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Genetically Modified Organisms

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GENETICALLY MODIFIED ORGANISMS

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I. INTRODUCTION

Genetically modified organisms (GMOs), also known as living modified organisms (LMOs), could solve many agricultural problems, such as food shortages and pesticide use.[1] A "living modified organism" is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[2] Scientists can now alter an organism by selecting the genes or traits they desire, rather than abiding by nature's selection process.[3] To date, biotechnology has already proven itself useful by increasing crop yields

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* This Comment was selected as the Best Comment for Spring 2000. To my parents, Rudy and Nancy Novotny, whose guidance, love, and support, throughout the years helped me achieve my goals.

1. *See* Interview by Lauren Thierry and Tony Guida, Hosts of *Market Review* with Tammy Shea, Environmental Activists, Gateway Green Alliance, and Ryan Utlaut, Bioengineering Farmer, Utlaut Farms (Feb. 21, 2000); *see also* Thomas O. McGarity, *International Regulation of Deliberate Release Biotechnologies*, 26 TEX. INT'L L.J. 423, 426 (1991) (discussing biotechnology's potential benefits).

2. Convention on Biological Diversity, Cartegena Protocol on Biosafety (last modified Oct. 23, 2000) <http://www.biodiv.org>.

3. *See* McGarity, *supra* note 1, at 426.

and reducing pesticide use by making plants resistant to pests.[4] For example, soybeans can be given genes from a virus, a soil bacterium and a petunia to make them resistant to insects; tomatoes can be given fish genes to delay the process of decomposition.[5]

However, research on biotechnology has not focused on safety concerns.[6] Because of scientific uncertainty as to its effects on the environment and human health, this technology has come under heated debate in the international community as to how it should be regulated.[7] This commentary will examine the unique problems GMOs have created for the international legal community by looking at the newly drafted Biosafety Protocol[8] and its adequacy in dealing with agricultural biotechnology. This commentary will also focus on the Protocol's effect on national regulations and multi-national trade.

II. BACKGROUND

The U.S. Department of Agriculture reports that farmers in the United States are growing increasing amounts of GMO produce: about one-third of corn production and fifty percent of soybean production come from GMO seed.[9] Corn and soybeans are used in many processed foods. For instance, corn sweeteners are used commonly in sodas, breakfast cereals, and granola bars.[10] Plus, there is a lot of money invested in GMOs. Even the United States government has funded some research and development of GMOs. The government has spent more than US $3.4 billion supporting these projects.[11]

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4. *See id.*

5. *See* Marcia Herman-Giddens, Editorial, *Beware Foods Produced With "Engineered" DNA*, HERALD-SUN (Durham, N.C.), Feb. 23, 2000, at A12. Little is known about the short or long-term effects on people, animals, insects, or the environment. *See id.*

6. *See* McGarity, *supra* note 1, at 430.

7. *See id.* at 434.

8. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2.

9. *See* Yoshiaki Sato, *Consumer Reaction Hampers GM Food Progress*, THE DAILY YOMIURI (Tokyo), Feb. 24, 2000, at 5, *available in LEXIS, News, by Individual Publication.* A Washington, D.C.-based think tank said that 40% more food would be needed by 2020 because of projected population growth. *See id.* GM technology might help to meet the demand for more food. *See id.*

10. *See* Alison Arnett, *A La Carte; Are You Buying Altered Foods?*, BOSTON GLOBE, Feb. 23, 2000, at E1. "Soy is not only in tofu products, such as gardenburgers but also in many other items, from baby formula to many kinds of cooking oils. *Id.*

11. *See* Judy Kim, *Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms*, 16 FORDHAM INT'L L.J. 1160, 1160 (1993). *See generally* Lee Egerstrom, *Scientists' Debate Over Altered Crops Leaves Many Waiting for Evidence*, ST. PAUL PIONEER PRESS, Feb. 20, 2000, at A4. "Multinational chemical and pharmaceutical firms have spent more than $100 billion buying and consolidating seed genetics companies over the past five years in a race to lead the biotechnology revolution. Financial markets

One problem is that no one knows how the consumption of GMOs may affect human health.[12] Many producers and suppliers are responding to public fears that GMOs may adversely affect human health.[13] For example, Frito-Lay, a giant producer of corn snacks, and Seagram, one of the largest distillers, told its suppliers that it would not buy GM corn this year.[14] Many European consumers want to ban imports of GM crops altogether.[15] Even though no clear scientific evidence has proven GM crops to be harmful, farmers are wondering if they will have problems in selling their GMO harvest to a world concerned about the consequences to human health and the environment.[16]

To develop this technology, GMOs must be tested in the field, not just in the laboratory. However, some scientists are concerned that this GMO field testing may cause environmental problems.[17] "Deliberate release" is the term commonly used for the introduction of GMOs into the environment.[18] Scientists believe that the deliberate release of GMOs is too environmentally risky and could lead to genetically engineered genes spreading and recombining out of control.[19] These genes could transfer their genetically engineered traits to wild relatives and destroy indigenous species.[20] There could be other unexpected consequences. For example, scientists at Cornell University found that monarch butterflies were dying after eating milkweed plants, the monarch's favorite food, which were covered with GMO corn plant pollen.[21] The corn plant had originally had its genes altered to resist pests, but the pollen, which can drift on to other plants, indiscriminately killed non-targeted insects, too.

Due to these concerns, the United Nations created the Convention on Biological Diversity during the United Nation's Conference on the Environment and Diversity (Earth Summit) in Rio De Janeiro in 1992.[22]

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have also embraced biotechnology because of its potential for creating extremely profitable products." *Id.*

12. *See* Interview with Tammy Shea, *supra* note 1.

13. *See* Arnett, *supra* note 10, at E1.

14. *See* Julian Borger, *U.S. Farmers Desert GM Crops*, THE GUARDIAN, (London) Feb. 17, 2000, at 3. Farmers are responding to public fears by planning to plant sixteen percent less GM corn than they did last year. *See id.*

15. *See* Glenn Hess, *U.N. Countries Sign a Landmark Accord to Regulate Trade in Biotech Foods*, CHEMICAL MARKET REPORTER, Feb. 7, 2000, at 1.

16. *See* Borger, *supra* note 14, at 3.

17. *See* Kim, *supra* note 11, at 1160.

18. *See id.*

19. *See* DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 997 (David L. Shapiro ed., Foundation Press 1998) (1961).

20. *See id.*

21. *See* Egerstrom, *supra* note 11, at A4.

22. *See* Magen Griffiths, *Land and Resource Management: Biosafety Protocol*, 1998 COLO. J. INT'L ENVTL. L. & POL'Y 113, 114. The primary challenge to creating the Protocol's regulations

This Convention was established to draft a legally binding protocol, which would regulate transboundary shipment and use of GMOs.[23] On January 29, 2000, the members of the Convention finally presented a final draft of the Biosafety Protocol for ratification.[24] The Protocol's goals are to harmonize international regulations for the deliberate release of GMOs into the environment, to encourage the development of GMOs, to promote international trade, and to protect human health and the environment with common safety standards.[25]

III. STATUS QUO

The deliberate release of GMOs is currently regulated by individual governments.[26] In general, nations have produced different types of regulations for GMOs, such as process-oriented regulations and product-specific regulations.[27] Some countries do not regulate deliberate release of GMOs at all. There are several advantages and disadvantages to each of these methods.

Process-oriented regulations view genetic engineering as a risk, and regulate the process of biotechnology and the end-product.[28] For example, Japan,[29] Denmark and Germany have created new laws to deal specifically with biotechnology.[30] Most of these laws include approval procedures that set safety standards.[31] These laws also provide for civil liability of manufacturers, and for criminal and civil penalty provisions to promote enforcement.[32] Even with stringent regulations, these countries have maintained strong biotechnology industries.[33]

However, there are some drawbacks to process-oriented regulations. Biotechnology industries in these countries fear for their competitiveness

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was that industrialized countries favored the adoption of voluntary guidelines; whereas, developing countries and many nongovernmental organizations wanted a binding biosafety protocol. *See id.*

23. *See id.* at 114. "Genetic engineering allows farmers to use less land to produce more food." *See id.* at 113.

24. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2.

25. *See id.* art. 1.

26. *See* Kim, *supra* note 11, at 1161-62.

27. *See id.* at 1170.

28. *See id.*

29. *See id.* at 1174.

30. *See id.* at 1171-72 (stating that strict measures were adopted in Denmark and Germany.) In Germany, the strict measures were adopted partly due to pressure from Green Party and other environmental activists. *Id.*

31. *See id.* at 1173.

32. *See* James T. O'Reilly, *Biotechnology Meets Products Liability: Problems Beyond the State of the Art*, 24 HOUS. L. REV. 451, 487-89 (1987) (recommending that liability be defined by statute for drugs and other biotechnology products).

33. *See* Kim, *supra* note 11, at 1174.

in international markets because the laws sometimes slow genetic research and development.[34] For instance, the Genetic Technology Law in Germany includes a provision, which requires public hearings for objections.[35] These public hearings can significantly delay GMO research. Applying this provision, a town in Germany had over 16,000 objections, which were made in response to a company's plans to test GMO petunias in an open field.[36] Thus, these public hearings and strict regulations can have an effect on the development of GMOs and may dissuade research scientists from testing GMOs in countries with process-oriented regulations.[37] These scientists would most likely go abroad to countries with less severe restrictions.[38]

In contrast, product-specific regulations are less stringent than process-oriented regulations because these regulations do not focus on the techniques used during GMO development, but rather on the use of the GMO end-product, such as foods or pesticides.[39] For instance, the United States interpreted pre-existing laws to regulate GMOs.[40] In 1986, the Coordinated Framework for Regulation of Biotechnology was created to divide the environmental regulation of biotechnology among several different federal agencies.[41] For example, the EPA regulates the introduction of GMOs into the environment.[42] The FDA reviews the safety of GMO food products before marketing is allowed.[43] The USDA regulates

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34. *See id.* at 1173.

35. *See id.* The author states: "The German National Parliament passed the process-oriented Genetic Technology Law in 1990. The Genetic Technology Law permits the release of genetically engineered organisms into the environment with the approval of the Federal Health Authority. ('Bundesgesundheitsamt'). Approvals depend upon the safety classification of the deliberate release." *Id.* at 1172-73.

36. *See id.* at 1173. The law reflects the impact of political pressure exerted by public groups. *See id.* at 1174.

37. *See id.*

38. *See id.* at 1173-74.

39. *See id.* at 1177.

> Although several federal agencies now regulate biotechnology, for nearly a decade, the National Institutes of Health (NIH) assumed primary responsibility for the safety of genetic engineering. The NIH first developed guidelines for research involving rDNA in 1976. These guidelines were designed to ensure the safety of laboratory work and to prevent the accidental escape of rDNA microorganisms.

Id. at 1178.

40. *See id.*

41. *See* Ruth E. Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 563 (1986) (discussing the current regulations as it applies to biotechnology).

42. *See id.* at 564.

43. *See id.*

the agricultural aspects of biotechnology research, such as the release of GMO plants, animals, and microorganisms.[44]

However, there are some drawbacks to product-specific regulations. One problem is that three separate agencies have jurisdiction over similar regulatory provisions which is not very efficient. Some commentators believe that a centralized agency to regulate biotechnology would improve efficiency, because then, the agency could focus on biotechnology issues and become experts in the field.[45] The second problem is that the pre-existing statutes, which are being used to regulate biotechnology, were originally created to regulate products unrelated to bioengineered substances.[46] These statutes do not regulate GMOs as a potential threat to the environment and human health.[47]

In contrast to countries with process-oriented or product-specific regulations, most developing countries do not have any regulations pertaining to biotechnology.[48] Because they do not have any regulations, some developing countries have become test sites for researchers, who are trying to escape the strict regulations in their own countries.[49] This may be a disadvantage to the developing country because scientists do not know the effects of GMOs on the environment or human health.[50] However, some developing countries, such as South Korea and Taiwan, are not concerned about the possible adverse effects on the environment or health, and promote the biotechnology industry for the income it generates.[51] Thus, they purposefully do not create any regulations. On the other hand, some countries such as several Latin American, Caribbean, and Eastern European nations are still learning how to regulate GMOs.[52]

Because individual governments have different methods of regulating GMOs, it is difficult to set up a system for international trade.[53] It is hard to know what one country requires and what another does not. In sum, an

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44. *See* Gary Marchant, *Modified Rules for Modified Bugs: Balancing Safety and Efficiency in the Regulation of Deliberate Release of Genetically Engineered Microorganisms*, 1 HARV. J.L. & TECH. 163, 170 (1988) (discussing dissatisfaction with the U.S. regulatory scheme for biotechnology).

45. *See* Harlow, *supra* note 41, at 555.

46. *See* Kim, *supra* note 11, at 1178.

47. *See id.* at 1180.

48. *See* HUNTER et al., *supra* note 19, at 997.

49. *See* Kim, *supra* note 11, at 1184.

50. *See* HUNTER et al., *supra* note 19, at 997.

51. *See* Peter Newmark, *Pacific Rim Tactic: U.S. Partners Now, Worldwide Bio-Markets Later*, BIOTECHNOLOGY NEWSWATCH, Sept. 19, 1988, at 7.

52. *See* Kim, *supra* note 11, at 1183.

53. *See* McGarity, *supra* note 1, at 437.

international agreement to harmonize the various nations' regulations is needed to help facilitate trade and to protect the environment.[54]

IV. ANALYSIS

On January 29, 2000, the Biosafety Protocol was finally drafted and sent for ratification after five years of talks[55] by the members of the Convention on Biological Diversity, a part of the United Nations.[56] More than 130 countries participated in the Convention.[57] However, the United States is not a party to the Convention or the Biosafety Protocol, because the United States favors voluntary guidelines.[58] The objectives of the Biosafety Protocol are to ensure the safe transfer, handling, and use of GMOs during transboundary[59] transport, because GMOs may have adverse effects on human health and the environment.[60] Basically, the Protocol focuses on the protection of the environment by regulating the deliberate release of GMOs, yet promotes trade by requiring scientific evidence to support the more protective regulations.

A. *Basic Provisions*

For an overview, the Biosafety Protocol requires several procedures to be completed before any GMO products may be shipped. The Protocol requires notification, advance informed consent, and documentation for each shipment containing GMOs.[61] These procedures only relate to transboundary shipments.[62] Countries may still have different internal regulations.[63]

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54. *See* Kim, *supra* note 11, at 1185.

55. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2.

56. *See* Griffiths, *supra* note 22, at 114.

57. *Caution Needed*, THE ECONOMIST NEWSPAPER, LTD., Feb. 5, 2000, at 5. The concern over potential health risks has prompted the EU to ban certain foods containing GMOs, such as beef that contains hormones or meat from livestock fed with genetically-altered feed. *See id.*

58. *See* Griffiths, *supra* note 22, at 117.

59. Convention on Biological Diversity, Cartagena Protocol on Biosafety, *supra* note 2, art. 3(k). Article 3(k) defines "transboundary movement" as the "movement of a living modified organism from one Party to another Party," which also extends to movement between Parties and non-Parties. *Id.*

60. *See id.* art. 4. This Protocol does not cover "contained use" of GMOs. In Article 3(b), "contained use means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with . . . the external environment." *Id.*

61. *See id.* arts. 7-9.

62. *See id.*

63. *See id.* Article 11, paragraph 4 states that a "[p]arty may take a decision on the import of living modified organisms intended . . . under its domestic regulatory framework that is consistent with the objective of this Protocol." *Id.*

First, there are several procedures to follow before an exporter can ship its GMO products. The notification provision in Article 8[64] requires an exporter to send information to the importer, stating that the exporter wants to ship its GMO products to their country, and that it will send all the information about the product required by Annex I.[65]

Next, the importer must tell the exporter it has received the notification.[66] Then, the importing country is given 270 days to study the information and to decide whether to accept the GMO products based on risk assessments and scientific evidence.[67] This is known as advance informed consent.[68] To decide whether to accept a GMO product, an importer may use their own existing regulations.[69] Developing countries who do not have regulations are given extra time to study risk assessments and are given the opportunity to ask for more information.[70] Article 7 specifies that an advance informed agreement shall apply prior to the first intentional transboundary movement of GMOs.[71] Therefore, the advance informed agreement only applies to the first shipment of GMO intended for release in the environment, instead of each shipment.[72]

Even though these provisions would help ensure the safe release of GMOs, there are several problems with these procedures. First, countries who do not have regulations[73] in place will have to spend a lot of time and money to completely change their shipping system to comply. Second, the advance informed consent procedure[74] gives the importing country a lot of

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64. *See id.* art. 8.

65. *See id.* annex 1. Annex I lists the information required in notifications under Articles 8, 10, and 13. *See id.*

66. *See id.* art. 9.

67. *See id.* art. 10. Article 10 pertains to the procedure for deciding whether to accept a GMO export. *See id.*

68. *See id.* art. 7. Article 7 pertains to the application of the advance informed agreement procedure. *See id.*

69. *See id.* art. 14. Article 14 states that any Party may determine that its domestic regulations shall apply with respect to specific imports to it. *See id.*

70. *See id.* art. 11. Article 11 states that a

> developing country Party, in the absence of domestic regulatory framework, declare through the Biosafety Clearing-House that its decision prior to the first import of a GMO, according to a) a risk assessment; and b) a decision made within a predictable timeframe, not exceeding two hundred and seventy days. However, if the Party does not communicate its decisions within the timeframe, it will not imply its consent, unless otherwise specified by the Party.

Id.

71. *See id.* art. 7.

72. *See id.*

73. *See* Kim, *supra* note 11, at 1170.

74. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2.

time to study the risk assessments,[75] which may be considered a trade restriction. Third, even though the members to the Convention say the Protocol is legally binding,[76] it may be hard to enforce. Several countries, such as the United States, are not parties to the Protocol and are not obliged to follow the Protocol.[77]

B. *Environmental Provisions*

The GMOs used for release into the environment, such as GMO seeds, are regulated stringently. Article 18 paragraph 2(c) specifies that for transboundary movements containing GMOs that will be released into the environment, "each Party shall take necessary measures to require that the GMOs are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards."[78] Article 18(3) also states that at the next meeting of the members, the drafters will try to develop specific standards for handling, packaging, and transporting GMOs.[79]

The problem with this provision is that it applies too many vague conditions. First, the phrase "handled, packaged and transported under conditions of safety"[80] does not explain how these GMOs should be sent. Perhaps once Article 18(3) is completed, it will be apparent how to interpret these phrases. Second, the phrase "taking into consideration relevant international rules"[81] implies that the GMOs should be shipped according to international standards. The problem is that these standards are not yet constructed.

C. *Health Provisions*

The GMOs used for food, feed, or processing are not as strictly regulated. Article 18 paragraph 2(a) requires documentation to accompany GMOs intended for use as food, feed, or processing, that clearly identifies that they "may contain" GMOs and are not intended for the intentional introduction into the environment.[82]

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75. *See id.* art. 15. Article 15 pertains to risk assessments. *See id.* Annex III states that the objective of a risk assessment is to identify and evaluate the potential adverse effects of GMOs in the potential receiving environment. *See id.*

76. *See* Griffiths, *supra* note 22, at 115.

77. *See id.* at 116.

78. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2.

79. *See id.* art. 18.

80. *See id.*

81. *See id.*

82. *See id.* Article 18 outlines the procedure for GMOs intended for direct use as food, feed, or processing. *See id.*

This provision may be beneficial for product-specific countries,[83] like the United States, because the documentation only specifies that the shipment "may contain" GMO products.[84] For example, farmers in the United States currently mix GMO food with conventional varieties.[85] It would be very expensive and time-consuming to separate all these shipments.[86] However, farmers may want to separate GMO food if process-oriented countries, such as the European Community, will not buy it.[87]

D. *Trade Provisions*

To help facilitate trade, Article 20 tries to unify these new international regulations by creating an internet-based Biosafety Clearing-House.[88] The Clearing-House will facilitate the "exchange of scientific, technical, environmental and legal information on GMOs; and assist parties to implement the Protocol."[89] This Biosafety Clearing-House will help facilitate trade by providing countries access to information on other countries' laws, advance informed agreements, import decisions, multi-national agreements, and prior risk assessments for GMOs.[90]

The main problem with this provision is the massive amounts of paperwork it will continually generate. It will also take a long time to initially set up this system. If the Clearing-House[91] will keep track of all GMO-related documents for over 130 parties,[92] it may soon become overloaded with information. Yet, if the Clearing-House[93] is prepared to meet this burden, the information would be very helpful in unifying the current system.

V. CONCLUSION

International guidelines are needed to help regulate the trade of GMOs between countries, while also providing for the protection of the

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83. Kim, *supra* note 11, at 1177.
84. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2, art. 11.
85. *See* Fred Pearce, *Let Battle* Commence, NEW SCIENTIST, Feb. 6, 2000, at 5.
86. *See id.*
87. *See id.*
88. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2, art. 20.
89. *Id.*
90. *See id.*
91. *See id.*
92. *Caution Needed*, *supra* note 57.
93. Convention on Biological Diversity, Cartegena Protocol on Biosafety, *supra* note 2.

environment and health.[94] Currently, the existing regulations are not unified and most do not provide for the safe deliberate release of GMOs into the environment.[95] Plus, scientists do not yet know the effects GMOs will have on human health or the environment.[96] The Biosafety Protocol may finally provide some guidance for countries to regulate GMOs. The Protocol's framework provides for some protective measures for the environment, while still allowing trade.

However, if trade interests continue to rule over environmental and human health interests, the potential adverse effects could be costly.[97] There needs to be more scientific tests concerning safety. The law has lagged behind technology long enough. The international legal and scientific communities must combine their efforts to adequately address this problem and promote the safe use of GMOs until more is known about them.

94. *See* McGarity, *supra* note 1, at 434.

95. *See id.*

96. *See* JULIE HILL, INTERPRETING THE PRECAUTIONARY PRINCIPLE 174 (James Cameron & Timothy O'Riordan eds., Earthscan) (1994).

97. *See* McGarity, *supra* note 1, at 430.