants are to be awarded on a competitive basis. Among the issues submitted proposals must address is "environmental risk analysis of large scale deployment of genetically engineered organisms, especially commercial uses of such organisms." 59 Fed. Reg. 59,348-49.

The grant program proves to be especially interesting in lieu of the fact that most current existing scientific evidence regarding genetically engineered plants is provided to the FDA by the manufacturers of such plants. 59 Fed. Reg. 26,700.

While the areas of environmental protection and international trade have developed independently, increasing trade and investment among nations causes increasing concerns about the environmental impact of this interaction. UNITED STATES CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, TRADE AND ENVIRONMENT, OTA-BP-ITE-94 3 (Washington, DC: United States Printing Office, May, 1992). The potential environmental effects of deliberate release is an area that has spawned significant international debate. GIBBS ET AL., *supra* note 5, at 1. International policies and priorities for regulating deliberate release vary. GIBBS ET AL., *supra* note 5, at 5. Canada uses a risk-based and policy-based approach to regulate biotechnology similar to that of the United States. *Don't Close the Door on Benefits of Genetically Engineered Crops*, OTTAWA CITIZEN, Nov. 20, 1994, at A9.

116. North American Free Trade Agreement Between the Government of Canada, The Government of the United Mexican States, and the Government of the United States, Dec. 17, 1992 (entered into force Jan. 1, 1994) [hereinafter NAFTA].

President Bill Clinton signed the North American Free Trade Agreement on December 8, 1993, to take effect in the United States on January 1, 1994. XLIX CONGRESSIONAL QUARTERLY ALMANAC, 103rd Cong., 1st Sess. 171 (1994) [hereinafter CONGRESSIONAL QUARTERLY].

117. William A. Orme, Jr., *A Fistful of Trade: NAFTA Is Just One Facet of a Growing Economic Cohesion*, WASH. POST, Nov. 14, 1993, at H1.

NAFTA is significant in that the environmental community was able to place environmental issues on the international trade agenda. *See* North American Agreement on Environmental Cooperation Between The Government of the United States of America, The Government of Canada, and The Government of the United Mexican States, Sept. 13, 1993, 32 INT'L LEGAL MATERIALS 1480 (1994) (entered into force Jan. 1, 1994).

member countries[118] over a fifteen year period, depending on the nature of the goods.[119]

NAFTA specifically regulates trade in agricultural products.[120] To minimize potential health risks posed by agricultural trade, NAFTA allows its member countries to adopt measures to protect human, animal and plant life and health.[121] The "Sanitary and Phytosanitary Measures"[122] of NAFTA allow each member country to adopt any "measure necessary for the protection of human, animal or plant life or health in its territory"[123] from risks arising from the "introduction, establishment or spread of pest or disease."[124] NAFTA both defines risk assessment and provides member countries with a specific list of relevant factors they should consider when evaluating these potential health risks.[125]

NAFTA instructs member countries to consider regional conditions when adopting sanitary and phytosanitary measures which relate to the introduc-

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118. Although NAFTA refers to Canada, Mexico and the United States as "the Parties," this comment will hereinafter refer to them as the "member countries."

119. CONGRESSIONAL QUARTERLY, *supra* note 116, at 181.

120. NAFTA, *supra* note 116, vol. I, ch. 7.

121. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 724.

122. NAFTA defines sanitary and phytosanitary measures as:

> a measure that a [member country] adopts, maintains or applies to:
> (a) protect animal or plant life or health in its territory from risks arising from the introduction, establishment or spread of a pest or disease,
> (b) protect human or animal life or health in its territory from risks arising from the presence of an additive, contaminant, toxin or disease-causing organism in a food, beverage or feedstuff,
> (c) protect human life or health in its territory from risks arising from a disease-causing organism or pest carried by an animal or plant, or a product thereof, or
> (d) prevent or limit other damage in its territory arising from the introduction, establishment or spread of a pest,
> including end product criteria; a product-related processing or production method; a testing, inspection, certification or approval procedure; a relevant statistical method; a sampling procedure; a method of risk assessment; a packaging and labeling requirement directly related to food safety; and a quarantine treatment, such as a relevant requirement associated with the transportation of animals or plants or with material necessary for their survival during transportation.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 724.

123. NAFTA, *supra* 116, vol. I, ch. 7, § B, art. 712.

124. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 724. The definition of "pest" under NAFTA includes weeds. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 724.

125. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 724. NAFTA defines risk assessment as evaluation of:

> (a) the potential for introduction, establishment or spread of a pest or disease and associated biological and economic consequences; or
> (b) the potential for adverse effects on human or animal life or health arising from the presence of an additive, contaminant, toxin or disease-causing organism in a food, beverage or feedstuff.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 724.

NAFTA also sets out guidelines for the manner in which member countries should conduct risk assessment.

> Article 715: Risk Assessment and Appropriate Level of Protection
> 1. In conducting risk assessment, each [member country] shall take into account:
> (a) relevant risk assessment techniques and methodologies developed by international or North American standardizing organizations;
> (b) relevant scientific evidence;
> (c) relevant processes and production methods;
> (d) relevant inspection, sampling and testing methods;
> (e) the prevalence of relevant diseases or pests, including the existence of pest-free or disease-free areas or areas of low pest or disease prevalence;
> (f) relevant treatments, such as quarantines.
> 2. Further to paragraph 1, each [member country] shall, in establishing its appropriate level of protection regarding the risk associated with the introduction, establishment or spread of an animal or plant pest or disease, and in assessing the risk, also take into account the following economic factors, where relevant:
> (a) loss of production or sales that may result from the pest or disease;
> (b) costs of control or eradication of the pest or disease in its territory; and
> (c) the relative cost-effectiveness of alternative approaches to limiting risks.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 715:1 & 715:2.

tion, establishment or spread of an animal or plant pest or disease.[126] Member countries must determine the prevalence of pests and diseases in both the area where the goods are produced and the area in their territory where the goods are destined.[127] The member country must then adapt their sanitary and phytosanitary measures to those conditions.[128] Once a member country establishes the prevalence of pests and disease of an area, it must also establish the likelihood that such prevalence in that area will remain stable.[129] NAFTA instructs exporting member countries to provide satisfactory information to importing member countries which supports their assessment of both the levels of pest or disease prevalence of certain relevant geographical areas and the likelihood that such levels will remain relatively stable.[130]

NAFTA recognizes that its member countries can achieve the same level of protection with different individual standards.[131]

NAFTA explicitly states that each member country, including states and localities within member countries, retains the right to set its own safety standards.[132] However, because the main thrust of NAFTA with respect to agricultural products is to reduce or eliminate import trade barriers between member countries,[133] NAFTA requires some equivalence between the sanitary and phy-

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126. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:1. Article 716:1 states specifically:

> 1. Each [member country] shall adapt any of its sanitary or phytosanitary measures relating to the introduction, establishment or spread of an animal or plant pest or disease, to the sanitary or phytosanitary characteristics of the area where a good subject to such measure is produced and the area in its territory to which the good is destined, taking into account any relevant conditions, including those relating to transportation and handling, between those areas. In assessing such characteristics of an area, including whether an area is, and is likely to remain, a pest-free or disease-free area or an area of low pest or disease prevalence, each [member country] shall take into account, among other factors:
> (a) the prevalence of relevant pests or diseases in that area;
> (b) the existence of eradication or control programs in that area; and
> (c) any relevant international standard, guideline or recommendation.

NAFTA, vol. I, ch. 7, § B, art. 716:1

127. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:1.

NAFTA instructs member countries to use scientific methods to determine the disease or pest prevalence of agricultural areas within their territories. Article 716:1 states specifically:

> 1. Each [member country] shall adapt any of its sanitary or phytosanitary measures relating to the introduction, establishment or spread of an animal or plant pest or disease, to the sanitary or phytosanitary characteristics of the area where a good subject to such measure is produced and the area in its territory to which the good is destined, taking into account any relevant conditions, including those relating to transportation and handling, between those areas. In assessing such characteristics of an area, including whether an area is, and is likely to remain, a pest-free or disease-free area or an area of low pest or disease prevalence, each [member country] shall take into account, among other factors:
> (a) the prevalence of relevant pests or diseases in that area;
> (b) the existence of eradication or control programs in that area; and
> (c) any relevant international standard, guideline or recommendation.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:1.

128. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716.

129. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:1.

130. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:3. Article 716:3 states specifically:

> 3. Each importing [member country] shall recognize that an area in the territory of the exporting [member country] is, and is likely to remain, a pest-free or disease-free area or an area of low pest or disease prevalence, where the exporting [member country] provides to the importing [member country] scientific evidence or other information sufficient to so demonstrate to the satisfaction of the importing [member country]. For this purpose, each exporting [member country] shall provide reasonable access in its territory to the importing [member country] for inspection, testing and other relevant procedures.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:3.

131. CONGRESSIONAL QUARTERLY, *supra* note 116, at 181.

NAFTA also allows member countries to adopt, apply and maintain different sanitary and phytosanitary measures within their territories. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:4. For example, NAFTA allows member countries to adopt, apply and maintain different risk assessment procedures depending disease or pest prevalence of geographic areas within their territories. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 716:4.

132. CONGRESSIONAL QUARTERLY, *supra* note 116, at 180.

133. NAFTA, *supra* note 116, vol. I, ch. 7, § A, art. 703.

tosanitary measures adopted by member countries.[134]

Member countries are not allowed to adopt sanitary or phytosanitary measures which differ so greatly from those adopted by other member countries that they become trade barriers.[135] To pursue equivalence among the sanitary and phytosanitary measures member countries adopt, NAFTA instructs member countries to consider both relevant international guidelines and standards[136] and actual and proposed sanitary and phytosanitary measures of other member countries.[137]

Although NAFTA requires its member countries to use international standards as a guideline, it does not foreclose them from adopting more stringent protective measures.[138] However, any measure adopted by a member country which is more stringent than international guidelines must be based upon scientific principles.[139] Furthermore, efforts by member countries to make their sanitary and phytosanitary measures equivalent should not force them to reduce their current levels of protection.[140] Member countries must take into account the technical and economic feasibility of the sanitary and phytosanitary measures they adopt to ensure that they do not become unnecessary obstacles to trade.[141]

NAFTA establishes a Committee on Sanitary and Phytosanitary Measures (Committee) composed of representatives of each member country who have responsibility for sanitary and phytosanitary measures within their country.[142] This Committee is responsible for facilitating the enhancement of food safety,

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134. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 714:1. Article 714:1 states specifically, "1. Without reducing the level of protection of human, animal or plant life or health, the [member countries] shall, to the greatest extent practicable and in accordance with this Section, pursue equivalence of their respective sanitary and phytosanitary measures." NAFTA, *supra* note 116, vol. I, ch. 7, § B, art 714:1.

135. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 712:6.

136. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 713:1. Article 713:1 states specifically:

> Without reducing the level of protection of human, animal or plant life or health, each [member country] should use as a basis for its sanitary and phytosanitary measures, relevant international standards, guidelines or recommendations with the objective . . . of making its sanitary and phytosanitary equivalent or, where appropriate, identical to those of other [member countries].

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 713:1.

Standards developed by the Codex Alimentarius Commission are among the accepted international standards upon which member countries may rely when adopting their sanitary and phytosanitary measures. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 713:5.

137. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 713:1.

138. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 713:3.

139. Any sanitary or phytosanitary measure adopted by a member country must be:

> (a) based on scientific principles, taking into account relevant factors including, where appropriate, different geographical conditions;
>
> (b) not maintained where there is no longer a scientific basis for it; and
>
> (c) based on a risk assessment, as appropriate to the circumstances.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 712:3.

If, while conducting a risk assessment, a member country discovers that available scientific principles and other information is insufficient to complete such risk assessment, NAFTA allows member countries to adopt provisional sanitary and phytosanitary measures. NAFTA, *supra* note 116, vol. I, ch. 7, §B, art. 715:4. Any provisional measures thus adopted by member countries must be based upon relevant available information, including information from international and North American standardizing organizations or from sanitary and phytosanitary measures adopted by other member countries. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 715:4. Once sufficient information is presented to a member country, however, it must complete its assessment and, if necessary, revise the provisional measure in light of the assessment. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 715:4.

However, NAFTA restricts member countries from adopting any sanitary or phytosanitary measures that "arbitrarily or unjustifiably discriminates between its goods and like goods of another [member country], or between goods of another [member country] and like goods of any other country, where identical or similar conditions prevail" or create a "disguised restriction on trade between the [member countries]." NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 712:4.

140. CONGRESSIONAL QUARTERLY, *supra* note 116, at 181.

141. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 712:5.

142. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 722.

the improvement of sanitary and phytosanitary conditions in the territories of member countries, and the equivalency of sanitary and phytosanitary measures among member countries.[143] The Committee must meet at the request of any member country and at least once a year, unless the member countries agree otherwise.[144]

NAFTA prohibits its member countries from adopting, applying, or maintaining sanitary and phytosanitary measures in any way that arbitrarily or unjustifiably discriminates against other member countries.[145] If an exporting member country demonstrates that it has equivalent protection from health dangers, the importing member country must let the goods enter.[146] If an importing member country wishes to exclude goods, it must notify the exporting member country of the measure applicable to the goods and the reasons that the goods are not in compliance with that measure.[147] Any member country that wishes to challenge a sanitary or phytosanitary measure of another member country may request a meeting of the Committee.[148] A member country challenging the standard of another member country carries the burden of establishing that the claimed inconsistency exists.[149]

D. The Codex Alimentarius Commission

The Codex Alimentarius Commission (Codex)[150] is an international body responsible for establishing and developing international food standards (1) to protect consumer health and (2) to facilitate world trade.[151] Codex acknowl-

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143. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 722:2. Article 722:2 states specifically:

> The Committee should facilitate:
> (a) the enhancement of food safety and improvement of sanitary and phytosanitary conditions in the territories of the [member countries];
> (b) activities of the [member countries] pursuant to Article 713 [International Standards and Standardizing Organizations] and Article 714 [Equivalence];
> (c) technical cooperation between the [member countries], including cooperation in the development, application and enforcement of sanitary or phytosanitary measures; and
> (d) consultations on specific matters relating to sanitary or phytosanitary measures.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 722:2.

144. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 722:3. Article 722:3 states specifically:

> The Committee:
> (a) shall, to the extent possible, in carrying out its functions, seek the assistance of relevant international and North American standardizing organizations to obtain available scientific and technical advice and minimize duplication of effort;
> (b) may draw on such experts and expert bodies as it considers appropriate;
> (c) shall report annually to the Commission on the implementation of this Section;
> (d) shall meet on the request of any [member country] and, unless the [member countries] otherwise agree, at least once a year; and
> (e) may, as it considers appropriate, establish and determine the scope and mandate of working groups.

NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 722:3.

145. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 712:4.

146. CONGRESSIONAL QUARTERLY, *supra* note 116, at 181.

147. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 718:6.

148. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 722:2(c).

149. NAFTA, *supra* note 116, vol. I, ch. 7, § B, art. 723:6.

150. The Codex Alimentarius Commission was established in 1963 by the Food and Agriculture Organization of the United Nations and the World Health Organization. U.S. DEPT. OF AGRIC., THE UNITED STATES ROLE IN INTERNATIONAL STANDARDS FOR FOOD PRODUCTS (1976) [hereinafter U.S. ROLE IN INTERNATIONAL STANDARDS].

The Latin words "codex alimentarius" mean food law or code. 7 CODEX ALIMENTARIUS, *Cereals, Pulses, Legumes and Derived Products and Vegetable Proteins* iii (2d ed. 1994).

151. U.S. ROLE IN INTERNATIONAL STANDARDS, *supra* note 150.

edges these dual goals as equal and interdependent.[152] Neither should have precedence over the other.[153]

For a given commodity, a Codex standard is essentially a combined standard of identity and quality.[154] A Codex identity standard prescribes the acceptable composition of a commodity.[155] With respect to quality standards, Codex prescribes minimum quality standards, including accepted levels of adulterants and additives.[156] Codex also has standards regarding required food labeling which is a hybrid standard that reflects both the identity and quality of the food.[157]

Codex standards are only recommendations, and compliance is strictly voluntary.[158] Once a country accepts a Codex standard, however, it becomes mandatory for both domestic and imported products within that country.[159]

III. ANALYSIS

If the DNA of a fish is spliced into the DNA of a tomato, is the tomato still a tomato or merely a facsimile thereof?[160] The agricultural policy provisions of NAFTA do not specifically address either the process of genetic engineering or the products it renders.[161] Member countries are therefore entitled to develop any measures they see fit to control genetically engineered produce.[162] Under current United States law, then, a gene-spliced tomato is still a tomato.[163] Because the FDA posits that DNA does not pose a safety concern as a component of food, it does not regulate all products derived from recombinant DNA technology.[164] Therefore, a tomato with the added DNA of a fish that looks like a tomato will be considered a tomato.[165] If it begins to swim, it will be subject to stricter regulations.[166]

Because the predominant purpose of NAFTA is to create a free trade zone

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152. Lester M. Crawford, *International Food Safety Regulations: Improving the Codex Alimentarius Process*, FOOD TECHNOLOGY, Feb. 1992, at 98.

153. *Id.*

154. U.S. ROLE IN INTERNATIONAL STANDARDS, *supra* note 150.

155. U.S. ROLE IN INTERNATIONAL STANDARDS, *supra* note 150.

156. U.S. ROLE IN INTERNATIONAL STANDARDS, *supra* note 150.

157. U.S. ROLE IN INTERNATIONAL STANDARDS, *supra* note 150.

158. U.S. ROLE IN INTERNATIONAL STANDARDS, *supra* note 150. *See also* Natalie Avery et al., *Codex Alimentarius: Who Is Allowed In? Who Is left Out?*, 23 THE ECOLOGIST, May/June 1993, at 110.

159. U.S. ROLE IN INTERNATIONAL STANDARDS, *supra* note 150.

The Codex Committee on Food Labeling recently met to address labeling genetically engineered foods. *International Impact*, *supra* note 103, at 4. This meeting was held in Ottawa, Canada on October 24-28, 1994. At this meeting, efforts by the United States to impose its domestic standards at the international level were countered by strong arguments in favor of mandatory labeling of all genetically engineered foods. The critical issue raised by proponents of mandatory labeling was consumer choice. *International Impact*, *supra* note 103, at 4.

Canada is presently examining a national approach to labeling genetically engineered food. *International Impact*, *supra* note 103, at 5.

160. This example is exaggerated to simplify this analysis. Although it is possible to inject fish genes into tomatoes, there is presently no information suggesting that this has actually been done.

161. *See generally* discussion on NAFTA, *supra* notes 116-149 and accompanying text.

162. Because genetic engineering and its products are not areas specifically regulated by NAFTA, member countries who choose not to regulate products of genetic engineering need not take any special steps.

163. *See generally* discussion regarding FDA regulation of food, including genetically engineered food, *supra* notes 65-108 and accompanying text.

164. *See supra* text accompanying notes 91 & 103, and note 108 for examples of types of products which may be prone to FDA regulation.

165. *See infra* note 169.

166. *See supra* note 103.

among the United States, Canada, and Mexico,[167] the fact that NAFTA's agricultural provisions do not directly address genetically engineered agricultural products is not surprising. Genetic engineering, however, may have economic as well as environmental ramifications which affect trade among member countries. The current Agricultural and Sanitary and Phytosanitary provisions of NAFTA may be adequate to deal with a variety of potential issues associated with genetic engineering.

Reliance on scientific principles is a common thread underlying the sanitary and phytosanitary provisions of NAFTA and genetic engineering.[168] NAFTA's requirement that any sanitary or phytosanitary measure adopted by a member country be based upon scientific principles accomplishes dual goals. It keeps member countries from (1) adopting arbitrary or discriminatory measures that might hinder free trade and (2) injecting into the realm of trade social, moral, or political beliefs which cannot be objectively measured. In this way, NAFTA conveniently bypasses objections to genetically engineered produce which are not firmly rooted in scientific principle.[169] While the process of recombinant DNA technology may be precise, the long-term effects are not equally predictable with such precision.[170] Bioengineered food raises concerns about both the safety of the food for human consumption and the safety of environmental release of the altered plant.[171]

A. *Labeling of Genetically Engineered Foods*

If the tomato spliced with fish genes[172] ends up at the local grocery, it will not be sporting a label to tell consumers that it may have relatives in the seafood department. This is presently true under both United States laws and international standards.[173] Only foods that have two or more ingredients require labeling and thus far, DNA has not been considered and "ingredient."[174]

Ingredient is not a word normally associated with fresh fruits and vegetables.[175] Because the FDA considers DNA to be an "inherent component of food," it does not consider DNA to be an ingredient.[176] This determination is based upon the FDA's recognition that "DNA is present in all living organisms, includ-

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167. *See supra* note 117 and accompanying text.

168. *See supra* notes 15-19 & 140 and accompanying text.

169. The fact that animal genes may be added to plant foods also raises concerns for vegetarians and some religious denominations. When specifically considering this issue, the FDA proffered that in most cases, the introduction of one or a few replicas of animal genes into food crops would "not change the essential nature of the plant nor . . . confer 'animal-like' characteristics to the plant." *International Impact*, *supra* note 103, at 6. The FDA thus concluded, based on purely scientific principles, that genetic material originating in an animal "is not 'animal' material once it has been incorporated into the genetically engineered food source." *International Impact*, *supra* note 103, at 6. The FDA attributes consumer rejection of this explanation to the incapability of consumers to understand the scientific explanation. *International Impact*, *supra* note 103, at 7. For 'legitimate' ethical and religious concerns, the FDA is willing to consider the manner in which other food matters have been previously addressed to determine whether or not labeling would be an appropriate solution. *International Impact*, *supra* note 103, at 7.

170. *See supra* note 41 and accompanying text.

171. See *supra* notes 39-50 & 52-61 and accompanying text.

172. See *supra* note 160 and accompanying text.

173. *See supra* notes 105-106 and accompanying text and note 159.

174. *See supra* notes 105-107 and accompanying text.

175. *See supra* note 86 and accompanying text.

176. *See supra* note 106 and accompanying text.

The definition of inherent is "existing as an essential constituent or characteristic." THE AMERICAN HERITAGE DICTIONARY 661 (2d College ed. 1985).

ing every plant and animal used for food by humans or animals."[177] Therefore, because DNA is present in all plants and animals, and plants and animals are food, DNA is an inherent component of food. The FDA's position is relatively simplistic and somewhat tautological.

The FDA defines ingredient as a substance used to fabricate food.[178] DNA is presently being used to fabricate food.[179] While DNA is undeniably an essential constituent of all living organisms, query whether the DNA of a fish is an essential constituent of a tomato? Phrased this way, the question is not as easily answered in the affirmative. Fish DNA may enhance certain desirable qualities of a tomato thus making the tomato more valuable to the human race, but it would be difficult if not absurd to contend that it is essential. The tomato will survive without it. Thus, labeling genetically engineered foods is not the black and white issue the FDA propounds it to be.

NAFTA member countries wishing to label genetically engineered food products may be able to look to Codex for relief.[180] The most recent meeting of the Codex Committee on Food Labeling revealed the shades of gray masked by the black and white policies of the United States.[181] Because NAFTA recognizes Codex as an international food standardizing organization, NAFTA member countries may adopt Codex regulations.[182] Therefore, should the Codex Committee on Food Labeling take the position that genetically engineered foods should be labeled and base its position upon principles which are not purely scientific in nature, any NAFTA member country could adopt the measures.

Requiring labeling of genetically engineered food could pose a significant obstacle to trade. This is especially true if labeling requirements differ among NAFTA member countries.[183] This issue is exacerbated by the fact that NAFTA member countries are supposed to pursue equivalency in their safety and health standards.[184] Although NAFTA allows member countries to adopt differing standards, this is based upon the premise that the different standards adopted will be sufficient to insure food safety.[185] While a NAFTA member country may set only minimal requirements for labeling genetically engineered food, this will still pose an insurmountable trade obstacle for another NAFTA member country if that member country has not adopted a labeling policy.

Labeling genetically engineered food is, therefore, an area which will have to be made uniform for all NAFTA member countries. If labeling genetically engineered food products comes to fruition, the Committee[186] will undoubtedly need to address a uniform labeling requirement. In light of the

177. 59 Fed. Reg. 26,700, 26,701 (1994).

178. *See supra* note 105

179. *See supra* text accompanying note 19.

Fabricate means to construct by combining or assembling. THE AMERICAN HERITAGE DICTIONARY 484 (2d College ed. 1985).

180. *See supra* note 159 and accompanying text.

181. *See supra* note 159 and accompanying text

182. *See supra* note 136 and accompanying text.

183. For example, while Canada is presently exploring a national approach to labeling genetically engineered food, existing United States policies view such a labeling requirement as undesirable. *See supra* note 104 and accompanying text and note 159.

184. *See supra* note 134 and accompanying text.

185. *See supra* note 131 and accompanying text.

186. *See supra* text accompanying note 142.

fact that Codex may adopt a labeling requirement, it would be beneficial for the NAFTA member countries to follow suit. This policy would not only facilitate trade among the member countries, but would facilitate trade between NAFTA member countries and the international trade market.

B. Potential Environmental Ramifications

Deliberate release of modified crop plants may have trade ramifications under NAFTA. As genetically engineered agricultural organisms are released into the environment and proliferate, they will naturally cross pollinate with existing wild plants within that environment.[187] Food crops engineered to resist herbicides may transfer this resistant trait to weeds, thus developing a new and heartier breed of weed that will require new herbicides or technology to eradicate. Rampant herbicide-resistant weeds will have both economic and environmental ramifications for NAFTA member countries.

NAFTA includes weeds among its definition of pests.[188] A NAFTA member country faced with the problem of a new breed of herbicide-resistant weed will therefore need to assess the risks associated with this new pest and adopt or modify sanitary and phytosanitary measures to minimize its effects on plant, animal or human health.[189] Assessing risks associated with this new pest requires the member country to consider both the direct and the indirect effects of the new pest on the surrounding environment.[190]

Because the number of possible indirect relationships is potentially enormous, the indirect effects a herbicide-resistant weed has on its surrounding environment is virtually impossible to anticipate.[191] The experiments of Gregor Mendel demonstrated the generation-skipping quality of some genetic traits.[192] Because the effects of introducing a foreign plant species into the environment may continue indefinitely,[193] assessing the risks presented by the spread of herbicide-resistant weeds will a difficult if not impossible task for the member country accomplish. No technology yet exists to assist the member country in its determination.[194]

NAFTA requires member countries to base risk assessments on scientific principles.[195] The existing lack of scientific principles relative to deliberate release will make it impossible for a member country to complete its risk assessment. An incomplete risk assessment will not, however, estop a member country from adopting sanitary and phytosanitary measures to deal with the problem of the rampant herbicide-resistant weeds. It may take advantage of the NAFTA provision which provides an exception to the requirement that sanitary

187. *See supra* text accompanying note 46.
188. *See supra* note 124.
189. *See supra* note 125 and accompanying text.
190. *See supra* note 126 and accompanying text.
191. *See supra* text accompanying notes 38, 41-42, & 47.
192. *See supra* note 9.
193. *See supra* note 49.
194. *See supra* note 42. This can also be inferred from the recently established USDA grant program seeking information to assist federal agencies in making scientifically based decisions on the effects of deliberate release. *See supra* note 115.
195. *See supra* note 139 and accompanying text.

and phytosanitary measures adopted by member countries be supported by a risk assessment using scientific principles.[196]

NAFTA allows member countries to adopt provisional measures when relevant scientific information is not available to complete a risk assessment.[197] This provision does not, however, give the member country *carte blanche* to regulate herbicide-resistant weeds based upon speculation of impending deleterious developments. Any provisional measures adopted to mitigate the effects of the rampant herbicide resistant weeds must be based upon other relevant information, including that available through international or North American standardizing organizations.[198] The NAFTA provisions regarding harmonization, unnecessary barriers to trade and discrimination are also all applicable.[199] NAFTA member countries with export interests in the agricultural products derived from the release site will need to be informed of the changing conditions and the measures adopted to deal with the changes.[200]

Any provisional measures adopted to deal with problems at the release site will have to be frequently reassessed and modified to assure that they remain effective in light of any changes in the incidence of pests as a result of the deliberate release.[201] Exporting member countries will also have to make continued alterations in their schemes regulating acceptance of agricultural products from the released area.[202] The economic burden of regulation for both sides is potentially enormous. Depending on the severity of problems that develop at the release site and the complexity of the measures necessary to mitigate these problems, trade may be stifled if not halted altogether.

The potential for deliberate release to create negative trade ramifications among NAFTA member countries elicits a need for a cooperative effort among NAFTA member countries deal with the issue of deliberate release before the problems arise. NAFTA member countries may need to develop and adopt special provisions to deal with a worst case scenario of deliberate release. A uniform policy would both ease some of the uncertainties associated with regulating deliberate release and enhance the cooperative nature of NAFTA.

IV. CONCLUSION

As it develops, biotechnology will have global economic and environmental ramifications. Countries should address the ramifications of genetic engineering with their collective wisdom. This approach will be more beneficial to the world than an egocentric view of any one country. Just as organisms are more than the sum of their genes, the planet is more than the sum of its countries.

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196. *See supra* note 139 and accompanying text.
197. *See supra* note 139 and accompanying text.
198. *See supra* note 139 and accompanying text.
199. *See supra* notes 134 & 139 and accompanying text.
200. *See supra* note 130.
201. *See supra* note 127 and accompanying text.
202. *See supra* note 130.

NAFTA represents a desire among the member countries for economic cooperation. Although the purpose of NAFTA as a trade agreement is predominantly economic in nature, the manner in which NAFTA eventually deals with regulating genetically engineered produce will have more than economic ramifications. Time will tell whether or not tampering with perfection will cost NAFTA member countries and the global population more than they bargained for.

Promises and perils accompany every new technology. Genetic engineering holds the promise to transform living organisms for the greater benefit of human beings. The peril of genetic engineering is the Frankenstein-conjuring mystique which accompanies the violation of taboos about meddling with life itself. Science may be exact, but it is not always correct. As with all other attempts of the human race to alter the planet to suit our convenience, the question is not of science, but of ethics.

Everything has a blueprint, an instruction manual of how it is put together. DNA is the blueprint for the living species of the earth, both flora and fauna, and these blueprints combine to make one blueprint of the ecosystem as a whole. Alteration of one component part will thus impact on for the whole.

The human race has deemed itself superior to all other living species of the earth. Rather than cultivate wisdom with this self-proclaimed superiority, the human race has chosen to forge the planet into a playground for its arrogance. Somewhere has been lost the humility of the roots of the human race, and if "[g]enetic engineering represents the ultimate negation of nature,"[203] it also represents the ultimate negation of the human race itself. "Nature never deceives us; it is always we who deceive ourselves."[204]

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203. APPLICATION OF BIOTECHNOLOGY, *supra* note 5, at 38 (quoting Jeremy Rifkin).
204. JEAN-JACQUES ROUSSEAU, EMILE OU, DE L'EDUCATION, pt. III (1762).
205. This article is dedicated to Birgit Svendsen.