

# *Fordham International Law Journal*

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*Volume 16, Issue 4*

1992

*Article 5*

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## Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms

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# Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms

Judy J. Kim

## **Abstract**

This Note analyzes current international regulations for the deliberate release of genetically modified organisms into the environment. Part I describes the benefits and risks associated with the introduction of GMOs into the environment and presents an overview of deliberate release regulations in various countries to show the range of standards in individual nations. Part II analyzes international multilateral efforts to regulate the deliberate release of GMOs. Part III critiques current international efforts to regulate deliberate releases and proposes harmonization of deliberate release regulations through an international body that would approve these releases upon proof of safety of the proposed release into the environment. This Note concludes that an international set of regulations for the deliberate release of GMOs into the environment is needed to facilitate trade and to protect the environment.

# OUT OF THE LAB AND INTO THE FIELD: HARMONIZATION OF DELIBERATE RELEASE REGULATIONS FOR GENETICALLY MODIFIED ORGANISMS\*

## INTRODUCTION

Biotechnology has the potential to revolutionize both industrial and agrarian economies.<sup>1</sup> Genetic engineering has produced bacteria capable of digesting petroleum,<sup>2</sup> viruses that act as insecticides,<sup>3</sup> pest-resistant crops,<sup>4</sup> and tomatoes that will stay firm for weeks on the shelf.<sup>5</sup> To develop such technologically advanced products, genetically modified organisms ("GMOs") must be used outside of the laboratory and tested in the field.<sup>6</sup> The introduction of GMOs into the envi-

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\* The author wishes to thank John H. Barton, George E. Osborne Professor of Law at Stanford Law School for his encouragement and guidance in the preparation of this Note.

1. See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *BIOTECHNOLOGY IN A GLOBAL ECONOMY* 29 (1991) [hereinafter OTA] (discussing biotechnology's potential); NATIONAL ACADEMY OF SCIENCES, *INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES* 8 (1987) [hereinafter *INTRODUCTION OF rDNA*] (stating that biotechnology offers exciting opportunities for the development of products in medicine, industry, agriculture, and environmental management); Thomas O. McGarity, *International Regulation of Deliberate Release Biotechnologies*, 26 TEX. INT'L L.J. 423, 424 (1991) (discussing biotechnology's potential).

2. See generally *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (granting patent to petroleum digesting bacteria).

3. See Jürg Huber, *Safety of Baculoviruses Used as Biological Insecticides*, in *RISK ASSESSMENT FOR DELIBERATE RELEASES* 65 (Walter Klingmüller ed., 1988) [hereinafter *RISK ASSESSMENT*].

4. See Laura Shapiro, *A Mystery in Your Lunchbox*, *NEWSWEEK*, June 8, 1992, at 48, 49. *Bacillus thuringiensis*, or BT, is a bacterium that is toxic to certain insects, but harmless when digested by humans. *Id.* The gene for BT can be transferred into plant cells to create new plants that are able to produce their own insecticide. *Id.* Monsanto, a U.S. chemical company, expects to introduce a new type of cotton that is resistant to the cotton bollworm, as well as a potato that kills the Colorado potato beetle. *Id.*

5. *Id.* at 48. Calgene Inc., a food manufacturer, is planning to introduce a genetically engineered tomato, the Flavr Savr, that resists rotting for more than three weeks. *Id.*; see Michael Schrage, *Genetically Engineered Foods May be Safe, but They Still Should be Labeled*, *WASH. POST*, June 5, 1992, at B11.

6. See M. CHIARA MANTEGAZZINI, *THE ENVIRONMENTAL RISKS FROM BIOTECHNOLOGY* 67 (1986). Field testing of genetically modified plants is necessary because many plants respond differently in greenhouse or chamber testing than they do in field conditions. *Id.*; U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE* 183 (1992) [hereinafter *NEW TECHNOLOGICAL ERA*] ("Greenhouse experiment, conducted in facilities designed to meet

ronment is commonly known as the "deliberate release" or "planned introduction" of genetically modified organisms into the environment.<sup>7</sup> The deliberate release of GMOs has given rise to intense debate about the possible risks to human health and the environment.<sup>8</sup> Research, however, has not focused on safety concerns.<sup>9</sup>

Regulators in individual nations, faced with the controversy surrounding the deliberate release of GMOs have responded with different policies.<sup>10</sup> Some nations have very stringent laws prohibiting deliberate releases while other nations have left this area unregulated.<sup>11</sup> Various international agreements have attempted to harmonize deliberate release regulations, but most of these efforts have resulted either in broad recommendations that fail to offer specific guidelines to the biotechnology industry or regulations with limited regional applications.<sup>12</sup>

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containment specifications, can provide only an initial screening; the field trial is an essential evaluative step.").

7. INTRODUCTION OF RDNA, *supra* note 1, at 8.

8. See EC "Stocktaking" on Biotechnology, BIOTECH. BUS. NEWS, Oct. 30, 1992, available in LEXIS, World Library, ALLNWS File. Environmentalists remain unsure about the ecological impact of biotechnology. *Id.* Consumers are demanding clear and objective information about biotechnology. *Id.*

9. See OTA, *supra* note 1, at 129 (noting that "research and product development in the environmental sectors are minuscule compared to more commercially lucrative sectors influenced by biotechnology and international activity to date is limited"); Martin Brown, *Science Technology and the Environment*, OECD OBSERVER, Feb-Mar., 1992, at 11 ("Although OECD governments have come to set a considerably larger role for research and development in their emerging environmental policies . . . this shift of views has so far not been fully reflected in the financing of environmental research and development ["R&D"]"); *German Law Endangering Biotech?*, BIOTECH. BUS. NEWS, July 17, 1992, available in LEXIS, World Library, ALLNWS File (stating that German parliament was told that there were now virtually no environmental studies on GMOs).

10. JEFFREY N. GIBBS, ET. AL., *BIOTECHNOLOGY & THE ENVIRONMENT: INTERNATIONAL REGULATION* 271 (1987) [hereinafter GIBBS].

11. *Id.* at 271 (discussing deliberate release regulations in individual countries).

12. See Report of the United Nations Conference on Environment and Development, U.N. Doc. A/CONF.151/26/Rev.1 (1993) [hereinafter Agenda 21] (containing non-binding recommendations); Convention on Biological Diversity, June 5, 1992, U.N. Doc. DPI/130 7 (1992), reprinted in 31 I.L.M. at 818 (1992) [hereinafter Biodiversity Treaty] (lacking specific guidance for regulating deliberate releases of GMOs); ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *SAFETY CONSIDERATIONS FOR BIOTECHNOLOGY* (OECD 1992) [hereinafter 1992 REPORT] (limited to members of the OECD); ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *RECOMBINANT DNA SAFETY CONSIDERATIONS—SAFETY CONSIDERATIONS FOR INDUSTRIAL, AGRICULTURAL AND ENVIRONMENTAL APPLICATIONS OF ORGA-*

Harmonization of international regulations for the deliberate release of GMOs into the environment is needed to encourage the development of genetically engineered products, to promote international trade, and to protect human health and the environment with common safety standards.<sup>13</sup> Although geographic and policy differences among nations are obstacles to harmonization, international regulations for the deliberate release of GMOs are possible.<sup>14</sup> Current international agreements, despite their limitations, show that a significant amount of co-operation between individual nations and international bodies already exists.<sup>15</sup>

This Note analyzes current international regulations for the deliberate release of genetically modified organisms into the environment. Part I describes the benefits and risks associated with the introduction of GMOs into the environment and presents an overview of deliberate release regulations in various countries to show the range of standards in individual nations. Part II analyzes international multilateral efforts to regulate the deliberate release of GMOs. Part III critiques current international efforts to regulate deliberate releases and proposes harmonization of deliberate release regulations through an international body that would approve these releases upon proof of safety of the proposed release into the environment. This Note concludes that an international set of regulations for the deliberate release of GMOs into the environment is needed to facilitate trade and to protect the environment.

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NISMS DERIVED BY RECOMBINANT DNA TECHNIQUES (OECD 1986) [hereinafter 1986 REPORT] (limited to members of the OECD); Council Directive No. 90/220, 1990 O.J. (L 117) (limited to European region).

13. See BIOTECHNOLOGY: THE SCIENCE AND THE BUSINESS 113 (Vivian Moses et al. eds., 1991) [hereinafter Moses] (arguing that international harmonization will lead to common safety standards and maintain free trade); Peter Aldhous, *Regulation cost concerns*, 354 NATURE 5, (Nov. 1991) (quoting representative of U.K.'s BioIndustry Association expressing desire for consistent approach to regulation costs throughout EC).

14. GIBBS, *supra* note 10, at 274.

15. See NEW TECHNOLOGICAL ERA, *supra* note 6, at 205 (stating that U.S. regulations harmonize with OECD recommendations); ROBERT T. YUAN & MARK D. DIBNER, JAPANESE BIOTECHNOLOGY, 4, 48 (1990) (commenting on effort by Japanese regulators to conform with OECD recommendations) [hereinafter JAPANESE BIOTECHNOLOGY]; *Economic Commission's Work Programme for 1990*, EUR. REP. Jan. 27, 1990 at § 313, available in LEXIS, Nexis Library, OMNI File (noting that EC has participated in international forums involving environment as well as in international negotiations).

# I. APPLICATIONS, HAZARDS, AND REGULATION OF DELIBERATE RELEASES

Some of the latest biotechnology applications necessitate the deliberate release of GMOs into the environment.<sup>16</sup> The public, however, views genetically modified organisms as harmful and opposes governmental policies that are designed to encourage the biotechnology industry.<sup>17</sup> Public interest groups opposed to genetic manipulation include political and religious groups.<sup>18</sup> Genetic activist groups in the United States have used litigation and other means of pressure to halt the large-scale release of GMOs into the environment.<sup>19</sup> The public's fears of the potential hazards of deliberate releases, as well as the scientific controversy over the safety of deliberate releases, has slowed the field testing of GMOs.<sup>20</sup> Confronted with public opposition and the absence of a full scientific consensus on the relative safety and risks of introducing modified organisms into the environment, regulators in some nations

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16. See *supra* note 6 and accompanying text (explaining need for field testing and deliberate releases of GMO products into environment).

17. See APPLICATION OF BIOTECHNOLOGY: ENVIRONMENTAL AND POLICY ISSUES 27 (John R. Fowle III ed., 1987) [hereinafter APPLICATION OF BIOTECHNOLOGY]. The public's concerns include the fear of potential risks of laboratory hazards, ethical concerns over the manipulation of human genes, anxiety over the development of biological weapons, and the potential for adverse effects on humans and the biosphere from releases of GMOs into the environment. *Id.*; EFB's Research Budget Worries, BIOTECH. BUS. NEWS, July 31, 1992, available in LEXIS, World Library, ALLNWS File (stating that members of European Federation of Biotechnology consider public fears about safety of genetic engineering one of major barriers to biotechnology).

18. See *Foundation on Economic Trends v. Heckler*, 587 F. Supp. 735 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985). The Foundation on Economic Trends in Washington D.C. opposes the marketing of any genetically engineered foods. *Id.*; *New Catechism for Catholics Defines Sins of Modern World*, N.Y. TIMES, Nov. 17, 1992, at A1 (reporting that Catholic Church's new catechism considers genetic engineering of human embryos sinful). Europe's Green party opposes genetic manipulations as part of its political platform. OTA, *supra* note 1, at 187.

19. See *Foundation on Economic Trends v. Heckler*, 756 F.2d 143; Lawrence M. Fisher, *Tomato Gene Is Submitted For Approval*, N.Y. TIMES, Jan. 6, 1993, at D4 [hereinafter *Tomato Gene*] (citing recent example of consumer advocates successfully exerting pressure on GMO product). The U.S. Food and Drug Administration's ruling in May 1992 that found that genetically engineered foods do not require special approval or labelling resulted in a storm of protest, including a petition signed by 1500 chefs across the country, and a threatened boycott of engineered foods. *Id.* Because of the public's reaction, Calgene, Inc. decided to ask the Food and Drug Administration to approve its genetically modified tomato, the Flavr Savr, as a food additive. *Id.*

20. NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 7 (1989) [hereinafter FIELD TESTING].

have responded with a wide range of deliberate release regulations. Other nations, however, have chosen to leave the area of deliberate releases of GMOs unregulated.<sup>21</sup>

### *A. Applications Requiring Deliberate Releases*

Biotechnology has been defined as "the industrial use of recombinant DNA ["rDNA"],<sup>22</sup> cell fusion, and novel bioprocessing techniques."<sup>23</sup> These genetic manipulation techniques are commonly referred to as genetic engineering.<sup>24</sup> In 1990 alone, the U.S. government spent more than US\$3.4 billion to support research and development in biotechnology-related areas.<sup>25</sup> The financial markets also have embraced biotechnology because of its potential for creating extremely profitable products.<sup>26</sup> Proponents of biotechnology believe that it will deliver many benefits to the agricultural, pharmaceutical, and chemical industries.<sup>27</sup>

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21. See OTA, *supra* note 1, at 189-92 (discussing nations with no regulations for biotechnology).

22. See INTRODUCTION OF rDNA, *supra* note 1, at 7 (explaining rDNA technology). rDNA techniques produce hybrid DNA by joining pieces of DNA from different organisms. *Id.*

23. See OTA, *supra* note 1, at 29. The Office of Technological Assessment of the U.S. Congress uses the term biotechnology to refer to novel bioprocessing techniques rather than the traditional definition of biotechnology that included traditional fermentation and breeding techniques. *Id.*; see 35 U.S.C. § 156(f)(2)(B) (1988 & Supp. III 1991) (referring to products "primarily manufactured using recombinant DNA, recombinant RNA, hydridoma technology, or other process involving site-specific genetic manipulation techniques").

24. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986).

25. OTA, *supra* note 1, at 19.

26. See *id.* at 8-12 (discussing financing of biotechnology). The pharmaceutical industry's use of biotechnology to produce high value-added products is particularly attractive to investors such as venture capitalists. *Id.* at 11. For example, one dose of Genetic's tissue plasminogen activator may cost U.S.\$2200.00. *Id.*

27. See *id.* at 73-96 (pharmaceutical), 99-115 (agricultural), 119-25 (chemical). For example, dairy farmers can control the sex of calves through biotechnological techniques. *Id.* at 100. Human estrogen receptor and insulin-like growth factor have been transferred to cattle in attempts to produce faster growing animals. *Id.* at 102; see FIELD TESTING, *supra* note 20, at 77-80; Salomon Wald, *The Biotechnological Revolution*, OECD OBSERVER, Feb. 1989, at 16.

Agriculture . . . will be transformed by biotechnology, which has the potential to boost food production substantially, both through increasing crop growth rates and improving the growth efficiency of livestock, and to reduce residues from pesticides and other agro-chemicals. . . . [T]he next decade will see enormous advances in the development of plants and trees — not

In agriculture, genetically modified rhizobium, a bacterium, has been used extensively to improve the yield of certain crops.<sup>28</sup> Industrial processes that use genetically modified microorganisms include microbial enhanced oil recovery, which uses GMOs to improve the efficiency of oil production from reservoirs,<sup>29</sup> and bioleaching, which uses GMOs to extract metals from ores.<sup>30</sup> Genetically modified organisms also have environmental applications.<sup>31</sup> Genetically engineered bacteria can degrade environmental pollutants and cleanse industrial and municipal waste streams.<sup>32</sup> These agricultural and environmental applications require the intentional release of genetically modified organisms into the environment to test the new organisms' effectiveness under actual conditions, rather

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least, maize, wheat and rice — that offer high growth rates and improved seed qualities, and tolerate salt or stress.

*Id.*

Opponents of biotechnology claim that despite its many benefits, there may also be some potential dangers in the new biotechnologies. Letter from Rebecca Goldberg, Senior Scientist, Environmental Defense Fund, to Dr. David Kessler, Commissioner, FDA (Oct. 1, 1991) (on file with the *Fordham International Law Journal*). Twenty-seven deaths and over 1500 serious illnesses have been attributed to L-tryptophan manufactured from genetically engineered bacteria. *Id.* at v. The L-tryptophan never received FDA review because "dietary supplements" do not need FDA approval before they are marketed. *Id.* The exact cause of the supplement's toxicity, including whether it is related to genetic engineering, remains unclear. *Id.* at 6.

28. FIELD TESTING, *supra* note 20, at 80; P.R. Hirsch & J.R. Spokes, *Rhizobium Leguminosarum as a Model for Investigating Gene Transfer in Soil*, in RISK ASSESSMENT, *supra* note 3, at 10-12. Genetically modified rhizobium is a nitrogen fixing bacteria that can increase the agricultural yield of legume crops. *Id.* at 12.

29. See Moses, *supra* note 13, at 537 (discussing microbial enhanced oil recovery).

30. See *id.* at 567 (discussing bioleaching); FIELD TESTING, *supra* note 20, at 82 (noting that genetically engineered microorganisms are used to enhance recovery of gold from ores); OTA, *supra* note 1, at 131 (noting use of genetically modified bacteria to extract uranium).

31. OTA, *supra* note 1, at 129-41. Genetically engineered bacteria degraded substituted benzoates presented in industrial sludge. See FIELD TESTING, *supra* note 20, at 80-81 (discussing use of microorganisms to treat waste); D.F. Dwyer et al. *Bacteria with New Pathways for the Degradation of Pollutants and their Fate in Model Ecosystems*, in RISK ASSESSMENT, *supra* note 3, at 100 (discussing use of bacteria to cleanse waste streams).

32. Dwyer, *supra* note 31, at 100. Genetically engineered bacteria survived within a model aerobic sludge ecosystem and were able to degrade chlorinated and methylated benzoic acids that were present in ordinarily inhibitory combinations. *Id.*; see FIELD TESTING, *supra* note 20, at 80-81 (discussing use of genetically modified microorganisms in waste treatment); Richard J.F. Brewly et. al., *Waste Treatment and Pollution Clean-up*, in MOSES, *supra* note 13, at 507-09 (discussing use of genetically modified microorganisms in waste treatment).



than in laboratory simulations.<sup>33</sup>

### B. Potential Hazards of Deliberate Releases

While the potential and actual benefits of releasing GMOs into the environment are widely acknowledged, there is controversy over the possible adverse effects of such releases.<sup>34</sup> Legitimate concerns exist about the biological and ecological consequences of introducing new or altered organisms into the environment on a large scale.<sup>35</sup> The greatest source of apprehension among ecologists is the potential hazards of introducing non-native organisms into a new environment.<sup>36</sup> For example, the introduction of a non-native or "exotic"<sup>37</sup> species into a new environment sometimes results in the new exotic

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33. See *supra* note 6 and accompanying text (explaining need for field testing and deliberate release of GMOs into environment).

34. Compare Martin Alexander, *Spread of Organisms with Novel Genotypes*, BIOTECHNOLOGY AND THE ENVIRONMENT: RISK AND REGULATION 123-26 (Albert H. Teich et al. eds., 1985) (analogizing possible effect of deliberate release of GMOs to deleterious effect of infectious disease on human populations with no resistance) with INTRODUCTION OF rDNA, *supra* note 1, at 8 ("Crops modified by molecular and cellular methods should pose no risks different from those modified by classical genetic methods for similar traits.") and Charles S. Gasser & Robert T. Fraley, *Transgenic Crops*, SCI. AM., June 1992, at 62 ("Although genetic engineering is more complex than traditional plant-breeding practices, it is just as safe.") and Simon A. Levin & Mark Harwell, *Environmental Risks and Genetically Engineered Organisms*, in BIOTECHNOLOGY: IMPLICATIONS FOR PUBLIC POLICY 56, 66 (Sandra Panen ed., 1985) (arguing that GMOs are not fundamentally new and different) and Proposals for Council Directives, COM(88) 160 final at 25 (stating that "intense debate" exists about possible risk of deliberate releases).

35. See STAFF OF HOUSE SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 98TH CONG., 2D SESS., REPORT ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 16 (Comm. Print 1984) (listing ecological disruptions, infectivity, pathogenity, or toxicity to nontarget organisms and exchange of genetic material with other organisms as potential dangers of deliberate releases); MANTEGAZZINI, *supra* note 6, at 65 ("Direct or indirect changes may affect the environment when deliberate or accidental release of micro-organisms takes place."); James M. Tiedje et al., *The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations*, 70 ECOLOGY 298 (1989) (addressing scientific issues in introduction of GMOs into environment).

36. Bernard D. Davis, *Bacterial Domestication; Underlying Assumptions*, 235 SCI. 1329 (1987).

37. See FIELD TESTING, *supra* note 20, at 39 (defining "exotic species"). Exotic species refers to entirely novel species in new habitats. *Id.* Exotic species may not be strictly analogous to genetically modified organisms because many exotic species differ by many traits while genetically modified plants that are likely to be introduced will differ by only one or a few traits from cultivated forms already in the environment. *Id.*

species displacing the native varieties and dominating the environment.<sup>38</sup> A small fraction of introductions of non-native organisms have caused major ecological disturbances.<sup>39</sup> Even though a naturally occurring exotic species is not directly analogous to GMOs, small genetic alterations may nevertheless create ecologically important changes.<sup>40</sup> Thus, GMOs introduced into new environments may also have ecological impacts similar to those of exotic species.<sup>41</sup>

Genetically engineered microorganisms, once released into the natural environment, theoretically may have a good chance to survive, multiply, and exchange genetic material, or hybridize, with other microorganisms in the environment.<sup>42</sup>

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38. See APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 95 (discussing risk of deliberate releases). Introduced species become problems when they are put into new environments that lack the pests, predators, and other controls that check growth in their native homes. *Id.*; see INTRODUCTION OF rDNA, *supra* note 1, at 19 (discussing introduction of non-native species as risk of deliberate releases).

39. APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 93; FIELD TESTING, *supra* note 20, at 39-40 (discussing ecological implications of introducing plants with many new traits).

40. See FIELD TESTING, *supra* note 20, at 39. Exotic species may not be strictly analogous to genetically modified organisms because many exotic species differ vastly from their neighbors in the new environment. *Id.* Genetically modified plants that are likely to be introduced in the near future will differ by only one or a few traits from cultivated forms already in the environment. *Id.* at 40-41.

41. See Levin, *supra* note 34, at 68-70 (arguing difficulty of predicting ecological consequences when gene from one species is inserted into another and resulting modified organism released into environment); McGarity, *supra* note 1, at 425 (arguing difficulty of predicting ecological consequences when gene from one species is inserted into another and resulting modified organism released into environment); see also APPLICATIONS OF BIOTECHNOLOGY, *supra* note 17, at 96, 130, 134 (rejecting exotic species model for case-by-case risk analysis); FIELD TESTING, *supra* note 20, at 137 (discussing United States regulatory scheme). "[A] fundamental concern is whether the limited current understanding of microbial ecology . . . enables the environmental fate of released organisms to be predicted." *Id.* at 139 (citations omitted).

42. See Jan Dirk van Elsas, et al., *Plasmid Transfer in Soil and Rhizosphere*, in RISK ASSESSMENT *supra* note 3, at 90 (conjugal gene transfer of plasmid encoding tetracycline resistance between two soil-isolated bacilli in soil); Z. Filip, *Some Ecological Aspects of the Release of Nonresident Microorganisms in Soil and Groundwater Environments*, in RISK ASSESSMENT *supra* note 3, at 86 (finding that GMOs released into environment may survive, multiply, and cause gene transfer). But see MANTEGAZZINI, *supra* note 6, at 32-33. Genetic information may be exchanged in soil or water, but this information is limited and usually comes from studies that were conducted under highly artificial conditions. *Id.*; K. Doherty & Walter Klingmüller, *Genetic Interaction of Rhizobium Leguminosarum Biovar Viceae with Gram-Negative Bacteria*, in RISK ASSESSMENT *supra* note 3, at 18 (finding gene transfer in lab, but not in field); P.R. Hirsh, *Rhizobium Leguminosarum as a Model for Investigating Gene Transfer in Soil*, in RISK ASSESSMENT *supra* note 3, at 10 (finding that genetically modified bacteria may not survive well in field); see

Such hybridization between genetically engineered organisms and naturally occurring counterparts may create new hazards.<sup>43</sup> For example, wheat that has been genetically modified to resist pesticides may pass its pesticide-resistant gene on to a weed, creating the risk of disrupting ecological cycles.<sup>44</sup> While most scientists believe that the risks associated with the introduction of a GMO are the same as those associated with the introduction of naturally occurring non-native organisms into the environment, some experts believe that other factors can affect the risks of introducing GMOs into an environment.<sup>45</sup>

A genetically engineered microorganism will also spread to the limits of its ecological niche, oblivious to international boundaries.<sup>46</sup> For example, many fungal and some bacterial

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also FIELD TESTING, *supra* note 20, at 43-53 (discussing genetic transfer); Alexander, *supra* note 34, at 139. "Even adequate [testing of GMOs before their release into the environment] will not prevent the organisms from picking up a harmful trait in the environment or from manifesting an unforeseen trait once they find an ecological niche." *Id.*

43. See APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 99-124 (discussing infectious spread of engineered genes); Huber, *supra* note 3, at 69 ("A major concern is the potential risk of transfer and exchange of genetically engineered characteristics with naturally occurring microorganisms, or with the host or non-target organisms, thereby creating new potential hazards.").

44. *Biotechnology: Parliament calls for More Stringent Controls on Genetically Modified Organisms*, EUR. REP., Mar. 17, 1990, at 9. Cf. Davis, *supra* note 36, at 1323 (discussing pesticide resistance and increase in drug resistance in bacteria).

45. See APPLICATIONS OF BIOTECHNOLOGY, *supra* note 17, at 96, 130, 134 (stating that instead of exotic species model, scientists should analyze risk involved in deliberate release of GMOs on case-by-case basis); INTRODUCTION OF rDNA, *supra* note 1, at 6-7 (declaring that risk associated with introduction of GMOs are comparable to risk associated with introduction of unmodified plants); Alexander, *supra* note 34, at 116-27 (analyzing components of risk analysis in regard to deliberate release of GMOs); Glasser & Fraley, *supra* note 34, at 62 (declaring genetically engineered plants safe); Huber, *supra* note 3, at 69 (stating that potential hazards foreseen with genetically engineered viruses are generally same as for non-engineered microbes); Levin, *supra* note 34, at 68-70 (stating genetic engineering techniques are more efficient than traditional breeding programs); see generally Davis, *supra* note 36 (proposing reliance on principles from evolutionary biology, microbiology, and epidemiology rather than exotic species model).

46. See APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 99-124 (discussing infectious spread of engineered genes); Davis, *supra* note 36, at 1332 (noting that it is not harmful effects of bacteria itself, but its capacity to multiply and spread that causes concern); see also MANTEGAZZINI, *supra* note 6, at 45. In 1958, *Peronospora tabacina*, tobacco blue mold, was imported into the United Kingdom for use in fungicide experiments. *Id.* That year, the mold appeared on tobacco plants at three other research institutes in England. *Id.* The following year, the mold appeared in the

diseases can be spread by the airborne transport of spores.<sup>47</sup> Once released into the environment, the spread of a GMO can be difficult to arrest.<sup>48</sup> Because GMOs, when released, may cross national borders, both the citizens and the environment of one country can be affected by a deliberate release originating in another country, thereby creating an international concern.<sup>49</sup>

### C. Deliberate Release Regulations in Individual Nations

Individual countries have responded in different ways to the problem of safeguarding the environment against possible adverse effects from the deliberate release of GMOs into the environment.<sup>50</sup> Denmark and Germany, for example, have

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tobacco fields of Belgium and the Netherlands. *Id.* Thereafter, the mold infected tobacco fields spread all over Europe, advancing in Germany at the rate of 5-20 Km per week. *Id.* Although the original source of the mold was a laboratory licensed by the British Plant Authority, its safety handling procedures were not sufficient to contain the tobacco blue mold from infecting crops. *Id.*

47. MANTEGAZZINI, *supra* note 6, at 46. Spores are unicellular reproductive bodies. WEBSTER'S NEW UNIVERSAL UNABRIDGED DICTIONARY 1756 (2nd. ed. 1983).

48. See S. Molin *et al.*, *Biological Containment of Bacteria and Plasmids to be Released into the Environment*, RISK ASSESSMENT *supra* note 3, at 127 (proposing suicide gene); "Suicide genes," which incorporate a cell killing function into genes and ensure that a GMO will not be able to survive in the environment once it has performed its task, may offer a method of biological containment. See *US Researchers Report Marker Gene Advances*, BIOTECH. BUS. NEWS, March 13, 1992, available in LEXIS, World Library, ALLNWS File. Concern about the potential hazards associated with the deliberate release of GMOs into the environment may be lessened. *Id.* One method removes marker genes from genetically modified plants to reduce the risk that unnecessary markers can be transferred into the environment. *Id.* Another method proposes bioluminescence for detection of GMOS released into the environment. *Id.*

49. See James T. O'Reilly, *Biotechnology Meets Products Liability: Problems Beyond the State of the Art*, 24 Hous. L. REV. 451, 488 (1987) (recommending that liability be defined by statute for drugs and other biotechnology products that cause personal injury). See generally Sanford E. Gaines, *International Principles for Transnational Environmental Liability: Can Developments in Municipal Law Help Break the Impasse?*, 30 HARV. INT'L. L.J. 311 (1989) (proposing strict liability for environmental harms caused by their products, so that investors and managers can begin to make appropriate arrangements to fund such potential liability).

50. See GIBBS, *supra* note 10, at 271. Most nations regulate deliberate releases at the national level. *Id.* *Contra* OTA, *supra* note 1, at 229-42. In Australia, biotechnology is regulated at the state level. *Id.* at 229. The federal government is developing regulations for biotechnology. *Id.* Australia's Genetic Manipulation Advisory Committee, composed of university faculty, oversees all proposals for research and commercial work involving genetic manipulation and planned releases of genetically modified organisms. *Id.* at 230; see Rebecca Goldberg, *Release of Genetically Engineered Organisms: An International Concern* 15 (Jan. 4, 1991) (paper presented to the Food and Agricultural Organization of the United Nations, on file with the Ford-

created new laws to deal specifically with biotechnology, while countries such as the United States have interpreted pre-existing laws to regulate the deliberate release of GMOs.<sup>51</sup> The newly enacted laws in Denmark and Germany follow a process-oriented approach.<sup>52</sup> Process-oriented regulations view the technique of genetic engineering itself as a risk and regulate the use of rDNA techniques, even if the end-product is not a GMO.<sup>53</sup> In contrast, product-specific regulations are not concerned with the use of biotechnology techniques, but with the use of the GMO end-product, such as foods or pesticides.<sup>54</sup> Under the product-specific approach, GMO end-products are regulated like similar products created by more traditional techniques.<sup>55</sup> In general, nations may be classified into three categories: nations with process-oriented regulations, nations with product-specific regulations, and nations with no regulations for the deliberate release of GMOs.

### 1. Process-Oriented Deliberate Release Regulations

Denmark and Germany possess the most stringent laws regarding the release of genetically engineered organisms.<sup>56</sup> Despite strict regulation, these two countries have maintained

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*ham International Law Journal*). Australia has permitted several field experiments that have released genetically engineered organisms into the environment. *Id.*

51. GIBBS, *supra* note 10, at 272; *Genetic Engineering: Bugs that Divide*, ECONOMIST, July 28, 1990, at 57 [hereinafter *Genetic Engineering*] (comparing product-specific and process-oriented regulation of biotechnology); Peter Newmark, *Danish law to be less rigid*, 339 NATURE 653 (1989) (citing Danish Environment and Gene Technology Act as specific legislation for gene experiments).

52. See *supra* note 51 and accompanying text (discussing Danish and German regulations for deliberate releases).

53. *Id.* (noting that new biotechnology laws of several European nations regard technique of genetic engineering itself as risk).

54. *Id.*; see, e.g., Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) (specifying U.S. regulatory approach as product-specific).

55. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) (declaring U.S. regulatory policy for biotechnology); *Genetic Engineering*, *supra* note 51, at 57.

American regulators have decided that, with a few exceptions such as genetically-engineered pharmaceuticals used to rectify human genetic diseases, there is nothing especially dangerous about biotechnology products. No new tests are required to prove their safety.

*Id.*; see GIBBS, *supra* note 10, at 272 (discussing product-oriented regulatory approach).

56. Newmark, *supra* note 51, at 653; see Michael Balter, *How Europe Regulates Its Genes*, 252 SCIENCE 1366 (1991) (stating that draconian measures were adopted in

strong biotechnology industries.<sup>57</sup> Representatives of the biotechnology industries in Denmark and Germany, however, have expressed concern about their continued competitiveness in an international forum when other countries are harmonizing their laws to foster trade.<sup>58</sup>

Denmark was the first European country to apply a process-oriented approach and enact a law specifically for the regulation of biotechnology.<sup>59</sup> The Environmental and Gene Technology Act of 1986 resulted in a virtual prohibition of the deliberate release of GMOs.<sup>60</sup> Although initially restrictive, this act was modified in May 1989 to allow field testing of genetically engineered sugar beets.<sup>61</sup> The stringency of Danish laws for the release of GMOs led the Danish biotechnology industry to fear for its competitiveness in international markets.<sup>62</sup> Perhaps in response to such industry concerns, the Environmental and Gene Technology Act was further modified in 1991 to relax the requirements for field testing GMOs.<sup>63</sup> This modification provides for the deliberate release of GMOs with approval procedures regulated by the Ministry of Environment.<sup>64</sup>

Germany, along with Denmark, possesses very stringent deliberate release regulations, yet its domestic and pharmaceutical industries rank among the most profitable in the world.<sup>65</sup>

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Denmark and Germany partly due to pressure from Green Party and other environmental activists).

57. See Newmark, *supra* note 51, at 653 (discussing status of Danish and German biotechnology industries).

58. *Id.*

59. See *supra* note 51 and accompanying text (discussing Danish and German regulations for deliberate releases).

60. Act No. 288 of 4 June 1986 on the Environment and Gene Technology (Den.) (English trans. on file with *The Fordham International Law Journal*); see OTA, *supra* note 1, at 233. Although Denmark is a member of the EC, Danish industries are still bound by Danish laws regarding the regulation of biotechnology. *Id.*

61. See Moses, *supra* note 13, at 112 (discussing Danish deliberate release regulations).

62. See OTA, *supra* note 1, at 233 (stating Danish industry has found law difficult).

63. Act No. 356 of 6 June 1991 on the Environment and Gene Technology (Den.) (English trans. on file with *The Fordham International Law Journal*).

64. Telephone Interview with Dr. Victor Morgenroth, Principal Administrator, OECD, Environmental Health and Safety Division, Paris, France (Apr. 5, 1993) (notes on file with the *Fordham International Law Journal*).

65. OTA, *supra* note 1, at 233.

Despite the world prominence of its biotechnology industry, Germany has faced opposition to biotechnology from popular movements within the country.<sup>66</sup> The strongest opposition to the industry has come from the Green party, a German political party that opposes the commercial use and public funding of all genetic engineering.<sup>67</sup>

Another obstacle to Germany's biotechnology industry has come from its judiciary.<sup>68</sup> In 1989, the Administrative Court of Appeals in Hessen blocked the completion of a plant to manufacture genetically engineered insulin.<sup>69</sup> The court held that express statutory basis for approval was required for the construction permit for the plant.<sup>70</sup> However, since German law did not expressly permit the application of genetic engineering, the court ruled that such facilities may not be built and operated.<sup>71</sup> This verdict was binding on all the states in Germany.<sup>72</sup>

In response to this opposition to biotechnology, the Ger-

66. *Id.* at 234; see *German Law Endangering Biotech?*, *supra* note 9 (stating that lack of public acceptance of genetic engineering is obstacle for German biotechnology industry); *Germany: Biotechnology Gets Go Ahead as New Legislation Comes Into Force*, Reuter Textline, Oct. 24, 1990 available in LEXIS, World Library, ALLNWS File [hereinafter *Germany: Biotechnology*] (stating that environmental pressure groups and Green Party made it nearly impossible for companies to get approval for both genetic engineering research projects and recombinant DNA products).

67. See *Germany: Biotechnology*, *supra* note 66; OTA, *supra* note 1, at 187. Opposition to genetic engineering is the Green Party's second political target, after opposition to nuclear power. *Id.* The Green Party platform calls for a total ban on biotechnology research, development, and production. *Id.* Until recently, Germany's Green Party was the most successful Green Party in Europe, holding 46 seats in the German National Parliament (*Deutscher Bundestag*) until December 1990. *Id.* Although the Green Party has been a potent force in the German National Parliament, it has recently lost much of its momentum and is currently in chaos. Alex Beam, *What Happened to the Greens?: After Startling Success in Germany, the Green Party has Disappeared*, THE GAZETTE, Mar. 23, 1992, at B3, available in LEXIS, World Library, ALLNWS File.

68. See OTA, *supra* note 1, at 234 (discussing German court's decision to block completion of genetic engineering plant); Claus-Joerg Ruetsch & Terry R. Broderick, *New Biotechnology Legislation in the European Community and Federal Republic of Germany*, 18 INT'L. BUS. LAW. 408, 410 (1990) (discussing German court's decision to block completion of genetic engineering plant).

69. VGH Kassel, *Beschl. v.6.11.1989 - 8 TH 685/89*, in *Neue Juristische Wochenschrift* 1990, Heft 5, at 336; see Ruetsch, *supra* note 68, at 18 (discussing German court's ruling).

70. See Ruetsch, *supra* note 68, at 410 (discussing German court's ruling on genetic engineering plant).

71. *Id.*

72. *Id.*; OTA, *supra* note 1, at 234.

man National Parliament passed the process-oriented Genetic Technology Law in 1990.<sup>73</sup> The Genetic Technology Law permits the release of genetically engineered organisms into the environment with the approval of the Federal Health Authority ("*Bundesgesundheitsamt*").<sup>74</sup> Approvals depend upon the safety classification of the deliberate release.<sup>75</sup> Safety classifications range from levels 1 to 4, with level 1 offering no risk to human health or the environment, and levels 2, 3, and 4 offering slight, moderate, and high levels of risk, respectively.<sup>76</sup> Recognizing that genetic technology retains a certain amount of risk, this Act provides for civil liability of manufacturers and other parties who create environmental risks up to DM160 million.<sup>77</sup> In addition, this Act contains criminal and penalty provisions to promote enforcement and to secure compliance with its terms.<sup>78</sup>

The Genetic Technology Law contains a provision for public hearings of objections.<sup>79</sup> In Cologne, over 16,000 objections were made in response to the Max-Delbrück Laboratory's plans to grow 10,000 genetically manipulated petunias in an open field as part of a experiment.<sup>80</sup> These lengthy public hearings have slowed genetic research and development in Germany.<sup>81</sup> Representatives of the German biotechnology industry claim that the current, strict regulations discourage the development of the industry and cause research scientists to

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73. Gesetz zur Regelung von Fragen der Gentechnik, 1990 BGBl. I 1080 (F.R.G.) [hereinafter *Gentechnikgesetz*]; see Ruetsch, *supra* note 68, at 410 n. 15 (discussing Bundestag Drucksache 11/6778, 27 March 1990); *Genetic Engineering*, *supra* note 51 (stating Germany has chosen process-oriented regulation of biotechnology); *Implementation of Biotechnology Rules Reassures Companies - Germany Leads the Way*, BUS. EUR., Apr. 24, 1992 available in LEXIS, World Library, ALLNWS File (citing to *Gentechnik-Gesetz*); see also *Germany: Biotechnology*, *supra* note 66 (responding to environmental pressure groups and Green party, German Bundestag passed Genetic Technology law in 1990).

74. See Ruetsch, *supra* note 68, at 410. Approvals for deliberate releases must be granted or denied by the Federal Health Authority within three months of application. *Id.*

75. *Id.*

76. *Gentechnikgesetz*, *supra* note 73, § 7, 1990 BGBl. I at 1083.

77. See Ruetsch, *supra* note 68, at 410.

78. *Id.* at 411.

79. See *Implementation of Biotech Rules Reassures Companies*, *supra* note 73 (discussing public hearings in Germany over genetically engineered petunias).

80. *Id.*

81. *Id.*



go abroad to countries with less severe restrictions.<sup>82</sup> At least one major German chemical manufacturer has moved its genetic research laboratory to the United States, where the regulations are less restrictive.<sup>83</sup> In its stringent requirements, the Genetic Technology Law reflects the impact of political pressure exerted by public groups.<sup>84</sup> The German public's distrust of biotechnology probably will continue until scientific evidence better establishes its safety.<sup>85</sup>

Like Germany, Japan also has a strong biotechnology industry with relatively stringent requirements for the deliberate release of GMOs. In Japan, concern regarding the field testing of genetically modified organisms is pervasive.<sup>86</sup> The first field test of a GMO in Japan, for a transgenic tomato, occurred in 1991.<sup>87</sup> Japan is one of the world's leaders in biotechnology, second only to the United States.<sup>88</sup> The Japanese government has identified biotechnology as one of the key technologies of

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82. See *German Law Endangering Biotech?*, *supra* note 9 (quoting president of German chemical industry association (VCI) stating, "The restrictive, bureaucratic and overloaded enforcement of the [German Gene Technology] Act . . . is paralysing development.")

83. See Richard L. Hudson, *German Debate on Genes Stings Drug Makers*, WALL ST. J., Aug. 31 1989, at B1 (stating that BASF plans to locate research labs in Boston); Robert R. Bliss, *BASF to Build Biotech Plant*, N.Y. TIMES, Apr. 29, 1990 (Real Estate), at 21, (stating that BASF plans to build worldwide headquarters for biomedical research and manufacturing center in Worcester, Massachusetts).

84. Ruetsch, *supra* note 68, at 410-11; see OTA, *supra* note 1, at 234. In other European countries where there is no Green Party, such as the Netherlands, governmental policies can favor industry. *Id.* at 236; *Dutch Official Urges Global Approach to Biotechnology Risk, Assessment Issues*, INT'L ENVTL. DAILY (Oct. 16, 1991) (BNA), available in LEXIS, World Library, ALLNWS File (quoting Dutch policymaker). Deliberate releases are regulated by the April 1991 Decree on Genetically Modified Organisms, under the Chemical Substances Act. *Id.* Under the decree, a new license must be granted for each new activity involving the deliberate release of organisms into the environment, in the form of engineered plants, insects, and animals. *Id.*

85. See *German Law Endangering Biotech?*, *supra* note 9 (stating that genetic engineering has become linked in German public's mind with emotional issues like prenatal diagnostics, artificial insemination, and genome analysis); OTA, *supra* note 1, at 234 (discussing Germany's regulatory environment). To assuage the German public's general safety concerns regarding genetic manipulation, the German government plans to fund a new research program to assess the risk of biotechnology through its Ministry for Research and Technology. *Id.*

86. OTA, *supra* note 1, at 20.

87. See NEW TECHNOLOGICAL ERA, *supra* note 6, at 207 (noting that field testing of tomatoes engineered to resist tobacco mosaic virus by National Institute of Agro-Environmental Science (NIAES)).

88. See OTA, *supra* note 1, at 19 (stating that Japan, rather than Europe, would most likely be leading competitor of United States in biotechnology).

the future, spending US\$604 million on biotechnology in 1989.<sup>89</sup> In Japan, the responsibility for regulating biotechnology is divided among several ministries.<sup>90</sup> The Ministry of Agriculture, Forestry, and Fisheries (the "MAFF") is responsible for agricultural environmental protection.<sup>91</sup> The MAFF's *Guidelines for the Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries in Japan*, published in 1989, are process-oriented regulations that apply to the release of GMOs.<sup>92</sup>

In contrast to Denmark, Germany, and Japan, the United Kingdom has been at the forefront of biotechnology regulation.<sup>93</sup> A number of field tests of GMOs have already occurred in the United Kingdom.<sup>94</sup> The Health and Safety at Work Act of 1974 (the "1974 Act") was the first U.K. regulation for biotechnology.<sup>95</sup> Under the 1974 Act, the Health and Safety

89. JAPANESE BIOTECHNOLOGY, *supra* note 15, at 1. Although the Japanese government spends only a fraction of the US\$2.7 billion spent by the U.S. government in 1987, the Japanese government still spends more than any of the Western European countries. *Id.* at 2.

90. *See id.* at 60-61. The Japanese Ministry of Education, Science and Culture regulates basic research at universities. *Id.* The Science and Technology Agency [hereinafter STA] regulates basic research in national laboratories and private industry. *Id.* The Ministry of Agriculture, Forestry, and Fish [hereinafter MAFF] regulates large-scale production of plants and animals. *Id.* The Ministry for Industrial Trade and Industry [hereinafter MITI] regulates large-scale manufacture of specialty chemicals. *Id.* MITI and the Environmental Protection Agency regulate waste treatment together. *Id.* The Ministry of Welfare and Health regulates the large-scale production of drugs. *Id.* MITI is the principal architect of Japanese biotechnology and developing biotechnology regulations that will forestall strong public opposition while at the same time comply with the OECD recommendations. *Id.* at 4, 48. *See* OTA, *supra* note 1, at 247. MITI oversees the "Guidelines for Industrial Application of Recombinant DNA Technology." *Id.* Introduced in 1986, these guidelines apply to large-scale industrial processes and the containment of GMOs. *Id.*

91. *See* NEW TECHNOLOGICAL ERA, *supra* note 6, at 206 (discussing Japanese regulations for biotechnology).

92. *See Guidelines for the Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries in Japan*, ch. 3 § 1, translated in JAPANESE BIOTECHNOLOGY, *supra* note 15, at 293 (stating regulation of deliberate release of GMOs); *see also id.*, ch. 2 § 1, at 287 (outlining fundamental principles of safety evaluation for rDNA Organisms). As of 1990, the STA was in the process of revising its guidelines to include the deliberate release of recombinant organisms. *Id.* at 61.

93. *See* Moses, *supra* note 13, at 109 (comparing Great Britain's passing biotechnology regulations in 1978 with majority of other European countries which had non-mandatory schemes until early 1980s).

94. *Id.*

95. The Health and Safety at Work, Etc Act, 1974, ch. 37 (Eng.), reprinted in 19

Commission (the "HSC") has the primary role of protecting health in the workplace while the Health and Safety Executive (the "HSE") regulates the safety of industrial processes using microorganisms and other biological processes.<sup>96</sup> The Advisory Committee on Genetic Modification (the "ACGM") advises both the HSC and the HSE on the safety of proposed activities involving GMOs.<sup>97</sup>

The 1974 Act was amended in 1989 to require notification to the HSE and the ACGM before any planned releases.<sup>98</sup> The Environmental Protection Act of 1990, administered by the Department of the Environment, now provides the basis for protecting the environment from the deliberate release of GMOs.<sup>99</sup> The new regulations are designed to comply with the European Community (the "EC") directives on the deliberate releases of GMOs into the environment and are process-oriented.<sup>100</sup> The HSC formed the Advisory Committee on Release to the Environment in 1990 to give advice on the safety of proposed releases into the environment.<sup>101</sup> The British government estimates that the new regulations will cost com-

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HALSBURY'S STATUTES OF ENGLAND AND WALES 620-88 (4th ed. 1990); see GIBBS, *supra* note 10, at 190 (discussing Health and Safety at Work, Etc Act).

96. GIBBS, *supra* note 10, at 190.

97. See OTA, *supra* note 1, at 193. The Advisory Committee on Genetic Modification was formerly the Advisory Committee on Genetic Manipulation. *Id.*

98. Genetic Manipulation Regulations, S.I. 1989, No. 1810; see GIBBS, *supra* note 10, at 192 (discussing Genetic Manipulation Regulations); Moses, *supra* note 13, at 111 (discussing Genetic Manipulation Regulations).

99. Environmental Protection Act, 1990, pt. VI (Eng.), Genetically Modified Organisms, 1990, ch. 43 (Eng.); see *Biotech Regulations Bite*, PHARMACEUTICAL MANUFACTURING REV., June 1991, at 18, available in LEXIS, World Library, ALLNWS File (reporting that Environmental Protection Act of 1990 was passed to comply with EC directives on deliberate releases); UK: *Department of the Environment — Proposals for New Regulations on Genetically Modified Organisms*, Reuter Textline, Aug. 18, 1992, available in LEXIS, World Library, ALLNWS File (reporting that Department of Environment and Health and Safety Commission have published proposals for new regulations on safe use and handling of GMO); see also *Proposal Would Carry Out EC Directives on Handling, Use of Modified Organisms*, INT'L ENVTL. Nov. 29, 1991 (BNA), available in LEXIS, World Library, ALLNWS File (quoting U.K. government official stating that Genetic Manipulations Regulations continue to protect human health and safety, but they were not designed to protect environment).

100. See Aldhous, *supra* note 13, at 5 (discussing U.K.'s compliance with 1990 EC Directive for deliberate releases); *Genetic Engineering*, *supra* note 51, at 57 (discussing process-oriented regulations).

101. UK: *Committee to Advise on Release of Genetically Modified Organisms Formed*, Reuter Textline, Apr. 30, 1990, available in LEXIS, World Library, ALLNWS File; see Roger Highfield, *Move to Allay Concern over Genetic Engineering*, DAILY TELEGRAPH, Jan.

panies and research institutions between £3 million and £10 million over the next five years.<sup>102</sup> Most of this money will be generated from filing fees associated with deliberate release applications for GMO market products and field tests.<sup>103</sup>

## 2. Product-Specific Deliberate Release Regulations

While Denmark, Germany, Japan, and the United Kingdom apply process-oriented approaches, passing new biotechnology laws to regulate deliberate releases, the United States has chosen a product-specific approach, regulating GMOs with pre-existing statutes.<sup>104</sup> For example, in the United States, a

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3, 1991, at 8 (reporting field testing of genetically modified oilseed rape plants approved by Advisory Committee for Release into Environment).

102. See Aldhous, *supra* note 13, at 5. Most consents for environmental releases in the U.K. will cost between £2000 and £4000 under the new regulations. *Id.* Germany and Denmark are proposing similar fees for deliberate release approvals. *Id.*

103. *Id.* (stating that Department of Environment plans to charge same fees to academics as to industry).

104. See, e.g., Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From *Escherichia* L-12, 55 Fed. Reg. 10,932 (1990) (to be codified at 21 C.F.R. pt. 184) (regulating genetically modified enzyme as food additive); see FIELD TESTING, *supra* note 20, at 138 (describing process-oriented approach); GIBBS, *supra* note 10, at 272 (describing product-specific approach); *Genetic Engineering*, *supra* note 51 (comparing process oriented approach of EC with product-specific regulatory approach of U.S.).

The use of pre-existing statutes by the United States to regulate biotechnology has been criticized by commentators who point out that these statutes were originally created to govern a class of products unrelated to bioengineered substances. Harrington, *supra* note 123, at 28; see ROBERT A. BOHRER, FROM RESEARCH TO REVOLUTION 119 (1985) ("TSCA is not a meaningful regulatory structure for environmental releases"); Ruth E. Harlow, Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 564 (1986) ("The current TSCA, as it applies to biotechnology, establishes insufficient regulatory power and fails to prescribe adequately the pre-release decisionmaking process."); see also Gary Marchant, Note, *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, 164 (1988) (discussing dissatisfaction with U.S. regulatory scheme for biotechnology).

Commentators have also criticized the U.S. multi-layered regulatory system for its interagency conflicts, delays, and expenses. See *Interagency Conflict and Administrative Accountability: Regulating the Release of Recombinant Organisms*, 77 GEO. L.J. 1787 (1989) (discussing interagency conflict in U.S. regulatory structure for deliberate release of GMOs); Harrington, *supra* note 123, at 28 ("jurisdictional overlap among various federal agencies creates a bureaucratic logjam"); Peter W. Huber, *Biotechnology and the Regulation Hydra*, 90 TECH. REV. 8, 57 (1987), available in LEXIS, World Library, ALLNWS File. "Effective regulatory approval can require a quiver of licenses" and "delays of month and years are now common . . . companies must invest large sums in the early stages of developing a product to satisfy agency regulations." *Id.* But see Declan Conroy, *USDA Moves to Speed Up Bio-Ag Commercialization*, FOOD & DRINK

cheesemaking enzyme produced by genetically altered bacteria is regulated as a food additive, like other enzymes under the Food Additives Amendment.<sup>105</sup> The United States regulates biotechnology at the federal level of government.<sup>106</sup> Although several federal agencies now regulate biotechnology, for nearly a decade, the National Institutes of Health (the "NIH") assumed primary responsibility for the safety of genetic engineering.<sup>107</sup>

The NIH first developed guidelines for research involving rDNA in 1976.<sup>108</sup> These guidelines were designed to ensure the safety of laboratory work and to prevent the accidental escape of rDNA microorganisms.<sup>109</sup> The guidelines eventually became binding on all institutions receiving any federal funding, in addition to those receiving NIH grants.<sup>110</sup> The influence of these guidelines has subsequently spread beyond federally funded research activities.<sup>111</sup> State and local governments, academic institutions, the industrial community, and non-US countries have voluntarily either applied the NIH guidelines or applied modified versions of them.<sup>112</sup>

Although experiments involving environmental introductions of GMOs were originally prohibited,<sup>113</sup> the NIH

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DAILY, Nov. 2, 1992, available in LEXIS, Nexis Library, OMNI File. (discussing USDA permitting procedures for field testing GMOs). The U.S. Department of Agriculture [hereinafter USDA] is proposing a new system whereby small-scale field tests could be conducted by notifying the Animal Plant Health and Inspection Service [hereinafter APHIS], without seeking a permit. *Id.*

Even the United States Office of Technological Assessment admits that the U.S. regulatory system has been criticized as "too confusing." OTA, *supra* note 1, at 186.

105. See 55 Fed. Reg. 10,932 (1990), *supra* note 104 (granting FDA approval for genetically engineered chymosin); see also OTA, *supra* note 1, at 107.

106. See generally Edward L. Korwek and Peter De La Cruz, *Federal Regulation of Environmental Releases of Genetically Manipulated Microorganisms*, 11 RUTGERS COMPUTER & TECH. L.J. 301 (1985) (discussing federal regulation of GMOs).

107. APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 28.

108. See FIELD TESTING, *supra* note 20, at 134-35 (discussing National Institutes of Health [hereinafter NIH] guidelines for genetic research).

109. *Id.* at 135.

110. *Id.* at 136.

111. *Id.*

112. APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 31. Although the NIH had no legal jurisdiction over the research in private companies, firms were not willing to risk the negative publicity that might arise if they violated the NIH guidelines. *Id.* at 29. The few cases where violations of the guidelines were reported took place at universities. *Id.*

113. FIELD TESTING, *supra* note 20, at 135.

amended its guidelines in 1978 to permit the NIH director to grant exceptions to the general prohibition on planned introductions of genetically manipulated organisms.<sup>114</sup> The first two NIH approvals of field tests produced no significant public reaction.<sup>115</sup> However, the third request for permission to field test frost resistant bacterium became a public controversy, culminating in a court challenge in 1984.<sup>116</sup>

In 1986, the Office of Science Technology Policy issued a policy statement called the Coordinated Framework for Regulation of Biotechnology (the "Framework").<sup>117</sup> The Framework divided jurisdiction over the environmental regulation of biotechnology among several federal agencies.<sup>118</sup> The Framework applies four general principles.<sup>119</sup> First, the Framework

114. *Id.* (stating that NIH guidelines were amended on the advice of Recombinant Advisory Committee). The guidelines developed by the National Institute of Health for the release of genetically modified organisms into the environment were binding only on those who received government funding. APPLICATIONS OF BIOTECHNOLOGY, *supra* note 18, at 61. The private sector was encouraged to comply, but there were no penalties for noncompliance. *Id.* at 61-62.

115. APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 35 (stating that genetically modified corn was subject of first request; genetically modified tomato and tobacco plants were subject of second request).

116. *See* Foundation on Economic Trends v. Heckler, 587 F. Supp. 735 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985). Three public interest groups, and two individuals successfully brought suit against the NIH, claiming that permitting the field test to proceed without an environmental impact statement would violate the National Environmental Policy Act of 1969, 42 U.S.C. § 4331-4335 (1988 & Supp. III 1991) ("NEPA"). *Id.* at 150-51. The D.C. Circuit court affirmed a preliminary injunction to stay the field testing of genetically altered soil bacterium on the grounds that the NIH had failed to comply with NEPA's environmental impact statement requirement. *Id.* at 150; *see* 42 U.S.C. § 4332(2)(c) (1988 & Supp. III 1991); *see also* APPLICATION OF BIOTECHNOLOGY, *supra* note 17, at 42 (discussing *Heckler*); FIELD TESTING, *supra* note 21, at 136 (discussing *Heckler*); *see generally* Kathryn Freistadt, Note, *Environmental Review of Recombinant DNA Experiments Under NEPA: Foundation on Economic Trends v. Heckler*, 21 U.S.F. L. REV. 501 (1987) (discussing *Heckler*).

117. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,301 (1986).

118. *See id.* (describing policies of Food and Drug Administration [hereinafter FDA], Environmental Protection Agency [hereinafter EPA], Occupational Safety and Health Administration [hereinafter OSHA], NIH, and USDA); Arthur Harrington & Harlan A. Loeb, *Agencies are Blinded by Science*, NAT'L L.J., Sept. 7, 1992, at 23 (discussing U.S. regulation of biotechnology).

119. Moses, *supra* note 13, at 105; *see generally* David T. Bonk, *FDA regulation of Biotechnology*, 43 FOOD DRUG COS. L.J. 67 (1988).

states that existing laws will regulate biotechnology.<sup>120</sup> Second, it provides that the products of biotechnology, rather than the process itself, will be regulated.<sup>121</sup> Third, the safety of a biotechnology product will be determined on an individual, or case-by-case, basis.<sup>122</sup> Last, it provides for a coordinated effort among all the agencies involved in regulating biotechnology.<sup>123</sup>

The Framework gave the Environmental Protection Agency (the "EPA") primary responsibility over the environmental regulation of biotechnology.<sup>124</sup> The EPA's regulation of biotechnology has focused on the introduction of microorganisms into the environment.<sup>125</sup> The EPA derives its specific authority to regulate the release of GMOs from two statutes: the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")<sup>126</sup> and the Toxic Substances Control Act ("TSCA").<sup>127</sup>

FIFRA treats biopesticides, microorganisms intended for use as pesticides, as chemical pesticides.<sup>128</sup> All pesticides must be registered with the EPA under FIFRA.<sup>129</sup> FIFRA's provisions also require the EPA to issue a permit before the field

120. 51 Fed. Reg. 23,302 (1986); *see* Moses, *supra* note 13, at 105 (discussing the Coordinated Framework for Regulation of Biotechnology).

121. 51 Fed. Reg. 23,302 (1986).

122. *Id.*

123. *Id.* The Coordinated Framework discusses the laws and policies of the NIH, the FDA, the EPA, the USDA, the OSHA, and the National Science Foundation. *Id.*

Commentators have argued that a centralized agency to regulate biotechnology would be more efficient. *See* Harrington, *supra* note 118, at 28 (suggesting that, "a centralized federal agency be created and charged with the responsibility of regulating only biotechnology"). *Id.*; Michael P. Vandenberg, Note, *The Rutabaga that Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529 (1986) (proposing centralized data bank for federal regulation of deliberate release); Marchant, *supra* note 104, at 207-08 (concluding that most promising approach for improving biotechnology regulation would be changes within current regulatory framework).

124. Moses, *supra* note 13, at 107; FIELD TESTING, *supra* note 20, at 138.

125. *See, e.g.*, Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313 (1986); Moses, *supra* note 13, at 107.

126. Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") 7 U.S.C. § 136-136(y) (1988 & Supp. III 1991).

127. *See* Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2601-2629 (1988 & Supp. III 1991).

128. *See* 7 U.S.C. § 136(u) (1988); *see also* 40 C.F.R. pt. 162.5(c)(4) (1991).

129. 7 U.S.C. § 136(a) (1988 & Supp. III 1991).

testing of any bioengineered pesticide.<sup>130</sup> In order to issue the permit, the EPA must determine that the field test will not cause an "unreasonable adverse effect" on the environment.<sup>131</sup> FIFRA places the burden of proof that the benefits of the product outweigh its risks on the permit applicant.<sup>132</sup>

The TSCA authorizes the EPA to acquire information on chemical substances in order to identify potential hazards and exposures.<sup>133</sup> The manufacturer of a new chemical must submit data on the chemical's safety to the EPA.<sup>134</sup> Unless the chemical presents an unreasonable risk to human health or the environment, the EPA must allow the marketing of the new chemical.<sup>135</sup> Under the TSCA, the EPA treats microorganisms and their DNA molecules as chemical substances subject to the TSCA's provisions.<sup>136</sup> Thus, the TSCA's requirements apply to bioremediation products, bioengineered growth hormones, and other biotechnology products.<sup>137</sup>

The Food and Drug Administration (the "FDA") reviews genetically engineered food products for food safety.<sup>138</sup> The FDA derives its regulatory authority from the Food, Drug, and Cosmetic Act, which requires that the manufacturer or importer of a product establish its safety to the FDA's satisfaction before marketing.<sup>139</sup> The FDA regulates human and animal drugs, medical devices, human and animal foods, food addi-

130. 40 C.F.R. § 158.170 (1991); Elizabeth A. Milewski, *The Approach of the U.S. Environmental Protection Agency in Regulating Certain Biotechnology Products*, in *Risk Assessment*, *supra* note 3, at 184.

131. 7 U.S.C. § 136c(d) (1988 & Supp. III 1991); see Milewski, *supra* note 130, at 184 (discussing FIFRA); Harrington, *supra* note 118, at 27 (discussing FIFRA).

132. See 7 U.S.C. § 136c(d) (1988 & Supp. III 1991).

133. See 15 U.S.C. §§ 2607(b) (1988 & Supp. III 1991).

134. 15 U.S.C. §§ 2602(1), 2604(a) (1988 & Supp. III 1991).

135. 15 U.S.C. § 2604(f) (1988 & Supp. III 1991).

136. 15 U.S.C. § 2602(2)(A) (1988 & Supp. III 1991); 51 Fed. Reg. 23,313 (1986).

137. See 51 Fed. Reg. 23,313 (1986) (discussing application of TSCA to biotechnology products); see also OTA, *supra* note 1, at 179. As of March 1991, nine applicants for field tests of genetically engineered micro-organisms had been approved by the EPA under TSCA, mainly for nitrogen-fixing bacteria. *Id.*

138. 51 Fed. Reg. 23,302 (1986); see Statement of Policy: Foods Derived From New Plant Varieties; Notice, 57 Fed. Reg. 22,984 (1992) (announcing FDA policy toward genetically modified foods); see generally *Tomato Gene*, *supra* note 19 (discussing FDA's decision not to require special approval for genetically engineered foods).

139. 21 U.S.C. § 342(a)(1) (1988 & Supp. III 1991).



tives, and cosmetics.<sup>140</sup>

While the FDA regulates the marketing of genetically modified foods,<sup>141</sup> the U.S. Department of Agriculture (the "USDA") regulates the release of genetically modified plants, animals, and microorganisms involved in agricultural biotechnology research.<sup>142</sup> The USDA uses the Federal Plant Pest Act (the "PPA") and the Plant Quarantine Act to regulate the release of genetically engineered micro-organisms derived from plant pests.<sup>143</sup> The PPA applies to environmental releases of insects or worms considered to be plant pests or organisms containing genetic material from plant pests.<sup>144</sup> The Animal Plant Health and Inspection Service ("APHIS") is the agency within the USDA responsible for the regulation of genetically engineered plants, microorganisms, and animal biologics.<sup>145</sup> APHIS requires that researchers submit a detailed description of their proposed field test in order to receive a permit.<sup>146</sup> As of September 1991, APHIS has issued 181 permits for small-scale field testing of genetically engineered plants or microorganisms.<sup>147</sup>

In March 1993, APHIS announced regulations for a notification process for the introduction of genetically engineered organisms and products.<sup>148</sup> The regulations also included a petition process allowing for a determination that certain arti-

140. 21 U.S.C. § 321 (1988 & Supp. III 1991).

141. See *NEW TECHNOLOGICAL ERA*, *supra* note 6, at 201 (stating that "FDA's authority is over the final food product in interstate commerce").

142. See Proposed USDA Guidelines for Research Involving the Planned Introduction Into the Environment of Organisms With Deliberately Modified Hereditary Traits, 56 Fed. Reg. 4134 (1991) (proposing USDA guidelines for assessing safety of planned releases of GMOs).

143. Federal Plant Pest Act, 7 U.S.C. § 150aa-150jj (1988 & Supp. III 1991); 7 C.F.R. § 340 (1991); *NEW TECHNOLOGICAL ERA*, *supra* note 6, at 185. The Plant Quarantine Act can also be used to regulate deliberate releases but has rarely been applied to GMOs. *Id.*; Plant Quarantine Act, 7 U.S.C. § 151-164a, § 166-67 (1988).

144. 7 C.F.R. § 340 (1993); see *NEW TECHNOLOGICAL ERA*, *supra* note 6, at 185 (discussing Plant Pest Act).

145. See Moses, *supra* note 13, at 107; see *NEW TECHNOLOGICAL ERA*, *supra* note 6, at 192-93 (explaining that vaccines and medical diagnostic tests are examples of biologics).

146. See Conroy, *supra* note 104 (applying for permit costs average of US\$5,000 and permit approval process may take up to four months).

147. *NEW TECHNOLOGICAL ERA*, *supra* note 6, at 183.

148. Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status; Final Rule, 58 Fed. Reg. 17044 (1993) (to be codified at 7 C.F.R. § 340).

cles are no longer regulated articles.<sup>149</sup>

### 3. No Deliberate Release Regulations

In order to encourage the growth of the biotechnology industry, many countries with active investments in biotechnology have declined to regulate the deliberate release of GMOs into the environment.<sup>150</sup> Examples of countries in this category are South Korea and Taiwan.<sup>151</sup> In South Korea, the Genetic Engineering Promotion law was passed in 1983 to promote the biotechnology industry by establishing a basic plan to form genetic research programs and by creating a council for genetic engineering policy.<sup>152</sup> Like South Korea, the government of Taiwan has focused its efforts on the promotion of biotechnology and has no regulations for deliberate releases.<sup>153</sup>

Other countries with no regulations for biotechnology include Latin American, Caribbean, and Eastern European nations.<sup>154</sup> Many of these countries have sent their representa-

149. *Id.*

150. OTA, *supra* note 1, at 188.

151. *Id.* at 152; *Biotech Grows in Hong Kong*, 352 NATURE 273, July 25 1991 (stating that "[s]everal Asian governments regard biotechnology as an obvious successor to consumer electronics in their struggle to succeed in the world's high-technology markets").

152. See OTA, *supra* note 1, at 238 (discussing Korean Genetic Engineering Promotion Law 1983). The Korean Genetic Research Association (KOGERA) includes the nineteen largest Korean firms engaged in biotechnology which dominate industrial activity in South Korea. *Id.*

153. *Id.* at 240. See *Biotech Grows in Hong Kong*, *supra* note 151, at 273 (stating that Taiwanese government has invested several million US dollars into biotechnology-related industries). *Id.*; McGarity, *supra* note 1, at 424 n.2 (citing *Pacific Rim Tactic: U.S. Partners Now, Worldwide Bio-Markets Later*, BIOTECH. NEWSWATCH, Sept. 19, 1988, at 7 (discussing Taiwanese government's tax incentives for research and development investments)).

154. See ORGANIZATION OF AMERICAN STATES, INTERNATIONAL OFFICE OF EPIZOOTICS, GUIDELINES FOR THE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS, Prologue (Inter-American Institute for Cooperation on Agriculture/Canadian International Development Agency Project 1991); *Biotech Regulations Bite*, *supra* note 99, at 18 (reporting that within Eastern European bloc, no specific legislation for biotechnology exists, although the former Yugoslavia has applied OECD's guidelines).

In general, developing countries have no regulations for biotechnology in their regulatory agencies. NEW TECHNOLOGICAL ERA, *supra* note 6, at 207. This situation, however, is changing very rapidly. Letter from John H. Barton, George E. Osborne Professor of Law at Stanford Law School, to author (May 26, 1993) (on file with the FORDHAM INTERNATIONAL LAW JOURNAL) [hereinafter Barton letter]. Mexico, the Phil-

tives to the United States to learn about biotechnology regulation.<sup>155</sup> Countries that have exchanged regulatory scheme information with the United States include China, India, Mexico, Costa Rica, Brazil,<sup>156</sup> Argentina, Chile, Nigeria, Kenya, Zimbabwe, Thailand, and the Philippines.<sup>157</sup> Some of these countries with no regulations for deliberate releases have served as test sites for researchers escaping the regulatory oversight of their own countries.<sup>158</sup> For example, the Wistar Institute of Philadelphia conducted tests for a genetically engineered vaccine on cattle in Argentina.<sup>159</sup>

## II. INTERNATIONAL AGREEMENTS

International harmonization of regulations for deliberate releases can reduce trade barriers and improve regulatory methodologies.<sup>160</sup> Recognizing the benefits of international harmonization, many nations have participated in multilateral efforts to regulate the deliberate release of GMOs.<sup>161</sup> Among these international efforts, the greatest number of nations participated in the 1992 United Nations Conference on the Envi-

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ippines, Thailand and India either have passed or are currently developing regulations for deliberate releases. *Id.*

155. NEW TECHNOLOGICAL ERA, *supra* note 6, at 207.

156. See OTA, *supra* note 1, at 231. Interestingly, Brazil has chosen to adopt the regulatory guidelines of the United States's NIH and EPA for laboratory and environmental safety. *Id.* Brazil presently has an entire branch of government devoted to biotechnology and is concerned about deliberate releases. *Id.* at 230.

157. *Id.*

158. Huber, *supra* note 104, at 57 (noting example of Wistar Institute's testing of vaccine in Argentina).

159. *Id.*; L. Chris Heinemeyer, Note, *Oversight of the Release of Genetically Altered Microorganisms: Suggestions for an International Approach*, 24 TEX. INTL. L.J. 331, 350 (1989).

160. See GIBBS, *supra* note 10, at 264 (stating that international harmonization would be beneficial). The formal U.S. policy is to promote scientific cooperation, reduce trade barriers, and gain recognition among nations of the importance of harmonizing biotechnology regulation. *Id.* at 264 n.1 (citing Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,308 (1986)).

161. See e.g., Agenda 21, *supra* note 12, U.N. Doc. A/CONF.151/26/Rev.1 (1993); Biodiversity Treaty, *supra* note 12, U.N. Doc. DPI/1307 (1992), reprinted in 31 I.L.M. at 818 (1992); 1992 REPORT, *supra* note 12; 1986 REPORT, *supra* 12; Council Directive No. 90/220, 1990 O.J. (L 117); see also *Environment: Seven States Sign Civil Liability Convention*, EUR. REP. Jun. 24, 1993, available in LEXIS, Nexis Library, OMNI File (stating that Cyprus, Finland, Greece, Italy, Liechtenstein, Luxembourg, and Netherlands have signed an international convention on civil liability for damage resulting from activities dangerous to environment, including the use of GMOs).

ronment and Development ("UNCED" or the "Earth Summit") in Rio de Janeiro, Brazil.<sup>162</sup> The Organization for Economic Co-Operation and Development (the "OECD"), in its effort to address the particular needs of industrialized nations, has produced reports recommending specific safety measures for field testing of GMOs.<sup>163</sup> To date, the most comprehensive multi-national deliberate release regulations are the EC directives for notification and endorsement of deliberate releases for both research and commercial purposes.<sup>164</sup>

#### A. *The Earth Summit in Rio*

The UNCED was held in Rio de Janeiro, Brazil on June 3-14, 1992.<sup>165</sup> The Earth Summit addressed many global issues, including the environmental management of biotechnology.<sup>166</sup> During the Earth Summit, 182 participating nations adopted Agenda 21, while 153 nations signed the Convention on Biological Diversity (the "Biodiversity Treaty").<sup>167</sup> Both Agenda 21 and the Biodiversity Treaty address safety regulations concerning GMOs.<sup>168</sup>

Agenda 21 is an action plan calling for sustainable economic growth through international cooperation.<sup>169</sup> Chapter

162. See *Earth Summit approves Agenda 21*, Rio Declaration Record number of world leaders attend, U.N. CHRONICLE, Sept. 1992, at 59 [hereinafter *Earth Summit approves Agenda 21*] (stating that 182 nations participated in Earth Summit); Bette Hileman, *Earth Summit Concludes With Agenda for Action, but Little Funding*, CHEMICAL & ENGINEERING NEWS, July 6, 1992, at 7 (stating that 153 nations had signed Biodiversity Treaty).

163. 1992 REPORT, *supra* note 12; 1986 REPORT, *supra* note 12.

164. See e.g., Council Directive No. 90/220, 1990 O.J. (L 117); Council Decision No. 92/146, 1992 O.J. (L 60).

165. United Nations Conference on Environment and Development, *supra* note 12, U.N. Doc. A/CONF. 151/26/Rev.1 (1993), reprinted in 31 I.L.M. 814 (1992); *Earth Summit*, U.N. CHRONICLE, June 1992, at 40.

166. *Earth Summit*, *supra* note 165, at 53.

167. See *Earth Summit approves Agenda 21*, *supra* note 162, at 59 (stating that 182 nations unanimously adopted Agenda 21 and Biodiversity Treaty was opened for signature); Hileman, *supra* note 162, at 7 (stating that 153 nations signed Biodiversity Treaty).

The Biodiversity Treaty will enter into force after ratification by 30 states. As of August 1993, there are only 19 ratifications, so the Biodiversity Treaty is not yet enforceable. Telephone interview with the United Nations, Office of Legal Affairs, Treaty Division, New York, N.Y. (Aug. 10, 1993).

168. Agenda 21, *supra* note 12, U.N. Doc. A/CONF. 151/26/Rev1 Vol. I ch. 16, at 218 (1993); Biodiversity Treaty, *supra* note 12, U.N. Doc. DPI/1307 (1992), 31 I.L.M. at 818.

169. See *Earth Summit*, *supra* note 165, at 44. Agenda 21 links economic develop-

16 of Agenda 21, entitled "Environmentally Sound Management of Biotechnology," states that Agenda 21's goal is to foster international principles for the environmental management of biotechnology, as well as to promote sustainable applications of biotechnology.<sup>170</sup> Other portions of Agenda 21 that address biotechnology include Chapter 14, which provides for the sharing of research and plant genetic resources among nations,<sup>171</sup> and Chapter 19, which deals with risk management of toxic chemicals and may also apply to certain biopesticides and other hazardous products of biotechnology.<sup>172</sup> Chapter 15 of Agenda 21 is intended to improve the conservation of biological diversity and supports the Biodiversity Treaty.<sup>173</sup>

The Biodiversity Treaty calls for the transfer of technology from economically more advanced countries to less developed countries in an attempt to create a more equitable world order.<sup>174</sup> To make reparations for genetic material taken out of a developing country, the Biodiversity Treaty requires that

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ment with environmental protection, in furtherance of achieving sustained development. *Id.* Agenda 21 aims to "lead to the fulfillment of basic needs, improved living standards for all, better protected and managed ecosystems and a safer, more prosperous future," extending into the twenty-first century." *Id.*

170. See Agenda 21, *supra* note 12, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I) ch. 16, at 218 (1993). Chapter 16 determined the final program areas in biotechnology: a) increasing the availability of food, feed and renewable raw materials; b) improving human health; c) enhancing protection of the environment; d) enhancing safety and developing international mechanisms for cooperation; and e) establishing enabling mechanisms for the development and the environmentally sound application of biotechnology. *Id.*

171. Agenda 21, *supra* note 12, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I) ¶ 14.57(d) at 195 (1993). "To take appropriate measures for the fair and equitable sharing of benefits and results of research and development in plant breeding between sources and users of plant genetic resources." *Id.*

172. Agenda 21, *supra* note 12, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I) ch. 19, at 315 (1993).

173. Agenda 21, *supra* note 12, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I) ch. 15, at 210 (1993).

174. Biodiversity Treaty, *supra* note 12, U.N. Doc. DPI/1307 art. 16 at 9 (1992); 31 I.L.M. at 829; see *The Biodiversity Treaty: Pandora's Box or Fair Deal?*, 245 Sci. 1624, June 19, 1992 (discussing technology transfer proposed in Biodiversity Treaty); see generally Timothy M. Swanson, *Economics of a Biodiversity Convention*, 21 AMBIO No.3, at 250 (May 1992) (discussing technology transfer proposed in Biodiversity Treaty). The rosy periwinkle flower of Madagascar was used to manufacture a remedy for Hodgkin's Disease. *Id.* at 255. Although sales of the remedy yielded millions of dollars in profits for pharmaceutical companies, Madagascar has not received any revenues from the sale of this important new drug. *Id.* The purpose of the Biodiversity Treaty was to rectify these types of situations. *Id.* at 255-56.

signatories either share technologies or remunerate the developing country.<sup>175</sup> Article 19 of the Biodiversity Treaty provides for safety regulations to guard against the potential adverse affects of specific genetically modified organisms.<sup>176</sup> The Biodiversity Treaty, however, does not mention GMOs, although GMOs are understood to be a part of the Treaty.<sup>177</sup> Because the Biodiversity Treaty does not enunciate specific regulations, the Treaty provides for the adoption of a later protocol that will specify detailed biotechnology safety measures, including the safe transfer of GMOs.<sup>178</sup>

### B. Organization of Economic Co-Operation and Development

The Organization of Economic Co-operation and Development (the "OECD") is an international organization of twenty-four industrialized countries whose purpose is to encourage economic growth and development for its members.<sup>179</sup> In 1986, the OECD published an extensive report

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175. Biodiversity Treaty, *supra* note 12, U.N. Doc. DPI/1307 arts. 16, 20, 21 at 9, 11, 12 (1992); 31 I.L.M. at 829, 830-32 (1993). The U.S. did not sign the Biodiversity Treaty because of the treaty's points on technology transfer, intellectual property rights, biotechnology and biosafety, and the financial mechanisms. 31 I.L.M. at 817 (1992). *But see* Timothy Noah, *Clinton to Back International Accord On Environment That Bush Spurned*, WALL ST. J. Apr. 22, 1992, at B7 (announcing that U.S. President Clinton will sign Biodiversity Treaty).

176. Biodiversity Treaty, *supra* note 12, U.N. Doc. DPI/1307 art. 19 at 10-11 (1992); 31 I.L.M. at 830.

177. *See* UNEP News Release, May 26, 1992 (on file with the *Fordham International Law Journal*) (stating that at urging of the United States, treaty did not refer specifically to genetically modified organisms (GMOs). But GMOs are understood to be included in broader terms, such as "living modified organisms resulting from biotechnology").

178. *See* Biodiversity Treaty, *supra* note 12, U.N. Doc. DPI/1307 art. 19(3) at 11 (1992), 31 I.L.M. at 830.

179. *See* ALAN T. BULL, *BIOTECHNOLOGY: INTERNATIONAL TRENDS AND PERSPECTIVES* 2 (OECD 1982). The OECD is an intergovernmental organization comprised of 24 industrialized countries: Australia, Austria, Belgium, Canada, Denmark, Finland, France, the former Federal Republic of Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States. *Id.* The OECD was set up under a convention in Paris on December 14, 1960. *Id.* The convention provides that the OECD shall promote policies designed to achieve the highest sustainable economic growth and employment . . . to contribute to sound economic expansion . . . to contribute to world trade on a multi-lateral, non-discriminatory basis in accordance with international obligation. *Id.*; OTA, *supra* note 1, at 135 (discussing OECD countries pursuing biotechnology research and development in improved waste treatment). Although several OECD countries have pursued bi-

identifying safety considerations associated with rDNA products.<sup>180</sup> In general, the *Recombinant DNA Safety Considerations—Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques* (the “1986 Report”) stated that there was no scientific basis for enacting process-oriented legislation to regulate the use of rDNA techniques.<sup>181</sup> The 1986 Report recommended that the regulations of member countries should not impede future developments in rDNA techniques.<sup>182</sup> The 1986 Report also stated that the development of international guidelines was premature, but that harmonization could be facilitated by exchanging information.<sup>183</sup> According to the 1986 Report, environmental and agricultural applications for deliberate releases should be reviewed by a “national or other authority” on a case-by-case basis.<sup>184</sup> The 1986 Report concluded that the available data on the introduction of GMOs should be used to evaluate risks and that the controlled field testing of GMOs should be encouraged as it may provide the only mechanism for obtaining valid data.<sup>185</sup>

The 1986 Report was followed in 1992 by *Safety Considerations for Biotechnology* (the “1992 Report”), which contained safety assessments for small-scale field tests of GMOs.<sup>186</sup> The 1992 Report developed general principles for the design and the safety assessment of small-scale field testing of GMOs that have low or negligible risk.<sup>187</sup> The principles, labeled Good Development Principles (“GDP”), are based on the assump-

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otechnological research and development in improved waste treatment, research efforts in safety issues have been minimal. *Id.*

180. 1986 REPORT, *supra* note 12, at 24-31.

181. *Id.* at 8.

182. *Id.*

183. *Id.* at 41-42.

184. *Id.* at 42. The phrase “case-by-case” was defined as, “an individual review of a proposal against assessment criteria which are relevant to the particular proposal; this is not intended to imply that every case will require review by a national or other authority since various classes of proposals may be excluded.” *Id.* For large-scale industrial applications involving GMOs, the OECD recommended that low-risk microorganisms could be handled under conditions of Good Industrial Large-Scale Practice (“GILSP”) which sets standards for the contained industrial use of GMOs.

*Id.*

185. *Id.* at 39; see GIBBS, *supra* note 10, at 265-66 (discussing conclusions of 1986 Report).

186. 1992 REPORT, *supra* note 12, at 25.

187. *Id.* at 25.

tion that low or negligible risk for small-scale field testing of GMOs can be identified.<sup>188</sup> The GDP were developed under three assumptions. First, certain general scientific principles are more important in determining the risk of a field test than others.<sup>189</sup> Second, the potential risk can be determined by evaluating the conditions of the experiment.<sup>190</sup> Third, assessing the interaction of these risk factors is easier in small-scale field experiments.<sup>191</sup> The 1992 Report identified the origin and characteristics of the GMO, the research site, and the experimental conditions as the three key safety factors in determining the safety of a field test.<sup>192</sup> The report developed two sets of GDP, one for plants and one for microorganisms.<sup>193</sup> The general guidelines set by the GDP are a significant departure from the case-by-case approach recommended by the 1986 Report.<sup>194</sup> The efforts of the OECD have been both lauded and criticized.<sup>195</sup> Nevertheless, the 1986 Report has had considerable influence on the development of regulations and guidelines worldwide.<sup>196</sup> The GDP were adopted by the

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188. *Id.* at 28.

189. *Id.*

190. *Id.* at 28-29.

191. *Id.* at 29.

192. *Id.*

193. *See id.* at 31-32 (stating that GDP for plants requires that genetically modified plants remain reproductively isolated from sexually compatible plants outside experimental site and not released beyond research site; or plants are used, which even without reproductive isolation, will not cause uncontrolled adverse effects). The GDP for microorganisms recommends that genetic transfer and dissemination be controlled or field experiment designed so that no unintended adverse effects on other organisms will occur, even though transfer and dissemination occur. *Id.* at 32.

194. Compare 1992 REPORT, *supra* note 12 (discussing GDP for Plants and microorganisms in 1990 OECD Report) with 1986 REPORT, *supra* note 12 (describing case-by-case risk analysis of deliberate releases recommended by 1986 OECD Report).

195. Compare NEW TECHNOLOGICAL ERA, *supra* note 6, at 205 (describing OECD report as "the most compelling example of harmonization in the development of a common document on biotechnology safety") and Moses, *supra* note 13, at 110, (describing OECD's 1990 report as step "towards harmonization of the scientific principles underpinning the regulatory approaches of its member countries") with GIBBS, *supra* note 10, at 272 (criticizing report as only identifying considerations, and "broad recommendations," rather than specific regulatory framework) and Heinemeyer, Note, *supra* note 159, at 358-59 (criticizing OECD recommendations). *See also* McGarity, *supra* note 1, at 446 n.96 (discussing case-by-case approach of OECD recommendations).

196. Moses, *supra* note 13, at 110. The OECD's principles of Good Industrial Large-Scale Practice, 1986 REPORT, *supra* note 12, has been widely applied. Moses,



twenty-four member countries of the OECD.<sup>197</sup> As the United States was the lead country in developing the document, the OECD recommendations are in harmony with the regulations of the United States and promote international trade among the OECD members.<sup>198</sup>

### C. European Community Directives

The European Community (the "EC") is an economic union of twelve European nations.<sup>199</sup> The Single European Act of 1987 ("SEA") gives the EC a legal basis to enact environmental legislation.<sup>200</sup> Article 130(t) of the SEA provides that decisions of the EC shall not prevent Member States of the EC from maintaining or introducing their own protective measures compatible with the EEC Treaty establishing the European Community.<sup>201</sup>

In 1990, the Council of Ministers of the EC issued Directive No. 90/220 ("Directive 90/220"), the first multilateral attempt in force to provide a specific legal framework for the deliberate release of GMOs.<sup>202</sup> Directive 90/220 defines key

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*supra* note 13, at 110; see JAPANESE BIOTECHNOLOGY, *supra* note 15, at 60 (citing Japan's efforts to comply with OECD recommendations).

197. NEW TECHNOLOGICAL ERA, *supra* note 6, at 205.

198. *Id.* (stating that OECD recommendations "ensures good harmonization with U.S. regulations; this in turn, should facilitate international trade.").

199. See Single European Act, 1987 O.J. (L 169) (amending Treaty Establishing European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 3 (1958)) [hereinafter SEA]. The Member States are France, Portugal, Spain, Italy, Greece, Germany, Holland, Belgium, United Kingdom, Ireland, Denmark, and Luxembourg. *Id.*; see also Gerhard Hitzler, *Creating the Single Market: The Legislative Agenda*, 19 PLANNING REV. 35 (July-Aug. 1991) (stating that SEA stresses creation of integrated economic union as central objective of EC).

200. SEA, *supra* note 199, arts. 130(r)-(t), 1987 O.J. (L 169) at 11-12; see David Freestone, *European Community Environmental Policy and Law*, LAW POLICY AND THE ENVIRONMENT 135, 137-38 (1991). Actions taken under Article 130 of the SEA are subject to the principle of subsidiarity: The Community shall take action relating to the environment to the extent to which that the objectives [of EC policy] can be attained better at the Community level than at the level of the individual Member States. SEA, *supra* note 199, at art. 130r(4). See GEORGE A. BERMAN, ET. AL., EUROPEAN COMMUNITY LAW 1121 (1993) [hereinafter EC LAW]. Subsidiarity requires that the Community should leave issues to the Member states when they are better equipped to handle such matters at the national level than the Community is at the Community level. *Id.* Article 100(a) of the SEA also provides for environmental protection. *Id.*

201. SEA, *supra* note 199, art. 130(t), 1987 O.J. (L 169) at 12.

202. Council Directive No. 90/220, 1990 O.J. (L 117). A directive on the contained use of genetically modified organisms, relating to the use of microbes in closed systems was adopted at the same time. Council Directive No. 90/219, 1990

terms regarding the deliberate release of GMOs, solving the problem of disparate definitions among Member States.<sup>203</sup> Directive 90/220 authorizes the deliberate release of GMOs and the marketing of commercial GMO products intended for subsequent release into the environment.<sup>204</sup> Although Directive 90/220 sets minimum standards for regulations, each individual Member State must enact its own law that implements the Directive.<sup>205</sup> Member States must also designate competent authorities because the Directive provides for explicit consent from a national authority before releases can proceed.<sup>206</sup> Directive 90/220 stipulates that biotechnological researchers must also comply with any national laws to which they are also subject.<sup>207</sup> Thus, the party proposing deliberate releases in Member States with strict regulations will have to comply with national regulations as well as the regulations set forth in Directive 90/220.<sup>208</sup>

Directive 90/220 distinguishes between deliberate releases for research and development,<sup>209</sup> and deliberate releases for commercial products containing GMOs.<sup>210</sup> Before carrying out a release for research purposes, the party proposing the release must notify the competent national authority in that party's Member State.<sup>211</sup> The notification of the party's competent national authority must be accompanied by a de-

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O.J. (L. 117). See Proposals for Council Directives on the Deliberate Release to the Environment of Genetically Modified Organisms, COM(88) 160 final at 2 (discussing reasons for EC's adoption of directive for deliberate releases).

203. See BULL, *supra* note 179, at 11 (identifying problem with definition of key terms in all countries); GIBBS, *supra* note 10, at 274 (discussing difficulty in standardizing terms).

204. Council Directive No. 90/220, 1990 O.J. (L 117) at 16.

205. *Id.* art. 4, 1990 O.J. (L 117), at 2-3.

206. *Id.* arts. 5(1) and 4(2)-(3), 1990 O.J. (L 117); see EC LAW, *supra* note 200, at 1105 (discussing legislative framework for EC environmental action). Article 198 of the EEC Treaty binds Member States to directives, but Member States have discretion over implementation and enforcement. *Id.* The use of directives in the environmental area leaves some discretion to the Member States on how to implement Community rules and considerable discretion respecting their enforcement. *Id.*

207. Council Directive No. 90/220, art. 4, 1990 O.J. (L 117) at 17.

208. *Id.*

209. *Id.* arts. 5-9, 1990 O.J. (L 117) at 17-18; see generally Coopers & Lybrand, *Pharmaceuticals*, EC COMMENTARIES Feb. 11, 1993 § 17.7, available in LEXIS, World Library, ALLNWS File (discussing Directive 90/220).

210. Council Directive No. 90/220, arts. 10-18, 1990 O.J. (L 117) at 18-20.

211. *Id.* at art. 5.

tailed risk assessment offering proof of safety of the proposed release.<sup>212</sup> The risk assessment notification must identify the conditions and the environment in which the release is to occur, and must include an assessment of the possible hazards for human health and the environment.<sup>213</sup> Because the risks of deliberate releases are difficult to predict, Directive 90/220 authorizes releases on a case-by-case basis.<sup>214</sup>

The procedure for the deliberate release of a commercial GMO product is similar to that previously discussed for research releases.<sup>215</sup> Before releasing a commercial GMO product, the responsible party must notify the competent authority, providing details on the organisms proposed for the release, the conditions and the environment in which such release is to take place, and an assessment of the possible hazards for human health and the environment.<sup>216</sup> To protect trade secrets, sensitive information supplied to the authorities is kept confidential.<sup>217</sup> In contrast to a research release, the endorsement procedure for a commercial release requires consultation with the Commission of the EC (the "Commission") and other Member States.<sup>218</sup> Under Article 11(1) of Directive 90/220, the manufacturer or importer is required to notify the authority in the Member State where the product will be placed on the market initially.<sup>219</sup> Releases require written consent by the Commission and the other Member States.<sup>220</sup> The competent authorities must either reject the application or forward it to the Commission with a favorable opinion.<sup>221</sup> When sending an application of approval for a commercial GMO product to the Commission, the competent authorities appointed by Member States must include notification dossiers with information on the product, the genetic modification, and its possible impact

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212. *Id.*

213. *Id.*; see Moses, *supra* note 13, at 113 (discussing Directive 90/220).

214. *Biotechnology: Green Light for EC Directives on Genetically Modified Organisms*, EUR. REP., Mar. 24, 1990, at 12, available in LEXIS, Nexis Library, OMNI File.

215. See *supra* notes 211-14 and accompanying text (discussing Directive 90/220's requirements for experimental releases).

216. Council Directive No. 90/220, arts. 5, 14, 1990 O.J. (L 117) at 17, 20.

217. *Id.* art. 19(1).

218. *Id.* arts. 10, 11.

219. *Id.* art. 11(1).

220. *Id.* art. 11(5).

221. *Id.* art. 12(2)-(3).

on the environment, the geographic areas affected by the release, and the type of environment for which the product is suited.<sup>222</sup> Notification dossiers submitted to the Commission for GMO products must also include a summary under Commission Decision No. 92/146, an amendment to Directive 90/220.<sup>223</sup> This amendment requires that the information provided in the summary be submitted in the format of a standardized, eleven-page questionnaire.<sup>224</sup>

Upon receiving an application for a commercial GMO product, the Commission then circulates the application to the other Member States.<sup>225</sup> If no Member State objects within sixty days, a written consent is issued and the product can be placed on the market.<sup>226</sup> In the case of an objection by a Member State that cannot be resolved, the Commission may authorize the release of the GMO product.<sup>227</sup> This decision is made by a majority vote of a committee composed of the representatives of the Member States and chaired by the Commission representative.<sup>228</sup>

Under Directive 90/220, the Commission must set up an information exchange system between the Member States.<sup>229</sup> Regular meetings between the Member States and the Commission are also required in order to exchange information.<sup>230</sup> Directive 90/220 also provides for public participation through consultation on planned releases.<sup>231</sup> Finally, the Official Journal will publish a list of all GMO products receiving final endorsement.<sup>232</sup>

Through Directive 90/220, the EC has chosen a process-oriented approach that is specific to biotechnology, instead of

222. *Id.* arts. 10-18.

223. Commission Decision No. 92/146, 1992 O.J. (L 60).

224. *Id.*

225. Council Directive No. 90/220, art. 13(1), 1990 O.J. (L 117) at 19.

226. *Id.* art. 13(2).

227. *Id.* art. 13(3). A release over a Member State objection requires a majority vote of a committee of representatives of Member States. *Id.* art. 21.

228. *Id.* arts. 21, 9-10. This endorsement procedure does not apply to organisms already covered by other Commission legislation if it has a similar risk assessment component. *Id.*

229. *Id.* art. 9.

230. *Id.* art. 22.

231. *Id.* art. 7.

232. *Id.* art. 22.

adapting pre-existing regulations.<sup>233</sup> Previous EC environmental regulations were not designed to control the risks that could arise from the deliberate or accidental release of new living organisms into the environment.<sup>234</sup> Directive 90/220 focuses on notification and product characterization and has no clear standard or guidelines for making risk assessments.<sup>235</sup>

#### D. *United Nations Guidelines*

Although developing countries have no government restrictions for the deliberate release of GMOs, the United Nations Industrial Development Organization has produced a voluntary code for developing countries to provide guidance for the deliberate release of GMOs.<sup>236</sup> In Latin America, the Inter-American Institute for Cooperation on Agriculture,<sup>237</sup> the Pan American Health Organization,<sup>238</sup> the Organization of American States,<sup>239</sup> and the International Office of Epizoot-

233. See Newmark, *supra* note 51, at 653 (explaining that EC examines GMO products as special category, unlike approach of U.S.).

234. *Id.*

235. Council Directive No. 90/220, 1990 O.J. (L 117) at 15-27; *Details of New EC GMO Regulations*, BIOTECH. BUS. NEWS, Mar 13, 1992, available in LEXIS, World Library, ALLNWS File (acknowledging risk assessment for deliberate releases cannot be carried out by Council on basis of eleven-page standardized notification summary).

236. *International Biosafety Guidelines and Code of Conduct for the Release of Genetically Engineered Microorganisms and Plants*, United Nations Industrial Development Organization [hereinafter UNIDO], reprinted in GENETIC ENGINEERING AND BIO-TECHNOLOGY MONITOR, Sept. 1992, at 1-28. An international group of scientific experts representing developing and developed nations were organized by UNIDO to prepare a voluntary code of conduct for releasing GMOs into the environment. *Id.* at 1. The group of experts also recommended the establishment of a biosafety information network and advisory service (BINAS) to advise developing countries without guidelines on biosafety matters. *Id.* The code stipulates general principles and attempts to harmonize existing guidelines for deliberate releases. *Id.* The code has been endorsed by UNIDO, the United Nations Environment Programme (hereinafter UNEP), the World Health Organization, and the Food and Agriculture Organization of the United Nations. *Id.*

237. INTERNATIONAL ORGANIZATIONS 193 (Linda Irvin ed., 1991). Inter-American Institute for Cooperation on Agriculture is an organization to promote economic and social development through teaching, research, technical assistance, and communication in the field of agriculture and rural life. *Id.* Members are countries of North, Central, South America and the Antilles. *Id.*

238. *Id.* at 737. The Pan American Health Organization is an organization composed of governments of Western Hemisphere nations united to improve physical and mental health in the Americas. *Id.*

239. *Id.* at 876. The Organization of American States is an organization for peace and justice among American nations, to promote their stability, to strengthen

ics,<sup>240</sup> have jointly developed guidelines for genetic engineering research.<sup>241</sup>

### III. HARMONIZATION OF DELIBERATE RELEASE REGULATIONS

The ecological and geographic ranges of GMOs transcend political boundaries.<sup>242</sup> The potential risks of deliberate releases, as well as the variation in current deliberate release regulations in individual countries, illustrate the need for an international approach to regulating deliberate releases.<sup>243</sup> Although international coordination of risk assessment and regulation of biotechnology is essential,<sup>244</sup> current international attempts to harmonize deliberate release regulations, however, are inadequate. These attempts either propose non-binding principles and vague recommendations, or apply only to regional areas rather than to an international forum.<sup>245</sup> An international system of regulations should set forth binding principles. The creation of an international body to regulate deliberate releases of GMOs is needed to limit potential environmental risks while fostering trade.<sup>246</sup>

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their collaboration, and to defend their sovereignty, territorial integrity, and independence. *Id.*

240. *Id.* at 809. The International Office of Epizootics offers veterinary services to national ministries of agriculture. *Id.*

241. GUIDELINES FOR THE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS, *supra* note 159, at 9.

242. Tiedje, *supra* note 35, at 311.

243. See *Biotechnology; Directives Could Cripple Biotech Sector, Critics Warn* 2 1992 - THE EXTERNAL IMPACT OF EUROPEAN UNIFICATION, No. 1, Apr. 6, 1990 at 1, available in LEXIS, Nexis Library, OMNI File (stating that industry are sources relieved that EC biotechnology directives would put an end to the growing confusion of national standards for marketing biotechnology products); see also *Dutch Official Urges Global Approach to Biotechnology Risk, Assessment Issues*, *supra* note 84 (stating that "a global approach to manage biotechnology safety would ensure that biotechnology's benefits are spread around, while risks are minimized").

244. Tiedje, *supra* note 35, at 311.

245. See GIBBS, *supra* note 10, at 272 (stating that broad nature of 1986 OECD report can result in two governments citing 1986 OECD report and still develop very different regulations); *supra* note 199 (listing EC Member States); Edith Brown Weiss, *International Environmental Law: Contemporary Issues & the Emergence of a New World Order*, 81 GEO. L.J. 675, 685 (1993) (describing Agenda 21 as non-binding instrument).

246. See Tiedje, *supra* note 35, at 311 (urging local, state, national, and international cooperation in regulation, risk assessment, and risk management of ecological effects of introduction of GMOs into environment); *supra* note 46 (discussing trans-

*A. Problems with Disparate Regulations in Different Countries*

Although the benefits of biotechnology should be available to as many people as possible, the disparate release regulations currently in effect in individual countries presents problems for both industrialized and smaller nations.<sup>247</sup> At present, a biotechnology company marketing a new GMO product internationally must comply with the deliberate release laws of each individual country.<sup>248</sup> Compliance with the regulations of each country can add incrementally to the cost of marketing a new product worldwide.<sup>249</sup> The cost associated with regulatory compliance may discourage the development of some GMO products.<sup>250</sup>

In addition, industrialized countries with very stringent regulations can restrict imports of bioengineered products from countries without the resources to comply with the stringent regulations.<sup>251</sup> Exporting countries, especially smaller ones without large home markets, will need to satisfy the regulations of potential importers of their products.<sup>252</sup> Thus nations may use their stringent deliberate release regulations to discourage the marketing of products from other countries and keep out unwanted foreign competition.<sup>253</sup>

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boundary dangers of GMOs); *see also* note 15, *supra* and accompanying text (discussing benefits of harmonization of deliberate release regulations).

247. *Dutch Official Urges Global Approach to Biotechnology Risk, Assessment Issues*, *supra* note 84 (quoting Dutch policymaker stating that director of UNCED secretariat, has proposed Biotechnology Consortium for Development, as joint venture among shareholders from developing countries, international agencies, and private sector); *see supra* notes 56-149 and accompanying text (discussing deliberate release regulations in individual nations).

248. *See supra* notes 56-149 and accompanying text (discussing deliberate release regulations in individual nations).

249. *Id.*

250. *See Aldhous, supra* note 13, at 5 (discussing costs associated with regulatory compliance).

251. *See McGarity, supra* note 1, at 438 (stating that health and environmental considerations may be used as ruse to erect protectionist walls against competing technology from another country).

252. OTA, *supra* note 1, at 186. Telephone Interview with Dr. Robert Yuan, Prof. of Microbiology at the University of Maryland, and co-author of *JAPANESE BIOTECHNOLOGY*, *supra* note 15 (Feb. 8, 1993) [hereinafter "Yuan interview"]. Forcing smaller nations to adapt to the regulatory standards of leaders in the field may even be viewed as colonialism. *Id.*

253. *See* Speech of Mr. Ripa Di Meana, Speech at the SCI Conference (Society of International Chemical Industries) Monte Carlo, Oct. 8, 1990, RAPID, *available in* LEXIS, World Library, ALLNWS File.

A multinational company that faces stringent regulatory requirements in one country is likely to choose to conduct field testing and marketing in a country with less-stringent regulations.<sup>254</sup> Because underdeveloped nations often have less stringent regulations, they may be easily exploited by both researchers and multinational companies escaping the strict regulatory climate of their own countries.<sup>255</sup>

### B. *Critique of Current International Treaties*

No adequate international framework for the regulation of deliberate releases currently exists, although attempts have been made.<sup>256</sup> The Earth Summit, the most recent attempt to regulate the deliberate release of GMOs into the environment, resulted in a large number of nations adopting Agenda 21.<sup>257</sup> The Earth Summit, however, failed to provide specific details for the implementation of the ambitious aims of the conference.<sup>258</sup> Although Agenda 21 identifies the need to develop a framework of internationally accepted guidelines for biotechnology safety,<sup>259</sup> it is a non-binding statement of broad principles and goals.<sup>260</sup> Agenda 21 offers no protection to countries because it lacks specific regulations and enforcement mecha-

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[I]t is very difficult to trace the line between measures adopted by a Member State in pursuance of its undoubted right to protect its own environment, and measures taken by a Member State in order to protect its market, for its home-produced products and against the imported, foreign products.

Member States must resist the temptation to introduce measures to restrict trade in the disguise [sic] of environmental protection measures.

*Id.*

254. See *supra* note 159 and accompanying text; Hudson, *supra* note 83, at B1 (stating that BASF Germany plans to move to Boston); see also McGarity, *supra* note 1, at 435 (discussing forum shopping).

255. McGarity *supra* note 1, at 435.

256. See *supra* notes 159-241 (discussing international agreements for deliberate releases of GMOs).

257. See *supra* note 167 and accompanying text (stating that 182 nations adopted Agenda 21 during Earth Summit).

258. See *supra* note 178 and accompanying text (describing need for protocol to specify needed concrete safety measures for biotechnology).

259. See *supra* note 170 (stating Agenda 21's goal of international biosafety regulations).

260. U.S. GENERAL ACCOUNTING OFFICE, INTERNATIONAL ENVIRONMENT: STRENGTHENING THE IMPLEMENTATION OF INTERNATIONAL AGREEMENTS, Aug. 1992 at 3 (describing Agenda 21 as non-binding action program which identifies specific measures for environmentally sustainable development).



nisms.<sup>261</sup> The Biodiversity Treaty is also a vague set of recommendations offering no specific guidance for regulating deliberate releases of GMOs.<sup>262</sup> Even the drafters of the Biodiversity Treaty recognized that there would be a need for specific regulations and inserted a provision into the Biodiversity Treaty for a biotechnology protocol to be enacted at a later date.<sup>263</sup>

Similarly, the OECD's 1986 Report offers only broad recommendations for deliberate releases.<sup>264</sup> Although the OECD's 1992 Report does offer specific guidelines for assessing the safety of small-scale field tests of GMOs, the GDP are only a starting point for risk assessment.<sup>265</sup> The effectiveness of the GDP published in the 1992 Report have yet to be tested.<sup>266</sup>

Although the OECD is a well-respected international body, with the United States, Japan and many European countries as members, the OECD's membership is limited to 24 industrialized nations.<sup>267</sup> Thus its guidelines do not address international concerns because they are limited to industrialized nations with specialized interests.<sup>268</sup> Developing nations probably will not implement these recommendations because they lack the advanced industrial needs addressed by the guidelines.<sup>269</sup>

The EC's Directive 90/220 for deliberate releases, along with its subsequent amendment, is also limited because of its regional application. International regulations that apply to

261. *Id.*

262. *See supra* notes 177-78 (discussing ambiguities in Biodiversity Treaty).

263. *See* Biodiversity Treaty, *supra* note 12, U.N. Doc. DPI/1307 art. 19(3), at 11 (1992), 31 I.L.M. at 830.

264. *See supra* notes 179-85 and accompanying text (discussing OECD's 1986 REPORT).

265. *See supra* note 186-98 (discussing GDP of 1992 REPORT).

266. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753 (1992) (announcing U.S. policy for assessing risk of deliberate releases). Categories of inclusion and exclusion are currently being developed by the United States in accordance with principles of risk assessment similar to the OECD's GDP. *Id.*

267. *See* BULL, *supra* note 179 (listing 24 member nations of OECD).

268. *See supra* note 179 and accompanying text (discussing goals of the OECD).

269. Heinemeyer, *supra* note 159, at 359. *Contra Biotech Regulations Bite*, *supra* note 99, at 18 (stating that Yugoslavia has applied OECD guidelines).

more than just EC Member States are necessary. An international regulatory scheme should include all countries active in biotechnology. Directive 90/220 also lacks harmonization with the United States and Japan, the world leaders in biotechnology.<sup>270</sup> Because other nations apply U.S. regulatory decisions in their own countries, the participation of the United States would be necessary in any international regulatory framework.<sup>271</sup> In addition, representatives of the European biotechnology industry have complained about the stringency of Directive 90/220.<sup>272</sup>

Even with its short comings, Directive 90/220, as amended, is the best attempt at international harmonization of deliberate release regulations thus far. The Directive provides a unified legal framework for all phases of deliberate releases, from small-scale field experiments to commercial releases of GMO products and, therefore, provides community safeguards.<sup>273</sup> The EC has successfully promulgated a Directive that encompass a wide range of regulatory schemes, ranging from Denmark's stringent regulations to countries with no regulations for deliberate releases.<sup>274</sup> Although Directive 90/220 does not subvert Member State regulation, it does set a minimum standard for regulating deliberate releases.<sup>275</sup> Directive 90/220, as amended, will promote international trade and a

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270. See *Genetic Engineering*, *supra* note 51 (stating that EC and US use different regulatory approaches); *supra* note 88 and accompanying text (stating that Japan ranks second in world in biotechnology after United States).

271. See *supra* note 157 (listing nations using U.S. as regulatory model).

272. See *supra* note 83 (discussing move by German chemical company to U.S.); *Biotechnology: Europe Suspected of Trailing Behind the United States*, EUR. REP., Mar. 14, 1992, at 7, available in LEXIS, Nexis Library, OMNI File (representative of EC biotechnology industry group suggesting that EC directive on field testing of GMOs will slow Europe's progress in biotechnology); *EFB's Research Budget Worries*, *supra* note 17 (discussing industry complaints in EC nations that regulations are more favorable in U.S. and Japan). But see *Even U.S. Regulations Stifle Research*, BIOTECH. BUS. NEWS, Oct. 30, 1992, available in LEXIS, Nexis Library, OMNI File (stating complaints of U.S. biotechnology industry that U.S. regulations stifle research).

273. See *supra* notes 202-35 (discussing Directive 90/220).

274. See *supra* notes 50-64 and accompanying text (discussing Danish laws); *EC "Stocktaking" on Biotechnology*, *supra* note 8, (Spain is currently in process of adopting biotechnology regulations to conform to EC Directives on biotechnology).

275. See *supra* note 205 and accompanying text (discussing minimum standard set by Directive 90/220 for EC member states); see also Balter, *supra* note 56 (stating that new EC regulations represent defeat for more extreme segments of Green Movement).

common market within the EC by eliminating trade barriers and harmonizing GMO product regulations.<sup>276</sup>

*C. Proposal for Harmonization of Deliberate Release Regulations:  
An International Regulatory Framework*

1. Benefits of Harmonization

Harmonization of international regulations for deliberate releases would solve many of the problems arising from disparate regulations in individual nations.<sup>277</sup> Harmonization facilitates the development of safe biotechnology along common international lines and provides the basis of a consensus on protection of health and environment.<sup>278</sup> Because GMOs, such as genetically engineered bacteria, can spread across transnational boundaries and affect the environments of other countries, countries without domestic legislation for deliberate releases should be subject to international laws regulating deliberate releases.<sup>279</sup>

Harmonization also leads to the promotion of technological and economic development and the reduction of national barriers to trade in this field.<sup>280</sup> Industry would be better served if manufacturers of GMO products had to comply with only a single set of regulations.<sup>281</sup> A uniform international standard would reduce trade barriers to make GMO products more readily available to consumers in all nations. Uniformity between nations in biotechnology regulation would also facilitate greatly the development of international markets.<sup>282</sup>

Smaller nations without the resources to sustain an expensive regulatory body would also benefit from international reg-

276. See MANTEGAZZINI, *supra* note 6, at 8 (discussing 1986 commentary on possible EC regulations).

277. See *id.* (stating that harmonization of regulations within the EC will prevent countries from "under-cutting" one another with less stringent regulations in order to attract industry); *supra* note 13 (discussing benefit of harmonization); *supra* notes 256-76 and accompanying text (criticizing current international attempts to regulate deliberate releases).

278. See Moses, *supra* note 13, at 110 (describing benefits of harmonization).

279. See *supra* notes 46-49 (discussing transboundary nature of genetically modified microorganisms).

280. MANTEGAZZINI, *supra* note 6, at 8-9.

281. See *Regulation cost concerns*, *supra* note 13 (discussing complaints of European biotechnology industry).

282. McGarity, *supra* note 1, at 437.

ulations.<sup>283</sup> Rather than rely upon the regulatory decisions of another country, developing countries could rely on the risk assessment of an international body.<sup>284</sup> International regulations would protect nations that do not have the expertise to evaluate the risks connected with new biotechnologies.<sup>285</sup> Thus, an international regulatory body would avoid the problem of contemporary colonialization.<sup>286</sup>

## 2. Proposal for an International Regulatory Framework

Because the benefits of biotechnology would not be available to the public without industrial efforts to market biotechnology products, the needs of industry must be considered in a proposal for an international regulatory framework.<sup>287</sup> Industrial regulatory needs include quick regulatory approvals, low compliance costs, and simplicity of regulations.<sup>288</sup> Strict international regulations would only hamper industrial efforts.<sup>289</sup> A very practical proposal for international standards calls for a regulatory scheme that would reduce risks to an acceptable level while allowing biotechnology companies to maintain their competitiveness.<sup>290</sup> Therefore, an international regulatory

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283. See *supra* notes 154-59 and accompanying text (stating that developing countries generally do not have biotechnology regulations).

284. See, e.g., *supra* note 236 and accompanying text (discussing UNIDO's *International Biosafety Guidelines and Code of Conduct for the Release of Genetically Engineered Microorganisms and Plants* for developing nations).

285. See *supra* notes 154-59 and accompanying text (discussing developing nations with no regulations); *EC "Stocktaking" on Biotechnology*, *supra* note 9. Italy and Spain had no previous regulations for deliberate releases and are now adopting the EC directive. *Id.*; see also *Environmental Assessment and Development Aid*, THE OECD OBSERVER, at 23-24 (June-July 1987).

286. Yuan interview, *supra* note 252. Contemporary colonialization occurs when lesser developed countries are forced to adapt to the regulatory standards of developed nations. *Id.*

287. See *Biotechnology: Industrialists Unhappy About GMO Directives*, EUR. REP. Oct. 7, 1992, available in LEXIS, Nexis Library, OMNI File (representative of 31 EC-based biotechnology companies stating that EC GMO directives results in longer time needed to develop and market new products and technologies); see generally OTA, *supra* note 1, at 3 (discussing biotechnology product development).

288. See Conroy, *supra* note 104 and accompanying text (discussing criticisms of U.S. regulatory scheme).

289. See *supra* note 287 and accompanying text (regulations can result in products taking longer to get to market); see, e.g., *supra* notes 82-83 and accompanying text (discussing complaints of German industry regarding stringent regulations).

290. See McGarity, *supra* note 1, at 439 (proposing controls to reduce risks posed by international proliferation of biotechnology to acceptable level and to provide "a

scheme should be designed to encourage industrial activity and research into the field, and to promote the flow of trade, while guarding against potential harms.

Uniformity through international law can be achieved by an international agreement for the deliberate release of viable genetically modified organisms into the air, water, or land.<sup>291</sup> The international agreement should provide minimum health and environmental protection in all countries in which companies are likely to conduct field tests, erect manufacturing facilities, or otherwise expose humans and the environment to genetically modified plants and microorganisms.<sup>292</sup> Such an agreement should also be flexible in its requirements.<sup>293</sup> Therefore, it should contain mechanisms by which provisions can be modified to reflect the latest scientific understanding.<sup>294</sup>

Each nation participating in the international agreement should appoint a representative to an international regulatory body which would administer the proposed international regulations.<sup>295</sup> Because GMOs can cross national borders, the participation of all nations that could be affected by the deliberate release of GMOs is essential for an international agreement for deliberate release regulations.<sup>296</sup> Besides the world leaders in biotechnology, such as the United States, Japan, and the EC,

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level playing field" for companies marketing genetically engineered products and processes).

291. *Id.* at 437.

292. *Id.*

293. See Weiss, *supra* note 245, at 687 (stating that international environmental agreements must have sufficient flexibility to allow parties to adapt to changes in scientific understanding and technological advances); see also GIBBS, *supra* note 10, at 276 (advocating flexibility in international biotechnology regulations).

294. See Weiss, *supra* note 245, at 688 (discussing movement in international environmental law away from traditional treaty amendment procedures that were too cumbersome to address rapid scientific advances).

295. See *New Environmental Debate Expected as U.N. Convenes*, N.Y. TIMES, Sept. 16, 1992, at A10 L (announcing creation of U.N. "Sustainable Development Commission" to hear and assess criticism of governmental treatment of environment); see also Yuan interview, *supra* note 252 (suggesting that international body similar to Intellectual Property Convention in Geneva may also be appropriate).

296. See Weiss, *supra* note 245, at 691 ("Because the global environmental system ignores political boundaries, it is important for countries that have an impact on the global environment not to remain outside the convention system and defeat the purposes of the agreement."); *supra* note 46 and accompanying text (discussing transboundary nature of microorganisms).

the international agreement should also include developing nations.

The representatives to the international regulatory body should be composed of scientists or administrators with expertise in risk assessment.<sup>297</sup> A qualified body with expertise in assessing the risk of the new biotechnology product would be better able to make an objective analysis of the GMO product than a politically elected party.<sup>298</sup> A single international governing body would be best suited to respond to the rapid pace of biotechnological developments that can quickly make any regulation for deliberate releases obsolete.<sup>299</sup>

The regulatory body should be responsible for granting approval for deliberate releases. Each representative should have one vote to approve a proposed deliberate release.<sup>300</sup> Periodic meetings of the representatives should be held to respond to new scientific developments.<sup>301</sup>

Similar to applicable EC directives, the procedure for obtaining consent from the regulatory body should begin with notification to the international regulatory body by the responsible party prior to the proposed deliberate release.<sup>302</sup> Notifi-

297. See Scott Deatherage, Note, *Scientific Uncertainty in Regulating Deliberate Release of Genetically Engineered Organisms: Substantive Judicial Review and Institutional Alternatives*, 11 HARV. ENVTL. L. REV. 203, 239-45 (1987) (proposing scientific advisory committee similar to U.S. NIH Recombinant DNA Advisory Committee to oversee deliberate releases in U.S.); see also Weiss, *supra* note 245, at 693 (stating that although nongovernmental organizations have assumed an increasingly important role in international environmental agreements, there is not yet widespread acceptance of the practice nor any systemic pattern of representation).

298. See Tiedje, *supra* note 35, at 307 (recommending objective, scientific criteria for regulatory oversight of deliberate releases of GMOs).

299. But see Barton letter, *supra* note 154, at 1-2. An alternative approach is one in which national regulators can harmonize their requirements and test standards so that one application package (with its supporting experimental data) can be used in each of many nations. *Id.* This method gives many of the benefits of full decision-making while providing respect for a relatively sensitive area of national sovereignty. *Id.*

300. See generally Peter H. Sand, *UNCED and the Development of International Environmental Law*, 3 Y.B. INT'L. ENVTL. L. (forthcoming) (manuscript at 16-18, available in WESTLAW, TP-All) (discussing bi-polarization between developed and developing nations at Earth Summit).

301. See Weiss, *supra* note 245, at 688 (citing procedures of Montreal Protocol on Substances that Deplete Ozone Layer in which parties can agree to reduce consumption of listed chemicals faster and further than provided in text without having to use formal and time consuming amendment procedures).

302. See Council Directive 90/220, art 12, 1990 O.J. (L 117) at 19 (requiring

cation should be accompanied by a product characterization, which entails identifying the source of the genetic modification that should be included in the notification.<sup>303</sup> Because revealing the source of the modification may conflict with trade secrecy, the information about the GMO product would be given to the international body on a confidential basis.<sup>304</sup>

Notification to this qualified body should also include an evaluation of the risks associated with the genetically modified product.<sup>305</sup> An adequate risk assessment must provide estimates of the probability that particular health and environmental consequences will occur.<sup>306</sup> Important factors to include are the GMO's potential for possible harmful effects on humans or the environment and its ability to survive and reproduce in hostile environments.<sup>307</sup> The latter factor will alert nations to potential transboundary problems.<sup>308</sup>

Although risk assessments were previously determined on a case-by-case basis, the publication of the OECD's 1992 Report and the passage of the German Genetic Technology Law shows that there is now sufficient data to begin formulating a standardized risk assessment for proposed deliberate releases

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notification for deliberate releases of GMO products be sent to Council of the European Community) *Contra* Heinemeyer, *supra* note 159, at 351 (stating that notification requirements are often ineffective in regulatory frameworks).

303. *See id.* art. 4, 1990 O.J. (L 117) at 17 (setting forth the requirements for product characterization); *see also* McGarity, *supra* note 1 (proposing product characterization as component of risk analysis for GMOs released in environment).

304. *See* Council Directive 90/220, art 19, 1990 O.J. (L 117) at 4 (providing for confidentiality of trade secrets); *see also supra* note 217 and accompanying text (discussing Directive 90/220's protection of trade secrets); *BIA on GMO Regulations*, BIOTECH. BUS. NEWS, Oct. 2, 1992, available in LEXIS, World Library, ALLNWS File (quoting representative of BioIndustry Association of UK stating that disclosure of information is seen as damaging to commercial interests and to future patent rights); *EEC Biotech Directives Approved Formally*, PHARMACEUTICAL BUS. NEWS, Apr. 27, 1990, available in LEXIS, World Library, ALLNWS File (stating concern of British pharmaceutical industry about impact of data disclosure requirements of EC directives).

305. *See* McGarity, *supra* note 1, at 439 (proposing that risk assessment should be divided into four categories: product characterization, hazard assessment, exposure assessment, and risk prediction); *see also* Council Directive No. 90/220, 1990 O.J. (L 117) (providing for notification to Member States in advance of deliberate releases).

306. *See* McGarity, *supra* note 1, at 439 (discussing components of risk assessment for deliberate releases).

307. *Id.*

308. *Id.*

of GMOS.<sup>309</sup> Factors of risk can now be quantified at least according to low, medium, and high classifications.<sup>310</sup> Rather than using the EC's practice of assessing risk on a case-by-case basis, the proposed international regulatory scheme should assign values as practiced in Germany and as proposed by the OECD.<sup>311</sup>

The determination of a low-risk deliberate release should be made on the basis of previous field tests and other available data. For low-risk or small-scale field tests, the party responsible for the release should be required only to notify the international regulatory body.<sup>312</sup> In contrast, express consent from the regulatory body should be required for deliberate releases of commercial GMO products, such as large-scale field tests, and higher risk field tests. For example, the field testing of pathogenic microorganisms capable of infecting indigenous crops, such as the field test of the tobacco blue mold, would require express approval from the regulatory body.<sup>313</sup> A deliberate release of genetically modified *Rhizobium*, which has been used for several years, should be classified as a low risk field test and allowed to proceed as long as the party proposing the release notifies the international regulatory body.<sup>314</sup>

The high cost of meeting regulatory requirements increases the cost of developing new products.<sup>315</sup> The expense

309. See 1992 REPORT, *supra* note 12, at 28-29 (discussing working assumptions for GDP); see also Gentechnikgesetz, *supra* note 73, § 7, 1990 BGBl. I at 1083 (setting safety levels for deliberate release of GMOS).

310. See Gentechnikgesetz, *supra* note 73, § 7, 1990 BGBl. I at 1080 (setting safety levels 1-4 for deliberate releases); see also 1992 REPORT, *supra* note 12, at 28 (proposing GDP for small-scale field testing GMOs); McGarity, *supra* note 1, at 444 (suggesting broad categories of "low", "medium" and "high" for assessing risk of deliberate releases).

311. See *supra* note 76 and accompanying text (stating German regulations use levels 1-4 in assessing risk of GMO); *supra* notes 186-94 and accompanying text (discussing OECD's latest proposal to apply GDP to determine low risk field testing of GMOs).

312. But see Heinemeyer, *supra* note 159, at 351 (suggesting that notification requirements are often ineffective).

313. See *supra* note 46 (discussing spread of tobacco blue mold across national boundaries).

314. See *supra* note 28 and accompanying text (discussing *Rhizobium*).

315. See Aldhous, *supra* note 13 (discussing cost of regulatory compliance); Conroy, *supra* note 104 (applying for permit in U.S. costs average of US\$5,000 and permit approval process may take up to four months); *supra* note 102 and accompanying text (discussing cost of compliance with new British regulations).



of developing new products then encourages industry to concentrate on commercially lucrative products rather than products whose commercial potential is relatively small or research the environmental impact of GMOs.<sup>316</sup> Eliminating express approval for low-risk field tests would reduce the cost of developing GMO products and partially alleviate the pressure on industry to develop commercial products that can justify the cost of development.

Once approval has been received from an international governing body, it should not be necessary to apply for approval in an individual country. Only if the receiving country can establish a specific danger or need for proof of safety particular to the receiving country would a separate approval be required to export products into that particular country.<sup>317</sup> The notification requirement is a burden on the party proposing the deliberate release to show proof of safety to the environment. Where a country objects to admitting a GMO product, the burden of proof initially placed on the party proposing the deliberate release would then shift to the objecting country to show valid grounds for refusing admission.<sup>318</sup> The shift in the burden of proof should act as a restraint on veto power so that countries cannot abuse their option to restrict the proposed deliberate release or GMO product.<sup>319</sup> But a majority vote by the regulatory body should override a single country's objections.<sup>320</sup>

In addition, some provision for public hearings should be

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316. See *supra* note 9 and accompanying text (noting research concentrates on lucrative areas); OTA, *supra* note 1, at 186 (stating that regulatory agency requirements discourage research on subjects with little potential for commercial reward); McGarity, *supra* note 1, at 445 (stating that enormous cost of internationalizing biotechnology could be unfortunate for beneficiaries of biotechnologies with small markets that would not warrant cost of complying with importing countries' additional risk assessment requirements).

317. See Council Directive 90/220, art. 16(1), 1990 O.J. (L 117) at 20 (allowing Member States to restrict sale of GMO product). But see Daniel G. Partan, Note, *International Administrative Law*, 75 AM. J. INT'L L. 639, 642 (1981) (discussing controversy over Codex Alimentarius Commission's procedures which allow countries to exclude products that do not conform to its "minor deviations").

318. See FROM RESEARCH TO REVOLUTION, *supra* note 104, at 111 (discussing burden of proof in regulatory schemes). "The burden of proof is probably the most important choice of all . . . a stringent regulatory framework is one in which the burden of proof is on the outside party seeking approval." *Id.*

319. See *id.* (discussing burden of proof in regulating environmental releases).

320. See *supra* note 227 (discussing EC Directive 90/220, which allows majority

included in the approval process to give the public a chance to express their reservations.<sup>321</sup> While regulatory decisions should not reject sound science to allay public fears,<sup>322</sup> the public should nevertheless have an opportunity to present their objections.<sup>323</sup> A sound regulatory process must successfully balance the competing objectives of maintaining public confidence in the regulatory process and basing regulatory decisions on reasonable scientific grounds.<sup>324</sup>

### CONCLUSION

Because genetically modified organisms can cross national boundaries, international harmonization is needed to protect against the potential hazards of deliberate releases. But while guarding against potential harms, an international regulatory scheme should also foster industrial activity, promote the flow of trade, and encourage research into the field. Besides facilitating trade for more developed countries, an international agreement would also serve to protect developing nations that do not have the resources to institute regulation of deliberate releases. The harmonization of regulations for deliberate releases should occur now, before the biotechnology industry has fully matured.

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vote of committee of representatives of Member States to overcome objection by one Member State).

321. See *supra* note 79 (discussing German Genetic Technology Law's provision for public hearings); Council Directive No. 90/220, art. 7, O.J. (L 117) at 18 (providing for public participation in regulation of deliberate release of GMOs).

322. *Id.*

323. *Biotechnology: Industrialists Demand Support From Politicians*, EUR. REP. Nov. 28, 190 at 5, available in LEXIS, Nexis, OMNI File (suggesting that solution is not to give scientists carte blanche but to permit public to give its opinion based on specific information about risks of new GMO product).

324. GIBBS, *supra* note 10, at 270. U.S. politicians and industry have agreed that public support is important. *Id.* Public support is vital in this area because public opposition can lead to litigation. See Tiedje, *supra* note 35, at 299 (stating that development of environmentally sound products through use of advanced biotechnology should occur within context of scientifically based regulatory policy that encourages innovation without compromising sound environmental management); *supra* note 20 and accompanying text (discussing litigation over deliberate release of genetically modified bacteria).

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