UIC Law Review

Volume 35 | Issue 3 Article 4

Spring 2002

Reaping the Benefits of Agricultural Biotechnology Through Uniform Regulation, 35 J. Marshall L. Rev. 433 (2002)

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COMMENTS

REAPING THE BENEFITS OF AGRICULTURAL BIOTECHNOLOGY THROUGH UNIFORM REGULATION

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As the technological gap between developed countries and developing countries increases, so does the nutritional gap. Instead of conveniently running out to the local grocery store to grab a nutritious meal, many malnourished children in developing countries stand, waiting in long lines at humanitarian aid stations for a small bowl of rice. Despite the research efforts of international organizations[1] to improve the availability of food

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1. *See generally* Future Harvest, *About Us*, *at http://www.futureharvest.org/about/index.shtml* (last visited Sept. 27, 2001). The organization's mission statement is as follows:

> [Future Harvest works to] promote awareness and educate the general public and decision makers about the importance of food production and the role of agricultural science in meeting the human and environmental challenges of today and tomorrow, and build financial support for scientific research and charitable projects that bring the results of this research to rural communities, farmers, and their families in the developing countries.

Id.; International Food Policy Research Institute, *Mission Statement*, *at http://www.ifpri.org/* (last visited Sept. 27, 2001). The organization's mission statement is as follows:

> [T]o identify and analyze policies for sustainably meeting the food needs of the developing world. Research at IFPRI concentrates on economic growth and poverty alleviation in low-income countries, improvement of the well being of poor people, and sound management of the natural resource base that supports agriculture. IFPRI seeks to make its research results available to all those in a position to use them and to strengthen institutions in developing countries that conduct research relevant to its mandate.

Id.

sources,[2] reports from the World Health Organization ("WHO") continue to document several micronutrient malnutrition problems throughout the developing world.[3] One million of those young children waiting in line will die.[4] Another 250 million children[5] will go blind because of vitamin A deficiency.[6]

Developing countries could stop much of these premature deaths and disabilities by introducing genetically modified crops, which are nutritionally altered to address such deficiencies. For example, the "golden rice" research project modified rice plants to produce a grain containing increased levels of beta-carotene, which the human body will then convert into vitamin A.[7] Developing countries facing vitamin A deficiencies often use rice as a dietary

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2. *See* Future Harvest, *Gloomy Outlook for Malnourished Children*, News Release (Aug. 28, 2001), *at http://www.futureharvest.org/health/impact_release.shtml* (reporting that, according to a news report from the International Food Policy Research Institute, without more aggressive measures taken to protect against child malnutrition, it is likely that progress in this area will slow over the next twenty years).

3. *See generally* World Health Organization, *Iron Deficiency Anaemia, Assessment, Prevention, and Control*, World Health Organization, (2001), *at http://www.who.int/ nut/documents/ida_assessment_prevention_control.pdf* (discussing ways to control iron deficiency); World Health Organization, *Micronutrient Deficiencies in Africa, WHO Intercountry Workshop for National Programme Managers*, Regional Office for Africa in Collaboration with ICCIDD, (1998), *at http://www.who.int/nut/documents/ assessment_idd_monitoring_elimininationpdf* (discussing ways to control iodine deficiency).

4. *See* Robert Lee Hotz, *California and the West Rice Laced with Vitamin A Created Nutrition: Scientists Hope to End Deadly Diet Deficiency Among World's Poor Children*, L.A. TIMES, Jan. 14, 2000 (reporting "golden rice" was infused with bacteria genes to increase the vitamin A content in the world's most common dietary staple, which researchers hope will end a deficiency that kills one million children per year), *available at* 2000 WL 2200721.

5. *See* Guy Gugliotta, *Genetics Team Unveils a Strain of 'Golden Rice'*, HOUS. CHRON., Jan. 14, 2000 (noting that "golden rice" allows a rice plant to produce beta-carotene that the human body converts to vitamin A, which could impact over 250 million children worldwide), *available at* 2000 WL 4274992

6. *See* World Health Organization, *Micronutrient Deficiencies: Combating Vitamin A Deficiency*, *at* http://www.who.int/nut/vad.htm (last updated March 13, 2002) (acknowledging that vitamin A deficiency is the leading cause of blindness among young children in most developing countries); *see also* World Health Organization, *Blindness and Visual Disability*, Fact Sheet No. 144, (Feb. 1997), *at http://www.who.int/inf-fs/en/fact144.html* (noting that vitamin A deficiency often leads to blindness (xerophthalmia) in approximately 350,000 children per year and additionally, vitamin A deficiency can cause night blindness among pregnant and lactating women).

7. Hotz, *supra* note 4; Gugliotta, *supra* note 5; *see also* Associated Press, *'Golden Rice' Symbolizes Biotech Clash*, THE NEWS & OBSERVER, June 26, 2001 (discussing the clash between supporters who favor "golden rice" for its ability to help developing nations stave off malnutrition, and critics who oppose golden rice and genetically modified foods as a food supply health hazard), *available at* 2001 WL 3471271.

staple. This "golden rice" could help countries combat malnutrition[8], saving millions of children each year.

However, genetically modified crops are not without opposition.[9] "Beware 'franken-food'"[10] and "franken-corn"[11] are common rally cries from consumer groups, environmental groups,[12] and members of the European Union ("E.U.").[13] Concern about food safety panics many members of the public, turning them away from the potential uses of genetically modified products. We should not allow the panicked few to overshadow the enormous potential agricultural biotechnology can offer the world.

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8. Gugliotta, *supra* note 5.

9. *See generally* Paul Elias, *New Rice Polarizes Biotech Gathering*, CHI. SUN-TIMES, June 26, 2001 (reporting that the world's largest biotech conference held in San Diego was met with heavy protesters complaining that businesses are releasing genetically modified food products without long-term scientific testing concerning their effects), *available at* 2001 WL 7235403; Margery Eagan, *Worried Food Will Kill You? Me Neither*, B. HERALD, Mar. 28, 2000 (reporting on the Bio 2000 Protest March regarding "mutant tomatoes" in Boston), *available at* 2000 WL 4320829; Helen Jung, *WTO Notebook—Most Know What's Going On - But Others . . .*, SEATTLE TIMES, Dec. 1, 1999 (reporting on protests at the World Trade Organization meeting in Seattle), *available at* 1999 WL 6302291.

10. *See* Debra Saunders, *Thereafter, A Fearful New World*, DENVER POST, June 28, 2001 (reporting "Frankenfood" protestors at the Biotechnology Conference in San Diego carried signs that read "Biotech Perverts, Get Out of Our Genes"), *available at* 2001 WL 6755756.

11. Troy Goodman, *Should You Fear Franken-corn?*, (Nov. 10, 2000), *at* http://www.cnn.com/2000/foodnews/11/10/starlink/index.html (discussing the evidence available concerning the genetically modified corn protein Cry9C discovered in taco shells).

12. *See generally* Greenpeace, *Genetic Engineering*, *at http://www.greenpeace.org/~geneng/* (last visited Sept. 27, 2001) (advocating a stance against genetically engineered food); Center for Food Safety, *at http://www.centerforfoodsafety.org/* (last visited Sept. 27, 2001):

> Specifically, the five major goals of CFS include: 1. Ensuring the testing, labeling and regulation of genetically engineered foods; 2. Preserving strict national organic food standards; 3. Preventing potential animal and human health crisis caused by food borne illness—including "mad cow" disease; 4. Preventing the expansion of food irradiation; and 5. Educating the public on the hazards of industrial agriculture.

Sierra Club, *Genetic Engineering Report*, (revised March 2001), *available at http://www.sierraclub.org/biotech/report.asp*. The Sierra Club's Genetic Engineering Committee ("GEC") was created to investigate ways to mobilize the strength of Sierra Club, because it is the "largest grassroots environmental organization in the U.S." *Id.* Specifically, the GEC researches ways to educate the public and influence regulatory reform to "protect the natural environment and human health from the threats posed by the release of genetically engineered organisms." *Id.*

13. *See* Chet Raymo, *Modification Part of Balanced Chain*, B. GLOBE, Sept. 4, 2001 (observing that planting a genetically modified crop anywhere in Europe will instantly draw crowds of protestors waving "Frankenfood" signs).

This Comment explains how proper biotechnology regulation can help alleviate fears about genetically modified crops. Part I of this Comment details the liberal approval regulations of genetically modified crops in the U.S. and the commercial approach the U.S. has taken. Part II of this Comment details the strict regulatory approval of the E.U. and the precautionary approach to which the E.U. adheres. Part III analyzes the two approaches and how they affect new product approvals and international trade. Part IV proposes adoption of a hybrid regulatory approach that would borrow from both the U.S. and E.U. regulatory systems to address food safety issues, while still allowing for timely product approval.

I. THE UNITED STATES REGULATION: LAX CAPITALISM

In 1986, the U.S. created the Coordinated Framework for Regulation of Biotechnology ("Framework").[14] Relying partly on a recent United States Supreme Court case,[15] the Framework combined agricultural biotechnology regulation under three separate agencies: the United States Department of Agriculture ("USDA"), the United States Environmental Protection Agency ("EPA"), and the United States Food and Drug Administration ("FDA").[16] These three U.S. regulatory agencies use existing statutes[17] to conform genetically modified organisms ("GMOs") into a three-agency system.[18] This approach[19] is more product-oriented

14. *See* Stanley H. Abramson & J. Thomas Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L. J. 241, 245 (2001) (outlining the history and procedures of the Framework and its application in recent biotechnology approval).

15. Diamond v. Chakrabarty, 447 U.S. 303 (1980). A researcher developed a genetically modified bacterium that could metabolize hydrocarbons that could be beneficial in cleaning up crude-oil spills. *Id.* at 305. When the researcher attempted to patent his invention, the Patent and Trademark Office rejected his claim on the grounds that living organisms could not be patented. *Id.* at 306. The U.S. Supreme Court reversed that ruling because the broad language of the Patent Act was designed to include genetically modified organisms as patentable subject matter. *Id.* at 313.

16. *See* A. Brian Endres, *'GMO': Genetically Modified Organisms or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453, 479 (2000) (noting that each agency controls a different aspect of genetically manufactured organisms ("GMOs") under separate regulations).

17. Abramson & Carrato, *supra* note 14, at 245. The Court realized that pre-existing statutes were not drafted with biotechnology in mind; however, the decisions not to create new statutes was based in part on *Diamond v. Chakrabarty*, "in which the Supreme Court upheld the patentability of a genetically engineered microorganism under the Patent Act originally drafted by Thomas Jefferson." *Id.*

18. *See* Ved P. Nanda, *Genetically Modified Food and International Law—The Biosafety Protocol and Regulations in Europe*, 28 DENV. J. INT'L L. & POL'Y 235, 244-45 (2000) (discussing the approval process in the USDA).

and driven by economics, as opposed to the more process-oriented[20] approach that some members of the E.U. and other countries use.[21]

A. USDA: United States Department of Agriculture Regulations

The Animal Plant and Health Inspection Service, ("APHIS") of the USDA, has the authority to regulate and approve GMOs under the recently enacted Plant Protection Act.[22] The Plant Protection Act, which is a reorganization of the Federal Plant Pest Act[23] and Plant Quarantine Act,[24] took effect May 24, 2000.[25] Companies that develop new GMO plant varieties must submit a petition to APHIS showing that, based upon field trials, the plant is safe and poses no risk as a plant pest.[26] If APHIS determines that the GMO is not a plant pest, it will then issue a "determination of non-regulated status."[27] This means that the new GMO plant does not fall into a regulated category and farmers are free to plant the GMO.[28]

B. FDA: United States Food and Drug Administration Regulations

FDA regulatory authority is derived from one Act,[29] the

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19. *Id.* at 243.

> [According to the U.S. regulatory Framework, four] general principles apply: (1) existing laws are to regulate biotechnology; (2) the products of biotechnology and not the process are to be regulated; (3) the safety of a biotechnology product is to be determined on a case-by-case basis; and (4) a coordinated effort is to be undertaken between all the agencies involved in regulating biotechnology.

Id.

20. *See* Judy J. 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, 1160-1207 (1993) (outlining and critiquing various countries' approaches to regulation). The United States uses pre-existing laws to regulate the deliberate release of GMOs into the environment while Denmark and Germany use a process-oriented approach. *Id.* at 1170. The process-oriented approach enables a country to create new laws that deal specifically with a new GMO product as it arises. *Id.*

21. Nanda, *supra* note 18, at 243. The process-oriented approach implements new biotechnology laws to regulate GMO products. *Id.*

22. 7 U.S.C. §§ 7701-7772 (2002).

23. 7 U.S.C. §§ 150aa-150jj (repealed June 20, 2000).

24. 7 U.S.C. §§ 151-154 (repealed June 20, 2000).

25. Agricultural Risk Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 454.

26. 7 C.F.R. §§ 340.0-340.9 (2002).

27. 7 C.F.R. § 340.6 (2002).

28. Nanda, *supra* note 18, at 245.

29. *Id.*

Federal Food, Drug and Cosmetic Act ("FFDCA").[30] The FDA requires that "new additives in food . . . be demonstrated safe through standard scientific testing before being released into the open market."[31] However, the FDA does not require prior testing of traditional food crops that have not been significantly modified or altered.[32] The FDA characterizes genetically modified food products that are sufficiently similar to conventional foods as "generally recognized as safe" ("GRAS").[33] Despite the environmentalist contention that this determination is inadequate,[34] companies producing genetically modified foods do not need approval from the FDA to introduce such GRAS foods into the U.S. market,[35] and thus they may bypass some expense of the approval process.

The FDA does, however, issue guidelines to assist companies that usually consult the FDA before marketing their products.[36] If a new food product raises specific health concerns, the FDA may

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30. 21 U.S.C. §§ 301-395 (2001).

31. *See* Nanda, *supra* note 18, at 245 (outlining the safety standards of the Federal Food, Drug, and Cosmetic Act (FFDCA)). The FFDCA defines the term food additive as:

> [A]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . , if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use . . ..

21 U.S.C. § 321(s).

32. Nanda, *supra* note 18, at 245-46.

33. *Id.* at 246.

34. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 181 (D. D.C. 2000). Petitioners, a consumer interest group, challenged the FDA Policy Statement regarding genetically modified foods on six grounds. *Id.* at 170. Specifically it alleged the "FDA's presumption that rDNA-developed foods are GRAS and therefore do not require food additive petition under 21 U.S.C. § 321(s) is arbitrary and capricious." *Id.* The court refused to accept this reasoning because it determined that since the determination of GRAS status is within the "technical expertise" of the FDA, it couldn't be said that presumption was arbitrary or capricious. *Id.* at 177. The court held that the FDA Statement did not violate the FDCA or FDA regulations and therefore the court granted the government's motion for summary judgment. *Id.* at 181. *See also* Alicia T. Simpson, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?*, 19 TEMP. ENVTL. L. & TECH. J. 225, 242 (2001) (analyzing *Alliance for Bio-Integrity v. Shalala* and the consumer concern that sparked the lawsuit).

35. Nanda, *supra* note 18, at 245-46.

36. FDA, *Statement of Policy: Foods Derived From New Plant Varieties*, 57 FED. REG. 22,984, 22,984, (May 29, 1992) [hereinafter FDA Statement]; Nanda, *supra* note 18, at 246.

require, under the FFDCA, that a corporation perform a pre-market review before the FDA will approve the GMO.[37] Companies introducing the food product are under a legal obligation to ensure the food is safe, and as a result can be civilly[38] or criminally liable for introducing unsafe foods.[39] Additionally, the FDA has the authority to bar a food's introduction if it does not believe that the food is safe for the public market.[40]

C. *EPA United States Environmental Protection Agency Regulations*

EPA regulatory authority arises from two statutes:[41] Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")[42] and the Toxic Substances Control Act.[43] For example, if a plant has a characteristic similar to a pesticide, the EPA must then approve that plant.[44] FIFRA also requires companies to register genetically modified plants with the EPA if the plants display any pesticide-like characteristics.[45]

D. *U.S. Commercial Approach*

The first mainstream commercial use of agricultural biotechnology was the introduction of the recombinant-DNA and transgenic crops in the early 1990's.[46] Although many of those

37. FDA Statement, 57 Fed Reg. 22,987 - 22,989 (May 29, 1992); Nanda, *supra* note 18, at 246.

38. Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 REV. LITIG. 589, 590 (2001). As biotechnology increases, so will litigation. *Id.* at 590. Biotechnology is vulnerable to litigation because of its newness, lack of regulatory guidelines, media sensationalism, and opposition from anti-biotech organizations, and poor consumer perception. *Id.* at 594-603. The most common biotechnology liability theories are products liability, including strict liability, negligence and breach of warranty. *Id.* at 603-07. In addition, manufacturers of biotechnology products may be susceptible to alternative liability, market share liability or enterprise liability. *Id.* at 608-09. The authors point to three specific biotechnology lawsuits: the StarLink Corn litigation, the AIDS and Hemophilia drugs litigation, and the Fen-Phen litigation. *Id.* at 613-21.

39. FDA Statement, 57 Fed. Reg. at 22,988; Nanda, *supra* note 18, at 246.

40. Nanda, *supra* note 18, at 246.

41. *Id.* at 244. The EPA performs two main regulatory functions: 1) it "establishes maximum tolerance levels for pesticide residues in foods, [and 2)] before new microorganisms, which include intergeneric organisms derived through biotechnology, can be manufactured or imported, the EPA must be notified in accordance with the Toxic Substances Control Act." *Id.*

42. 7 U.S.C. §§ 136-136y (2002).

43. 15 U.S.C. §§ 2601-2629 (2002).

44. Nanda, *supra* note 18, at 244. "[T]he EPA . . . approve[s] pesticides derived from . . . bioengineered plants that contain Bacillus thuringiensis ("Bt"), which is toxic to certain [corn] pests." *Id.*

45. *Id.*

46. Abramson & Carrato, *supra* note 14, at 243.

products were met with anti-biotechnology resistance, agricultural biotechnology has become widespread and is generally acknowledged by U.S. consumers to be considered safe.[47] Since 1990, the U.S. has approved nearly 100 genetically modified products,[48] with fifty of these GMOs being plant varieties.[49]

One example of the negative impact of the U.S.'s liberal approval is StarLink Corn; a corn variety that contains a genetically modified protein called Bt Cry9C, which allows the plant to naturally protect itself from pests.[50] This protein is similar to a protein found in peanuts, which is a common allergen.[51] The product was approved by all three governmental agencies (USDA, EPA and FDA), for use in animal feed, but not for human consumption.[52] Although there was no evidence of a human allergic reaction, the regulatory agencies attempted to limit StarLink Corn's risk by confining it to animal consumption only.[53]

Some StarLink Corn was inadvertently mixed with food grade corn, and when traces of the genetically modified protein were detected in taco shells, these products were immediately pulled from grocery store shelves.[54] The resulting class action lawsuit filed by StarLink corn growers cost Aventis, the parent company

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47. Mary Lynne Kupchella, *Agricultural Biotechnology: Why It Can Save the Environment and Developing Nations, but May Never Get a Chance*, 25 WM. & MARY ENVTL. L. & POL'Y REV. 721, 731 (2001). Of the millions of acres planted with GMO crops in 1998, eighty-eight percent were planted in North America, while only one percent were planted in the E.U. *Id.* at 732.

48. Prepared Statement of Ambassador David L. Aaron, Under Secretary of Commerce for International Trade Before the Subcommittee on Trade of the House Committee on Ways and Means, July 28, 1998, *at* 1998 WL 12762839.

49. *See* EU/US: *Washington Recoils from Gene Food Fight*, EUR. REP., July 28, 1999 (noting the building tension between the rapid approval of fifty plant variety GMOs in the U.S. while the E.U. continues to lag behind), *available at* 1999 WL 8306732.

50. *See* Goodman, *supra* note 11 (discussing the evidence that the genetically modified corn protein Cry9C is toxic to the European corn borer, a common corn pest).

51. *See id.* (analyzing the similarity between the gene that was spliced into StarLink Corn and its relative similarity to a common peanut allergen). *See also* Peanut Advisory Board, *The Facts About Food Allergies*, (last visited Feb. 2, 2002), *at* *http://www.peanutbutterlovers.com/allergies/index.html* (warning that a small number of people allergic to the proteins found in peanut butter are susceptible to severe and potentially fatal anaphylactic shock).

52. *See* Goodman, *supra* note 11 (discussing the approval of StarLink Corn only for animal consumption although there were no reported cases of human allergic reactions to the Cry9c protein).

53. *Id.*

54. *See* FDA, Recall and Field Corrections: Foods—Class I, FDA Enforcement Report (Nov. 1, 2000), *at* http://www.fda.gov/bbs/topics/enforce/enf00666.html#star (recalling products that contained genetically modified StarLink Corn protein Cry9C).

and licensor of StarLink Corn, several million dollars.[55] Currently, Aventis is still defending lawsuits filed by other American corn growers alleging profit losses from the drop in corn prices after the incident.[56]

II. THE EUROPEAN UNION REGULATION: CLASSICAL EUROPEAN

In the E.U., the European Commission consolidated regulatory decisions by specifically adopting Council Directive 90/220 ("Directive 90/220") to deal with the release of GMOs into the European environment.[57] According to the procedure of Directive 90/220, approval of a GMO for release is required by all the member states before it can proceed into the open market.[58] This approval process is true for GMOs created in the E.U. or GMOs imported from other countries, primarily the U.S.[59]

A. The Directive: Council Directive 90/220/EEC

European Council Directive 90/220[60] focuses on the "deliberate release" of GMOs into the environment.[61] Directive 90/220 "seeks to provide a high level of protection throughout the community on health, safety, environmental and consumer protection and to ensure the safe development of industrial products utilizing GMOs."[62] Each member state is required to follow Directive 90/220 by appointing a competent authority and notifying this authority about the research risks of GMOs.[63] The duties of the

55. *See* Mike Glover, *Biotech Corn Deal Reached*, SAN ANTONIO EXPRESS-NEWS, Jan. 24, 2001 (reporting that Aventis agreed to settle the class action lawsuit for an undisclosed amount estimated to be $100 million to $1 billion), *available at* 2001 WL 5228144.

56. *See, e.g.*, Sutter v. Aventis Cropscience USA Holding, Inc., 145 F. Supp. 2d 1050, 1053-54 (S.D. Iowa. 2001); Dupraz v. Aventis Cropscience USA Holding, Inc., 153 F. Supp. 2d 1102, 1103 (D. S.D. 2001).

57. Endres, *supra* note 16, at 458-59; *see also* Julie Teel, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L.J. 649, 669 (2000). However, Directive 90/220 does not apply to GMOs that have been developed through common techniques and have a long safety record. *Id.*

58. *See* Nanda, *supra* note 18, at 255-59 (documenting the process and steps necessary to reach approval of a GMO in the E.U.).

59. *See* Endres, *supra* note 16, at 459-60 (noting that this strict approval process is causing a sharp decline in agricultural trade between the U.S. and E.U.).

60. Council Directive 90/220 of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L117/15) [hereinafter Directive 90/220].

61. Nanda, *supra* note 18, at 256.

62. *Id.*

63. *Id.* "Each member state is to designate the competent authority responsible for the implementation of the Directive and to ensure that such authority takes appropriate control measures for such implementation." *Id.* "Before deliberately releasing a GMO for research purposes, the person

competent authority include examining the notification, evaluating the risks, and providing written consent as a prerequisite for "deliberate release"[64] into the environment.[65]

After a release is completed, the requestor sends the result of the release (such as any potential risk to human health or the environment) to the competent authority.[66] The competent authority must then send a report to the European Commission, which forwards the report to other member states for their approval or rejection of the GMOs' release into each of their respective markets.[67]

Despite this very restrained approach, according to Directive 90/220, no member state of the E.U. is to "prohibit, restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive."[68] There have been several failed attempts by individual member states to further toughen restrictions regarding the release of GMOs, and to extend the reach of European regulations concerning GMOs.[69]

B. E.U. Precautionary Principle

The driving force behind this strict approach is public distrust of GMOs and public safety concerns.[70] The precautionary

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proposing such release must notify the competent national authority within the pertinent territory of the risks involved and the conditions and the environment in which the release is to take place." *Id.* at 257. *See also* Teel, *supra* note 57, at 669-70 (describing briefly the approval process under Directive 90/220).

64. Article 2 of Council Directive 90/220 defines "deliberate release" as "any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment." Directive 90/220. *See also* Julia Novotny, *Genetically Modified Organisms*, 13 FLA. J. INT'L L. 231, 233 (2001) (noting that the term "deliberate release" refers to the planned introduction of GMOs into the general environment, but some scientists still fear the risk of an accidental gene transfer to wild relatives).

65. Nanda, *supra* note 18, at 257.

66. *Id.* at 257; Council Directive 90/220, art. 8, 1990 O.J. (L117/15).

67. Nanda, *supra* note 18, at 257. The competent authorities send a summary of every notification to the Commission, and the Commission forwards these summaries to other member states. *Id.* The competent authorities inform the other member states and the Commission of whether the notification complies with this Directive 90/220. *Id.* If the release does not meet Directive 90/220's conditions it may be rejected. *Id.*

68. *Id.* at 258. *See also* Council Directive 90/220, art. 15, 1990 O.J. (L117/15).

69. Nanda, *supra* note 18, at 258-59.

70. *See* Endres, *supra* note 16, at 458 (noting that as a result of growing public skepticism in Europe over possible GMO risks, the "European Parliament's Committee on the Environment, Public Health, and Consumer

principle's premise is to protect the public food supply from potentially dangerous GMOs.[71] Inherent in the precautionary principle is that pro-active measures must be taken to reduce the risk of uncertain scientific dangers in GMOs.[72] This principle is strongly favored and supported by environmental groups[73] and stresses the difference in approaches to GMOs between the U.S. and the E.U.[74]

The criticism of the precautionary principle is that in the last decade, the E.U. has only approved fourteen GMOs for use in the market place, while the U.S., Japan, and Canada approved approximately one hundred GMOs for "general release."[75] Moreover, the E.U.'s overly cautious guiding principle has slowed policy changes and, in turn, deterred scientific research.[76] In addition, the precautionary principle has reduced agricultural trade between the U.S. and the E.U.[77]

III. ANALYSIS: TWO SYSTEMS OUT OF TUNE

The relaxed U.S. and the restrictive E.U. GMO regulatory

Protection adopted a proposal advocating a 'safety first' principle").

71. *Id.* at 457-59.

72. *See* Deborah Katz, *The Mismatch Between the Biosafety Protocol and the Precautionary Principle*, 13 GEO. INT'L ENVTL. L. REV. 949, 981-82 (2001) (discussing the Biosafety Protocol and the Precautionary Principle and the impact of the Precautionary Principle on transgenic plants).

73. *The Sierra Club Genetic Engineering Committee Report* (April 2000), *available at http://www.sierraclub.org/biotech/report.asp* (revised March 2001). Sierra Club's Genetic Engineering Committee strongly supports the precautionary principle in relation to biotechnology and GMOs and recognizes the flaws of the present risk assessment systems. *Id.* According to the Wingspread Consensus Statement on the Precautionary Principle, Jan., 1998, "[w]hen an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." *Id.* The conference participants addressed risk assessment as follows: "We believe existing environmental regulations and other decisions, particularly those based on risk assessment, have failed to protect adequately human health and the environment, the larger system of which humans are but a part." *Id.* The precautionary principle is primarily important for GMOs, because these technologies are so new and untested that the potential harm could be irreversible. *Id.* Once a GMO is released into the environment, it is impossible to recall the GMO. *Id.*

74. *See* Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L & COMP. L. 129, 141-74 (2000) (discussing the commercialized regulatory battle between the U.S. and E.U. and urging uniform international regulation).

75. Endres, *supra* note 16, at 469-70.

76. *See* Kupchella, *supra* note 47, at 733 (noting that "[t]he EU has been extremely slow to match scientific advances with the necessary related policy and regulatory adjustments.").

77. *See* Endres, *supra* note 16, at 460 (noting that "E.U. restrictions on genetically modified corn cost U.S. farmers $200 million in sales in 1998").

systems have left the global GMO regulatory system in disarray. Part A discusses the benefits and disadvantages of the U.S.'s laissez-faire attitude towards approval of GMOs. Similarly, Part B evaluates the benefits and disadvantages of the more precautionary approach to GMO regulation that the E.U. adopted. Part C discusses how the adoption of these systems, or variations on these systems, has had a splintering effect on GMO regulation throughout the world. Finally, Part D demonstrates how the fractured regulatory schemes are affecting the international trade of GMO products, the continued research of GMO products, and the unfortunate effect this is having on developing countries.

A. Critiquing the U.S. System

1. Benefits

The crux of the U.S. regulatory system is rooted in economic and business principles that focus mainly on profit.[78] The most beneficial aspect of the U.S. regulatory system is the liberal approval of GMOs.[79] Because corporations in the U.S. are heavily involved in the research and development of GMOs, they receive the most benefit in getting GMO approval.[80] In addition, the U.S. government has an interest in assisting GMO technology because it has invested billions of governmental dollars into these projects.[81] Easy approval leads to increased profits for corporations, and, in turn, funds future research and development projects for GMO products. Better GMOs will help increase crop yields, reduce pesticide use, and feed more people, which will aid U.S. trade.[82] As GMOs are introduced into the agricultural

78. *See* Lee Egerstrom, *Scientists' Debate Over Altered Crops Leaves Many Waiting for Evidence*, ST. PAUL PIONEER PRESS, Feb. 20, 2000 (noting that the U.S. financial markets have accepted biotechnology for its potential to create profitable GMO products), *available at* 2000 WL 14920878.

79. Kim, *supra* note 20, at 1179-82. From the time the U.S. Framework was instituted in 1986 to September 1991, APHIS had approved 181 permits for small-scale trial tests for genetically modified plants. *Id. See also* Marc Victor, *Precaution or Protectionism? The Precautionary Principle, Genetically Modified Organisms, and Allowing Unfounded Fear to Undermine Free Trade*, 14 TRANSNAT'L LAW. 295, 296 (2001) (recognizing that the USDA has approved fifty GMO plant varieties, but that the E.U. has only approved eighteen GMOs in the same amount of time).

80. *See* Egerstrom, *supra* note 78 (stating that multinational corporations have spent over $100 billion consolidating seed genetic companies and technology to lead the biotechnology race because of the potential for extremely profitable GMO products).

81. *See* Novotny, *supra* note 64, at 232 (noting that the U.S. government has invested over $3.4 billion in supporting GMO research projects).

82. *Id.* at 231. Biotechnology has already proven its efficiency by increasing crop yields and reducing the use of pesticides because some genetically modified plants can ward off pests on their own. *Id.* at 231-32.

system, the products increase efficiency and output, which help improve trade exports.[83]

2. Disadvantages

The main disadvantage of the U.S. regulatory system is the multi-agency approach and the confusion this divided system creates. Instead of meeting the regulatory agenda proscribed by each agency's statute, each agency has fallen short in some way. First, the FDA's statutory concern for comprehensive food safety[84] is not being met, as witnessed by the recent StarLink Corn incident.[85] Second, the EPA must determine whether the GMO will have an "unreasonable adverse effect" on the environment.[86] However, it is often impossible to determine the environmental contamination until after the product's release into the environment.[87] Finally, the USDA's objective is to regulate the release of GMOs in agriculture biotechnology research; however, StarLink Corn proved that even limited agency approval[88] is not necessarily appropriate for the release of every GMO product.

Moreover, having a multi-agency approval system is an inefficient use of agency resources.[89] The intricacy of the system creates gaps in the approval process because certain products do not require approval from each agency or any agency.[90] Overall,

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83. The U.S. is the world leader in GMOs. Endres, *supra* note 16, at 459. The U.S. government's Trade Commission believes that soon 100% of U.S. agricultural exports will be GMO products, or at least mixed with GMO products. *Id.* at 459-60.

84. Kim, *supra* note 20, at 1181.

85. *See* Goodman, *supra* note 11 (discussing the regulatory agency embarrassment and huge monetary loss involved with the StarLink Corn incident).

86. Kim, *supra* note 20, at 1181.

87. Novotny, *supra* note 64, at 233. Since the impact of GMO food products is uncertain, both Frito Lay, a large corn snack producer, and Seagram, a large distiller, have informed their suppliers they will not purchase genetically modified corn this year. *Id.* Additionally, it is feared that genetically modified crops could have unforeseen environmental consequences. *Id.* Scientists are unsure if genetically modified plants will crossbreed with other wild relatives and spread their genetic material uncontrollably through the environment. *Id.* Corn genetically modified to resist pests has already indiscriminately killed a non-targeted insect. *Id.* Pollen from the corn drifted onto milkweed plants and killed monarch butterflies that commonly feed on the milkweed plant. *Id.*

88. *See* Goodman, *supra* note 11 (explaining that StarLink Corn was specifically approved only for animal consumption, even without evidence of human allergic reactions to the Cry9c protein).

89. Novotny, *supra* note 64, at 236. Since each of the three agencies have jurisdiction over the same regulatory provisions, there is an inefficient overlap. *Id.*

90. Nanda, *supra* note 18, at 243-46. A company may not have to receive approval from the EPA if the GMO does not have a pesticide-like quality or is not toxic. *Id.* at 244. The USDA does not have to approve a product if it

the benefits of liberal approval and expanded trade of the U.S. regulatory system are outweighed by the flaws in the system.

B. Critiquing the E.U. System

1. Benefits

The main focus behind the E.U. regulatory system is the precautionary principle, which stresses concern for public safety and the environment.[91] Since consumers dictate the market response to GMOs, knowing that food safety is the major consumer concern allows businesses to assess which GMOs they should attempt to get approved.

Placing regulatory approval under one governing body eliminates the confusion and inefficiency[92] of the fragmented U.S. system. The E.U. recognized that using pre-existing statutes to regulate GMOs would be inadequate, so it recently created and amended Directive 90/220 to have the ability to adapt to new GMO products very quickly.[93] Additionally, having one governing body creates a uniform approval standard for each of the member states in the E.U.[94] Moreover, consolidating regulation into one governing agency with one governing statute allows for efficient guideline approval and distribution.[95]

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determines the GMO falls under "non-regulated status," meaning it is not a plant pest. *Id.* at 245. Finally, the FDA does not have to approve a GMO if it is considered GRAS, meaning it is sufficiently similar to regular foods. *Id.* at 245-46.

91. *Id.* at 256. *See also* Victor, *supra* note 79, at 315 (noting the original purpose of the "precautionary principle" was to control pollution and to protect public health and the environment).

92. Novotny, *supra* note 64, at 236. Centralizing biotechnology regulation into one agency could increase efficiency because the agency could focus specifically on biotechnology issues and would become experts in biotechnology regulation. *Id.*

93. Kim, *supra* note 20, at 1193-94. The E.U. recognized that older environmental regulations were inadequate to address the environmental risks associated with GMOs. *Id.* at 1194. Therefore, the E.U. avoided adapting its pre-existing regulations to approve GMOs by choosing a process-oriented approach that targets biotechnology techniques specifically. *Id.* at 1193-94.

94. *Id.* at 1199. Directive 90/220 provides a comprehensive legal framework for all phases of GMO product release. *Id.* In addition, the E.U. has implemented a system that encompasses several nations into one system, even though its member states have a wide range of regulatory systems. *Id.* Moreover, despite the problems with Directive 90/220, it has been the most comprehensive, multi-national approach to harmonization of international GMO regulation to date. *Id.*

95. *Id.* at 1190-91. Directive 90/220 sets minimum standards that every member state must follow in approving GMO products, although the individual states enact their own laws incorporating the Directive. *Id.* at 1191. In addition, the European Commission schedules regular meetings

2. Disadvantages

The problem with a precautionary approach to GMO approval is that the process is too arduous, even for the E.U. member states that must adhere to the precautionary principle and Directive 90/220.[96] Additionally, the precautionary principle and Directive 90/220 are not being uniformly adapted throughout all of the E.U. member states.[97]

The denial of outside GMO products severely reduces and restricts trade between the E.U. and countries that use GMO crops extensively, most notably the U.S.[98] Under Directive 90/220, an individual E.U. member state can further restrict GMO products if the member state believes there is a "justifiable reason" based on potential risks to human health or the environment.[99] A few member states exercised the right to restrict GMO product importation into their countries.[100] One member state's government used political pressure in an attempt to shut down any research of GMOs within its borders.[101] This excessive

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between the member states to exchange information regarding GMOs. *Id.* at 1193.

96. Novotny, *supra* note 64, at 234-35. The drawback to the process-oriented approach is that it takes too long for approval and slows research. *Id.* 234-35. For example, a recent GMO petunia project was abandoned in Germany because the local town filed 16,000 complaints pursuant to Directive 90/220. *Id.* at 235.

97. Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the Untied States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 287 (2000). Directive 90/220 requires that each individual member state draft its own implementing provisions for GMOs. *Id.* However, because of Directive 90/220's lack of detail, individual members are creating their own data and risk assessment factors for GMOs. *Id.*

98. *See* Victor, *supra* note 79, at 321 (noting that the precautionary principle reduces global free trade and has come into severe conflict with international trade law).

99. Council Directive 90/220, art. 16, 1990 O.J. (L117/15). Victor, *supra* note 79, at 302. If an E.U. member state believes it has a justifiable reason, the European Commission must still decide whether to approve that member state's provisional restriction argument. *Id.* The Commission has three months to decide and uses the same guidelines as it would to determine initial notification of a GMO. *Id.* However, if the Commission fails to reach a decision it will be considered an approval of the provisional restriction. *Id.*

100. Victor, *supra* note 79, at 303-04. France, Austria, and Luxembourg have each received provisional restrictions on the future importation of GMO products into their countries. *Id.* at 303. Furthermore, the European Commission Regulation Committee has not issued an opinion verifying or nullifying the alleged justifiable reason. *Id.* at 303-04. Because the Regulation Committee has not acted, the restrictions are still legally valid. *Id.* at 304.

101. Drew L. Kershen, *Essay: The Risks of Going Non-GMO*, 53 OKLA. L. REV. 631, 648 (2000). Italy's Green Party has been campaigning against the use of modern genetic science and research in agriculture. *Id.* The current Agriculture Minister is attempting to foreclose all research that includes

restriction will deter companies from researching what the uniformed or non-scientific[102] public deems controversial. Companies may doubt they could attain approval in the E.U.

C. *The Regulatory Effect in the World: Marching to Their Own Drummer*

The gaps, inconsistencies, and disadvantages of the two opposite approaches to regulation have led to fractured regulatory schemes throughout the world. A few countries, fearing lost profits from large corporate research, have refused to regulate GMOs.[103] Those countries have sacrificed the unknown potential environmental and health risks[104] of GMO food products to gain the economic benefits of big business.[105] This lack of concern shows just how shortsighted a governing body can be when faced with the potential economic benefits that accompany GMOs.

Countries, like the U.S., that have concerns about GMO food product effects and public safety have taken a more moderate approach.[106] Most of these moderate approach countries have adopted voluntary guidelines.[107] A country will send regulatory representatives to study the U.S. regulatory system and determine which aspects should be implemented.[108] Additionally, a few countries have decided to directly exchange information about the U.S. regulatory scheme to create their own system.[109] Though these countries are more protective than countries that refuse to regulate GMOs, this approach still leaves too much uncertainty and inefficiency. Moreover, it adds even more conflicts and disorganization into the international biotechnology regulatory

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GMOs anywhere in Italy. *Id.* This could cause Italian agriculture to lag behind other developed countries in the biotechnology sciences. *Id.* at 649.

102. *Id.* at 644. The risk of scientific ignorance is that lay people can force their government to use the "precautionary principle" as a preventative principle because they do not take into account the overwhelming scientific evidence that current GMO food products are safe for human consumption. *Id.* at 645. Even the Irish government has acknowledged the appropriate scientific understanding regarding agricultural biotechnology. *Id.* The author notes, "[i]f society is driven by fears or ideologies, it can quickly degenerate into quackery or worse." *Id.* at 648.

103. Kim, *supra* note 20, at 1196.

104. Francer, *supra* note 97, at 290. There is some fear among scientists that genetically altered plants could have unexpected adverse health effects on humans. *Id.* at 291. Scientists have proven that some genetically modified plants could retain their allergenic traits, which could affect sensitive members of the population. *Id.* at 292. In addition, there is a possibility that genetically modified food products containing certain antibiotic genetic material could cause antibiotic resistance among some humans. *Id.* at 293.

105. Kim, *supra* note 20, at 1183.

106. *Id.*

107. *Id.* at 1183-84.

108. *Id.*

109. *Id.* at 1184.

field.[110]

Conversely, the E.U.'s excessive concern about public safety has kept their regulatory scheme deeply entrenched within the precautionary principle.[111] Their paternalistic[112] attitude may appease the average consumer by being overprotective, but they are receiving complaints from member states, which are trying to approve new GMO products, that Directive 90/220 is too strict.[113] In effect, the E.U. approach hampers GMO research and development and deters companies from seeking biotechnology approval within its borders.

D. Sour Notes: International Disharmony

Several scholars and commentators have called for international harmonization of regulatory systems, but there have been few remedies to address the problem.[114] With so many different regulatory approaches regarding GMOs, a business that seeks to release a GMO product must qualify under all individual nations' laws.[115] Inefficient and divergent regulatory plans increase the cost of an already expensive regulatory compliance process.[116] This added expense becomes even more of a deterrent

110. Kim, *supra* note 20, at 1196. *See also* Victor, *supra* note 79, at 309 (noting the previous regulatory conflict between the U.S. and E.U. regulatory approaches of genetically altered beef hormones).

111. Victor, *supra* note 79, at 304. On June 25, 1999, the European Commission recommended that Directive 90/220 be amended to include a precautionary approach requiring positive proof that a GMO would have no affect on public safety or the environment, without which there would be no authorization. *Id.* Each E.U. member state agreed, and a GMO moratorium ensued. *Id.* The U.S. accused the E.U. of using the food safety claim as a guise to restrict GMO imports. *Id.* at 296-97.

112. Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729, 730 (1991) (noting a recent speaker's opinion was that in a broad conservative view, almost all government regulation is paternalistic, but especially so in the technology-based regulatory field).

113. *See* Victor, *supra* note 79, at 304 (noting that despite the recent moratorium on GMO approval, seven E.U. member states are still asking for approval of new GMO products).

114. Kim, *supra* note 20, at 1195. There is an immediate need to harmonize international GMO regulations because of the risk of deliberate release of GMOs into the environment. *Id.* Once released, these GMOs could quickly "transcend political boundaries" and spread unchecked across geographic regions. *Id.* Harmonizing regulatory schemes will avoid the problems associated with widely disparate regulations. *Id.* at 1200. Harmonization will also develop an international consensus regarding the safe release of GMOs based upon protection of human health and the environment. *Id. See also* Souza, *supra* note 74, at 160 (noting that the two most important economies, the U.S. and E.U., are on opposite sides of the GMO debate and that this lack of clear regulation requires harmonization).

115. Kim, *supra* note 20, at 1196.

116. *Id.*

when coupled with the expensive research and development process.[117] Increasing the cost of regulatory compliance may cause businesses to either forego product introduction in a particularly strict regulatory nation,[118] or perhaps abandon some GMO products completely.[119] In effect, this added regulatory approval cost could become a major factor when a corporation decides on new GMO product research.

There is also the possibility that countries could use strict regulatory systems as a means to severely restrict the foreign importation of GMO products.[120] Any country that wishes to export GMO products to other markets must adhere to the strict safety regulations of the potential importing nation[121] or risk being excluded from that market altogether. In essence, a country employing a strict regulatory system could force its economy to restrict unwelcome foreign competitors[122] and monopolize its domestic GMO product market.

Furthermore, a corporation that is barred from competitive alternatives in a strict regulatory country will look to countries that have less strict regulations as their most profitable markets.[123] The most likely choice for such international companies is to turn to underdeveloped countries that have less severe regulatory schemes,[124] or possibly no regulatory scheme at all.[125] Without a proper regulatory system to monitor the potential human and environmental risks associated with GMOs, multinational corporations will easily exploit the developing world.[126]

Just as American federal jurisprudence seeks to avoid "forum

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117. *Id.*

118. *Id.*

119. Francer, *supra* note 97, at 292. Pioneer Hi-Bred International developed a soybean plant to be used in animal feed, which was infused with a Brazil-nut protein. *Id.* During safety testing, the company discovered that the Brazil nut protein retained its human allergenic qualities and was being expressed in the new genetically modified soybean plant. *Id.* Pioneer voluntarily refrained from marketing this new product because of the possibility that it could be mistakenly mixed with human food sources. *Id.*

120. Kim, *supra* note 20, at 1196.

121. *Id.*

122. *Id.* *See also* Kershen, *supra* note 101, at 645 (observing the public could force the government to use the "precautionary principle" as a preventative principle to keep out GMO products).

123. Kim, *supra* note 20, at 1197.

124. *Id.*

125. *See* Kim, *supra* note 20, at 1196 (noting that South Korea and Taiwan both specifically refuse to adopt regulatory schemes to court corporate investing and encourage economic growth).

126. *Id.* at 1197. *See also* Novotny, *supra* note 64, at 236 (observing that some developing countries are being used as test sites for researchers in an attempt to avoid countries with stricter regulatory schemes).

shopping,"[127] international regulatory schemes should be structured to avoid "regulation shopping" in the developing world.[128] Until there is international harmony of GMO regulatory schemes, there will continue to be gaps and inconsistencies that will create a cacophony of multinational corporations' regulatory loopholes avoiding restrictive GMO research countries or relaxed risk assessment guidelines.

IV. SWEET REGULATORY MUSIC: BLENDING LAX CAPITALISM WITH CLASSICAL EUROPEAN

Creating a hybrid regulatory system composed of the most beneficial aspects of both the U.S. and E.U. approaches would provide a model international scheme that developing countries could adopt. Specifically, developing countries could use the genetically modified "golden rice" to help combat the vitamin A malnutrition epidemic. In addition, these two international leaders in GMO regulation could take special note of this hybrid approach in an attempt to bring both systems closer to a globally harmonized system.

A. The Hybrid International Regulatory System

To create this hybrid regulatory scheme, it is important to capitalize on the pros of the U.S. and E.U. systems, while at the same time avoiding the pitfalls of each system. While providing consistency, this new system must have some flexibility, allowing each developing country to meet its malnourished childrens' needs.

The ideal hybrid system would have one regulatory agency that controls all aspects of GMO testing, release, and market approval. A unified body, like the E.U. model, would avoid the inefficiencies that plague the multi-agency system in the U.S.

The single agency would create new regulations that deal

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127. *See* Erie R.R. Co. v. Tompkins, 304 U.S. 64, 82 (1938) (noting that one of the principles directing the opinion was to discourage potential litigants from "forum shopping" in the federal court system hoping for more beneficial judgments). Multinational corporations' direct influence on biotechnology makes less-stringent regulatory countries more tempting as primary areas to conduct GMO field-testing and marketing. Thomas O. McGarity, *International Regulation of Deliberate Release Biotechnologies*, 26 TEX. INT'L L.J. 423, 435 (1991). Some corporations have proposed that approach. *Id.* at 436. This particular hazard was demonstrated when Argentine workers tested positive for antibodies found in a genetically modified vaccine for cattle. *Id.* 436-37. The workers had been exposed to the vaccine by drinking milk from the inoculated cattle. *Id.* at 437. Argentina did not have a regulatory scheme in place to deal with GMOs at the time, and did not receive notification from Wistar, the company conducting the tests. *Id.* at 436.

128. *See* Novotny, *supra* note 64, at 235 (noting that a scientist or researcher faced with strict, process-oriented regulations would most likely be drawn to countries with less imposing restrictions).

specifically with GMOs. It would also promulgate guidelines to assist companies seeking GMO approval. Like the FDA, genetically modified foods that are "generally recognized as safe" (GRAS),[129] or can be considered a "substantial equivalent"[130] to their natural counterpart, would be approved without extraneous testing. The main focus of either of these tests would be to determine how similar the genetically modified food product is to the conventional precursor. Depending on the test results,[131] any approved genetically modified food product could then be released into the open market.

Additionally, unlike the E.U. system, this agency could make pre-market review optional instead of mandatory.[132] If there is a reasonable belief by the agency to require a pre-market review, it should ask the company seeking approval for a risk assessment before the GMO could be approved. This would provide the hybrid system a way to avoid the arduous approval process stifling the E.U. regulatory system.

Sound scientific principles must underlie the entire hybrid regulatory approval system. The main focus for this requirement is to avoid the problems faced by the E.U. system's precautionary principle. However, weighing the scientific principles against other competing social, environmental, and economic interests should effectively assure consumer safety. This hybrid system

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129. *See generally* 21 U.S.C. § 321 (2002) (stating that if the particular characteristic of the genetically modified food product is not generally recognized as safe (GRAS), according to qualified scientific experts, then that determination will affect the approval process).

130. David L. Devernoe, Note, *Substantial Equivalence: A Valid International Sanitary and Phytosanitary Risk Assessment Objective for Genetically Modified Foods*, 51 CASE W. RES. L. REV. 257, 277 (2000). The substantial equivalence compares the genetically modified food product with the non-genetically modified parental variety, also called the conventional precursor. *Id.* at 278. It uses multiple factors including nutritional, toxicological, immunological, and pathogenic criteria in the comparison. *Id.* This standard "is not a safety assessment in itself[,]" but it does provide genetically modified food regulators with guidelines directed at food safety. *Id.*

131. *Id.* at 279. There are three possible endpoints in a substantial equivalence analysis: (1) the genetically modified food product is substantially equivalent to its conventional precursor; (2) the genetically modified food product, though not determined as substantially equivalent, could still be determined as substantially equivalent because of particular differences; or (3) the genetically modified food product's substantial equivalence is unascertainable either because the differences are ambiguous or because no conventional precursor exists. *Id.* If the analysis ends with either of the last two conclusions, more testing will be necessary, which will be done on a case-by-case basis. *Id.*

132. *See* Francer, *supra* note 97, at 279 (observing that mandatory pre-market approval is the "centerpiece of Directive 90/220's" regulatory scheme for the deliberate release of GMOs into the E.U. environment).

should still allow liberal approval, discourage regulatory "forum shopping," and provide consumers with a sense of confidence in their regulatory system.

On an international level, the hybrid system could be monitored by the World Trade Organization ("WTO") because it is the main forum to settle agricultural trade disputes.[133] Since the WTO already handles trade disputes related to GMOs,[134] it could also monitor trade disputes that arise from the adoption of this hybrid GMO regulatory system. As more nations adopted this approach, the global regulatory system would begin to blend and harmonize.[135] No one country would become a trade barrier to any other country, and international trade would flourish.[136] As a result, the hybrid system would create a free flow of genetically modified products across national boundaries.[137]

Additionally, multinational corporations would stop exploiting less regulated countries.[138] As regulatory schemes begin to harmonize, approval costs would become internationally consistent. Corporations doing GMO research could factor that expense as a constant in determining overall expenses for GMO

133. Teel, *supra* note 57, at 683. The two agreements that involve GMOs are the Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS"). *Id.* Although it is unclear which of these provisions controls the GMO debate, at least one, if not both, should address the issue. *Id.* at 683-84. The WTO does not set international standards for sanitary and phytosanitary protections mentioned in the SPS. *Id.* at 693. However, those standards are set by three international organizations mentioned by the SPS Agreement: 1) the Codex Alimentarius Commission; 2) the International Office of Epizootics; and 3) the International Plant Protection Convention. *Id.*

134. *Id.* at 694-97 (discussing Beef-Hormone dispute settlement process between the U.S. and the E.U.).

135. Kim, *supra* note 20, at 1200. Harmonizing international regulations for the deliberate releases of GMOs can solve the problem of disparate regulations in individual nations. *Id.* Harmonization allows all nations to develop safe biotechnology according to a common goal for protection of health and environment. *Id.*

136. *Id.* Harmonization promotes economic development and reduces national trade barriers regarding GMOs. *Id.* In addition, uniform international standards would reduce trade barriers by making GMO products more readily available to consumers in all nations. *Id.*

137. *Id.* This international GMO regulation uniformity also helps the development of international markets, by making it the most attractive option for multinational corporations attempting to market biotechnology products, instead of forum shopping. *Id.*

138. *Id.* Developing nations that do not have resources to develop their own regulatory body because of expense can also benefit from uniform international regulations. *Id.* at 1200-01. The poorest developing nations could rely on risk assessments from one international governing body (for example the WTO), instead of any other nation. *Id.* at 1201. This would protect developing countries that do not have qualified scientific experts skilled in the assessment of GMOs. *Id.*

approval.[139] This would hopefully dissuade corporations from cutting safety corners merely to save money on approval. Since the hybrid system would remove the regulatory gaps, international trade of GMOs could maintain safety while still being economically beneficial.

B. Example: Golden Rice

One can test this proposed hybrid system using "golden rice" as an example. Hypothetically, a developing nation that adopts this hybrid scheme could evaluate the risk of this "golden rice" using the multi-factor analysis discussed above. Under either the GRAS test or the "substantial equivalence" test, the vitamin A fortified rice would be compared to its naturally occurring parent variety of rice. If either test determines that "golden rice" is similar enough to the conventional precursor, then the nation's regulatory agency could approve the product for deliberate release into the environment.

Consequently, domestic producers could begin growing "golden Rice" or importing "golden Rice" from another country. For developing countries that use rice as a dietary staple and face vitamin A deficiency, this GMO approval process creates a proper risk assessment tool that helps solve an epidemic malnutrition problem. The built-in safety guidelines of the hybrid system could adequately protect humans and the environment; while at the same time allow the timely approval of genetically modified food products that address current social needs.

C. Revising the U.S. and E.U. Regulatory Approaches

The hybrid system does sound ideal, but it will be met with opposition from many sources, much like GMOs have been met with opposition. The U.S. regulators, E.U. regulators, environmentalists, and consumer groups will all have reservations to the hybrid regulatory system. The first step is for the world's two largest economies, the U.S. and E.U., to begin harmonizing their own regulatory systems.

Since the U.S. and E.U. are so deeply entrenched in their regulatory systems, immediate change may not be feasible for either one. However, there are certain characteristics of the hybrid approach that each system could implement. By continually shifting toward one common system, the U.S. and E.U. could significantly aid the international harmonization of GMO regulations.

First, the U.S. should streamline GMO regulation by

139. *See id.* at 1200 (noting the GMO industry would be better served if multinational corporations producing GMOs only have to comply with a single set of uniform regulations).

incorporating it into one regulatory agency, whether in a new agency or an existing regulatory agency.[140] This would be the first step in curing the gaps, overlaps, and inconsistencies that cause the U.S. regulatory system so many problems.

Meanwhile, the E.U. must reduce its reliance on the precautionary principle, and instead use other means to address consumer food safety. The precautionary principle does not effectively meet the regulatory needs of E.U. consumers and has been heavily criticized.[141] Instead of maintaining this over-protectionist principle, it is possible for the E.U. to adopt a "substantial equivalence" test for GMO approval. If the E.U. decides this test does not adequately address food safety, it can require additional scientific proof regarding GMOs that are allergenic or potentially toxic. Adopting this system would bring the E.U. closer to global harmony, while still adequately protecting humans and the environment.

V. A REGULATORY JAM SESSION

Developing countries can meet the humanitarian goal to end vitamin A deficiency by using GMO products such as "golden rice." However, the effort to prevent blindness in young children begins with a better GMO regulatory system. A hybrid regulatory approach would help developing countries reap the benefits of GMO products, while still protecting consumers and the environment. While neither the U.S. nor the E.U. will be prepared to completely dismantle their GMO regulations, each side must

140. Richard A. Merril & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 115 (2000). There have been wide ranging proposals to consolidate all federal food safety functions under one agency. *Id.* At one end are advocates who would place all food safety regulations under the USDA, while at the other end are advocates who would place all of these duties under the FDA. *Id.* During the Clinton Administration's National Performance Review, it was found that at least twenty-one agencies were involved in food safety research, which created too many "bureaucratic cracks" and lacked inter-agency cooperation. *Id.* at 121. Subsequently, a 1998 report by the National Academy of Sciences urged Congress to restructure food safety regulations under one uniform framework. *Id.* at 123.

141. Jonathan H. Adler, *More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 196 (2000). The precautionary principle's mantra, "it is better to be safe than sorry," biases a regulatory agency against the introduction of any new technology. *Id.* The precautionary principle "turns a blind eye" toward harms that restraining technological development causes. *Id.* Comparing it to the FDA's "drug lag," it has the same effect that those waiting for the benefit may be harmed waiting for excessively "safe" regulatory approval. *Id. See also* Katz, *supra* note 72, at 965 (noting that the precautionary principle itself provides its own risks, which include avoiding technology based on fear even though the risk is unrealized and creating a chilling effect on research and development).

continually focus on the scientific evidence and the social, ethical, and moral aspects behind GMOs. If the E.U. and U.S. come closer to a hybrid regulatory approach, the global community could realize the full benefits of GMO regulatory harmony, and possibly save many of those children waiting in lines.