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# Genetically Modified Organisms: A New Proposal Regarding Deliberate Release

## INTRODUCTION

Biotechnology refers to the development of techniques using organisms, or parts of organisms, to provide or improve goods or services.<sup>1</sup> Within the field of biotechnology, advancements in genetic engineering have yielded microorganisms known as genetically modified organisms (GMOs)—organisms or microorganisms in which genetic material has been altered in a manner that does not occur naturally by mating or recombination.<sup>2</sup> Deliberate release is the intentional introduction of GMOs into the environment without provision for containment.<sup>3</sup> GMOs may be released into the atmosphere for various environmental and agricultural purposes, such as to degrade toxic waste, or to propagate new varieties of cultivated plants.<sup>4</sup> The release of GMOs, however, entails environmental risks such as the possibility of accidental release or unforeseen negative effects on the ecosystem.<sup>5</sup> Thus, as biotechnology becomes more prevalent, a greater need emerges for coherent and effective safeguards to protect people and the environment.<sup>6</sup>

The European Community's (EC or Community) environmental legislation in the 1990s has led to an increase in precautionary

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<sup>1</sup> WORLD HEALTH ORGANIZATION (WHO), *Health Impact of Biotechnology, Report on a WHO Working Group*, SWISS BIOTECH, No. 5, 1984.

<sup>2</sup> Dr. Claus-Joerg Ruetsch & Terry R. Broderick, *New Biotechnology Legislation in the European Community and Federal Republic of Germany*, 18 INT'L BUS. LAW. 408, 408 (1990).

<sup>3</sup> *Id.*

<sup>4</sup> WHO, *supra* note 1.

<sup>5</sup> *Biotechnology: Parliament Calls for More Stringent Controls on Genetically Modified Organisms*, Eur. Rep. (Eur. Info. Serv.), Mar. 17, 1990, available in LEXIS, Europe Library, ECInfo File [hereinafter *Stringent Controls*].

For example, if a new type of pesticide-resistant wheat is devised, the pesticide-resistant genes may be passed accidentally to a weed. Thus, the risk of disrupting ecological cycles is considerable.

<sup>6</sup> See, e.g., Council Decision 92/218 of 26 March 1992 Adopting a Specific Research and Technological Development Programme in the Field of Biotechnology (1990 to 1994), 1992 O.J. (L 107) 1.

The royal commission on environmental pollution reported 28 genetically modified organism (GMO) releases in Great Britain alone as of mid-1991. See Michael McCarthy, *Keeping a Step Ahead of Genetic Mistakes*, THE TIMES (London), June 19, 1991, available in LEXIS, Europe Library, ECInfo File.

and preventive policies.<sup>7</sup> Biotechnology is a prime example of the European regulatory philosophy.<sup>8</sup> Although the United States has no regulations regarding genetic engineering, the Community, as well as each European nation, regulates biotechnology to a certain degree.<sup>9</sup> On November 4, 1991, the Council of the European Communities (Council) addressed a Decision to the Member States regarding the deliberate release of GMOs.<sup>10</sup> Council Decision 91/596 specifies the content and format of the notification every researcher or manufacturer must submit to a national authority prior to the intentional release of any GMO.<sup>11</sup>

This Comment will assess the potential effectiveness of Council Decision 91/596 in light of the EC's environmental policies. Part I briefly discusses EC environmental policy prior to and after the Single European Act of 1987 (SEA). Part II describes the European biotechnology industry and the 1990 Directives regarding GMOs. Part III examines Decision 91/596 by focusing on its provisions, anticipated effects, and likelihood of enforcement. This Comment concludes that Summary Notification has the potential to be an effective and efficient means of regulating advancements in biotechnology in the interest of environmental protection.

## I. EUROPEAN COMMUNITY ENVIRONMENTAL POLICY

Environmental policies raise complex problems which require balancing the competing interests of industry and the concerns of those who advocate safeguarding natural resources and human health.<sup>12</sup> Environmental safeguards are a particular point of contention in the EC; environmental provisions must be introduced gradually, economic and regional specialties must be taken into

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<sup>7</sup> 1992 *Euroscope: Environment*, Coopers & Lybrand, Apr. 2, 1992, available in LEXIS, Europe Library, Alleur File, at \*1 [hereinafter Coopers & Lybrand, *Environment*].

<sup>8</sup> See, e.g., 1992 *Euroscope: Pharmaceuticals*, Coopers & Lybrand, Aug. 20, 1992, available in LEXIS, Europe Library, Alleur File, at \*17.6, \*17.7 [hereinafter Coopers & Lybrand, *Pharmaceuticals*].

<sup>9</sup> Catherine Arnst, *EC Report to Propose Biotechnology Incentives*, Reuters, Apr. 15, 1991, available in LEXIS, Nexis Library, Omni File; Ruedi Sandmeier, *Political Roadblocks Hinder Biotechnology Industry*, S. F. CHRON., June 3, 1991, at B2.

<sup>10</sup> Council Decision 91/596 of 4 November 1991 Concerning the Summary Notification Information Format Referred to in Article 9 of Directive 90/220 on the Deliberate Release Into the Environment of Genetically Modified Organisms, 1991 O.J. (L 322) 1.

<sup>11</sup> See *id.*

<sup>12</sup> See generally ZYGMUNT J.B. PLATER, *ENVIRONMENTAL LAW POLICY: A COURSEBOOK ON LAW, NATURE & SOCIETY* (1992).

account, and the possibility of transferring costs to consumers must be considered.<sup>13</sup> Environmental legislation, including any measure regulating biotechnology, is assessed according to whether protection of the environment can be attained better by measures at the Community level or at the level of the Member States.<sup>14</sup> It is important to realize that EC environmental policy neither supplants national environmental policy nor renders it redundant.<sup>15</sup>

#### A. *Environmental Policy Before the Single European Act*

Protection of the environment was not among the Community's objectives in 1958;<sup>16</sup> the Treaty of Rome (Treaty) did not even include the concepts "environment" or "environmental policy."<sup>17</sup> During the last three decades, however, the Community has developed an integrated approach to implement stricter standards for environmental protection.<sup>18</sup> In the absence of specific legal authorization, the Community has invoked Articles 2, 100, and 235 of the Treaty to achieve its environmental objectives.<sup>19</sup> The Community has also enacted environmental measures by using binding legal acts pursuant to Articles of the Treaty.<sup>20</sup>

While Articles 2, 100, and 235 have been used to attain environmental objectives, Article 30 is an important restriction on

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<sup>13</sup> Ludwig Kramer, *The Single European Act and Environment Protection: Reflections on Several New Provisions in Community Law*, 24 COMMON MKT. L. REV. 659, 669 (1987).

<sup>14</sup> Single European Act, Feb. 17, 1986, art. 130r(4), 1987 O.J. (L 169) 1 [hereinafter SEA].

<sup>15</sup> Kramer, *supra* note 13, at 669.

<sup>16</sup> Coopers & Lybrand, *Environment*, *supra* note 7, at \*2.1; see generally TREATY ESTABLISHING THE EUROPEAN ECONOMIC COMMUNITY [EEC TREATY].

<sup>17</sup> Fourth Environment Action Programme, 1987 O.J. (C 328) 6.

<sup>18</sup> Kramer, *supra* note 13, at 663. Article 2 of the EEC Treaty states the Community's objectives broadly: "[to] establish a common market and progressively approximat[e] the economic policies of Member States, to promote throughout the Community a harmonious development of economic activities, a continuous and balanced expansion, an increase in stability, an accelerated raising of the standard of living and closer relations between the Member States belonging to it."

Article 100 of the Treaty of Rome addresses the need for harmonization of national provisions which have a direct effect on the establishment or functioning of the Common Market.

Article 235 authorizes action by the Community which appears necessary to attain any one of the Community's stated objectives in the course of the operation of the Common Market.

<sup>19</sup> Coopers & Lybrand, *Environment*, *supra* note 7, at \*2.1.

<sup>20</sup> Kramer, *supra* note 13, at 688.

any environmental measure undertaken by the EC.<sup>21</sup> As interpreted by the European Court of Justice (ECJ), Article 30 prohibits all measures enacted by Member States which are capable of hindering intra-Community trade, either directly or indirectly, actually or potentially.<sup>22</sup> Nonetheless, since 1973 the EC has adopted four successive Environment Action Programmes.<sup>23</sup>

The first two Environment Action Programmes identified necessary Community-wide remedial actions,<sup>24</sup> and resulted in reactive rather than proactive policy.<sup>25</sup> The Third Environment Action Programme focused on preventive measures by integrating environmental requirements with the planning and execution of further economic and social development.<sup>26</sup> The Community's earliest regulations regarding biotechnology were also promulgated at this time; they applied to areas such as foodstuffs, pharmaceuticals, and agriculture.<sup>27</sup> In 1985, the Commission authorized a Biotechnology Research Action Programme to develop risk assessment techniques specific to the biotechnology industry.<sup>28</sup> The Commission expressed its belief that potential risks should be evaluated as far in advance of production as possible to allow for preventive action.<sup>29</sup>

### B. *Environmental Policy After the Single European Act*

The current Environment Action Programme is premised on the belief that high standards of environmental protection are an

<sup>21</sup> *Id.*; EEC TREATY arts. 2, 30, 100, 235.

<sup>22</sup> Kramer, *supra* note 13, at 688.

<sup>23</sup> Each Environment Action Programme spanned four or five years. The first three commenced in 1973, 1977, and 1983. The Fourth Environment Action Programme is for the six-year period 1987–1992. Fourth Environment Action Programme, *supra* note 17.

<sup>24</sup> 1973 J.O. (C 112) 20; Coopers & Lybrand, *Environment*, *supra* note 7, at 2.1.

<sup>25</sup> Issues were addressed as they occurred, rather than before they became a problem. See Coopers & Lybrand, *Environment*, *supra* note 7, at 2.1. The Community's environmental policy at this time concentrated on trade creation, industrial pollution, and issues brought to the forefront by strong public pressure. *Id.*

<sup>26</sup> An example of such preventive measures is Directive 85/337, promulgated during the Third Environment Action Programme. It requires an assessment of the effects of certain public and private projects on the environment before the project begins. 1985 O.J. (L 175) 7.

<sup>27</sup> Fourth Environment Action Programme, *supra* note 17, at 4.4.1. In addition, the EC instituted policies in advance of other nations to manage the development of recombinant DNA research. *Id.*

<sup>28</sup> *Id.* at 4.4.3. In conjunction with the philosophy of the Third Action Programme, the Biotechnology Research Action Programme was created out of concern that with a rapid development in the biotechnology industry, detrimental effects on the environment might multiply rapidly if appropriate precautions were not taken. *Id.*

<sup>29</sup> *Id.* at 4.4.4.

economic imperative, and that Community industry will not be successful unless it can satisfy public demands for environmentally safe goods.<sup>30</sup> The Action Programme's agenda reflects that of the SEA, which amended the Treaty of Rome by updating and refining many of its provisions.<sup>31</sup> The SEA incorporated the Community's environmental objectives by adding a new chapter on the environment: Articles 130r, 130s, and 130t.<sup>32</sup> In addition, Title VII of the SEA specifically empowers the Community to protect the environment.<sup>33</sup>

The first two objectives outlined in Article 130r(1) of the SEA encompass biotechnology measures committed to preserving and protecting the environment and to improving conditions of human health.<sup>34</sup> The Council has also outlined a more specific development program for the field of biotechnology.<sup>35</sup> The EC's goal of internal harmonization prompted concerns that enforcement of stringent environmental standards would result in the overregulation of the biotechnology industry.<sup>36</sup> The Commission therefore strongly advocated a single procedure, now referred to as Summary Notification, for assessment and notification on the basis of three criteria: quality, safety, and effectiveness.<sup>37</sup>

## II. THE BIOTECHNOLOGY INDUSTRY AND THE 1990 DIRECTIVES

The focus of the Community's environmental policy has shifted from "continuous and balanced expansion" under the Treaty of Rome to the promotion of "sustainable and non-inflationary growth respecting the environment" under the SEA.<sup>38</sup> Prior to Directives 90/219 and 90/220, which established a European notification and permit system for GMO releases,<sup>39</sup> biotechnology

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<sup>30</sup> *Id.* at 1.3.

<sup>31</sup> Coopers & Lybrand, *Environment*, *supra* note 7, at \*2.2.

<sup>32</sup> SEA, *supra* note 14. Article 130r(1) describes the Community objectives as: (1) to preserve, protect, and improve the quality of the environment; (2) to contribute toward protecting human health; and (3) to ensure a prudent and rational utilization of natural resources.

<sup>33</sup> Coopers & Lybrand, *Environment*, *supra* note 7, at \*2.1.

<sup>34</sup> SEA, *supra* note 14; Kramer, *supra* note 13, at 664.

<sup>35</sup> See Council Decision 92/218, *supra* note 6.

<sup>36</sup> See *Biotechnology: Proposals for New EEC Strategy Receive Green Light*, Eur. Rep. (Eur. Info. Serv.), Apr. 20, 1991, available in LEXIS, Europe Library, ECInfo File [hereinafter *Biotechnology*].

<sup>37</sup> *Id.*

<sup>38</sup> Coopers & Lybrand, *Environment*, *supra* note 7, at \*2.1.

<sup>39</sup> Council Directive 90/219, 1990 O.J. (L 117) 1; Council Directive 90/220, art. 9, 1990 O.J. (L 117) 15.

regulation existed in varying degrees in the Member States. Laws in Germany, Denmark, and the Netherlands virtually banned the release of GMOs, while other countries had no legislation on the issue.<sup>40</sup> This lack of uniformity among national provisions has resulted in a fragmented biotechnology database which places the EC's approximately 800 firms at a disadvantage relative to the United States and Japan.<sup>41</sup> Patchwork regulation may also explain, in part, why investment in European biotechnology is currently a fraction of what it is in the United States.<sup>42</sup>

Directives 90/219 and 90/220 introduced a common legislative framework and eliminated existing disparities between Member States' regulations for the evaluation and reduction of potential risks involved in the use of GMOs.<sup>43</sup> The Commission enumerated nine areas of concern regarding the contained use or deliberate release of GMOs,<sup>44</sup> and required Member States to ensure that all appropriate measures are taken to avoid adverse effects on human health or the environment.<sup>45</sup> Although both Directives excluded products already regulated by the Community,<sup>46</sup> representatives of the biotechnology industry immediately accused the EC of hampering industry development with such stringent regulations.<sup>47</sup>

The first Directive, 90/219, addresses contained or laboratory use of GMOs.<sup>48</sup> It is intended to establish a permanent inventory within each Member State to monitor developments and trace

<sup>40</sup> Arnst, *supra* note 9.

<sup>41</sup> *Biotechnology*, *supra* note 36. Of the worldwide biotechnology patents obtained by the end of 1989, the United States accounted for 41 percent, Japan 36 percent, and Europe 19 percent. None of the world's five top-selling bioengineered drugs were made in Europe. Arnst, *supra* note 9.

<sup>42</sup> See Arnst, *supra* note 9.

<sup>43</sup> See Ruetsch & Broderick, *supra* note 2, at 408.

<sup>44</sup> The Commission focused on: (1) the nature of the organisms produced; (2) the production processes used; (3) operating discharges to the environment; (4) waste disposal and management practices; (5) accident prevention; (6) application methods and intended sites for release; (7) detection, monitoring, and control of survival, multiplication, and dissemination; (8) exposed populations; and (9) effects of the organisms on humans and other species. Fourth Environment Action Programme, *supra* note 17, at 4.4.6.

<sup>45</sup> Ruetsch & Broderick, *supra* note 2, at 408.

<sup>46</sup> These products are human and veterinary pharmaceuticals, foodstuffs, additives, feedingstuffs, plants, and animals. *Directives Could Cripple Biotech Sector, Critics Warn*, External Impact of European Unification, Apr. 6, 1990, available in LEXIS, Europe Library, ECInfo File [hereinafter *Directives Could Cripple*].

<sup>47</sup> Arnst, *supra* note 9.

<sup>48</sup> See Council Directive 90/219, *supra* note 39.

the origin of negative effects resulting from the use of GMOS.<sup>49</sup> Directive 90/220, the second directive, instituted controls on the deliberate release of GMOs into the environment.<sup>50</sup> Articles 5 through 9 of this Directive provide for release of GMOs into the environment for research, development, or purposes other than placing products on the market.<sup>51</sup> According to this directive, information must be made available to the local population prior to a planned GMO release in the area.<sup>52</sup> In addition, the use of a GMO may not proceed without the consent of a competent authority.<sup>53</sup>

Both Directives unequivocally place the burden on the innovator to identify and thoroughly assess all relevant risks in advance.<sup>54</sup> The Council's goal is to supplement evaluations through close monitoring of GMOs after their release.<sup>55</sup> The user of the GMO must submit adequate information to the competent authorities in the Member State where the release will take place.<sup>56</sup> Article 9 is pivotal in this regard, in that it creates a procedure for sharing specific information among Member States about the characteristics of GMOs and the intended release.<sup>57</sup> Article 9 thus provides authorization for Decision 91/596—the establishment of summary notification for the deliberate release of GMOs.<sup>58</sup>

### III. COUNCIL DECISION 91/596

#### A. *A New Regulatory Decision*

Council Decision 91/596 is part of an integrated strategy to harmonize national legislation and to promote the safe development of biotechnology.<sup>59</sup> The Decision creates a regulatory system

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<sup>49</sup> See *id.* A controversial provision requires industrialists and research workers to assume the responsibility for any harm caused and to take out insurance policies to that effect.

<sup>50</sup> See Council Directive 90/220, *supra* note 39.

<sup>51</sup> *Id.* at arts. 5–9; see also Ruetsch & Broderick, *supra* note 2, at 409.

<sup>52</sup> Council Directive 90/220, *supra* note 39, at art. 9.

<sup>53</sup> Fourth Environment Action Programme, *supra* note 17, at 4.4.4. Each Member State designates the competent authority to receive the information. Council Directive 90/220, *supra* note 39, at arts. 4(2), 4(3).

<sup>54</sup> See Council Directive 90/220, *supra* note 39, at arts. 1(1), 4(1).

<sup>55</sup> Proposal for a Council Directive on the Deliberate Release to the Environment of Genetically Modified Organisms, COM(90)160 at 57 [hereinafter Proposal for a Council Directive].

<sup>56</sup> *Id.* at art. 5(1).

<sup>57</sup> See Council Directive 90/220, *supra* note 39, at art. 9.

<sup>58</sup> See *id.* at art. 9.

<sup>59</sup> See Ruetsch & Broderick, *supra* note 2, at 408.



designed to improve European industry's ability to compete with the United States and Japan.<sup>60</sup> It requires researchers, or the competent authority overseeing the project, to provide detailed information about the introduction of the GMO.<sup>61</sup> Toward that end, researchers must answer 56 multiple-part questions grouped in eight categories, which are notable for their breadth and comprehensive coverage.<sup>62</sup>

The first Summary Notification category requires researchers to characterize the GMO by identifying and describing the purpose of the microorganism.<sup>63</sup> The second and third categories request detailed information relating to the recipient or parental organism as well as information about the genetic modification.<sup>64</sup> The fourth category focuses on the release of the GMO—the purpose, location, method and amount of the intended release, and procedures to avoid or minimize the spread of the GMO beyond the release site.<sup>65</sup>

The fifth part of the Summary Notification attempts to gauge the potential impact on the environment. Under this provision, the researcher must evaluate the target organism, the potential affects on other organisms, and the ecosystem in which the GMO will be introduced.<sup>66</sup> The sixth and seventh categories request information relating to monitoring, post-release, and waste treatment.<sup>67</sup> The final set of questions, and perhaps the most important, require the preparation of emergency response plans.<sup>68</sup>

It is interesting to note that the Annex to the Decision explicitly states that Summary Notification is not designed to contain all the information required for carrying out a detailed environmental risk assessment.<sup>69</sup> Summary Notification is similar to the EC assessment process in that it is intended to predict the direct and indirect effects of a project on human beings, flora, fauna,

<sup>60</sup> *Id.*

<sup>61</sup> *See generally* Council Decision 91/596, *supra* note 10, at ANNEX. The bulk of Decision 91/596 is the actual format of the required Summary Notification researchers will utilize. *See id.*

<sup>62</sup> *See* Council Decision 91/596, *supra* note 10.

<sup>63</sup> *Id.* at 4–7.

<sup>64</sup> *Id.* at 7–10.

<sup>65</sup> *Id.* at 11–12.

<sup>66</sup> *Id.* at 12–13.

<sup>67</sup> *Id.* at 13–15.

<sup>68</sup> *Id.* at 16.

<sup>69</sup> *Id.* at ANNEX.

soil, water, air, climate, and landscape.<sup>70</sup> The procedures differ, however, in that Summary Notification does not require a consideration of the effect of GMOs on material assets and cultural heritages.<sup>71</sup>

More significantly, detailed environmental risk assessments require consultation with the competent authorities, all affected Member States, and the public.<sup>72</sup> The project may not proceed until all opinions are evaluated and the public is informed of the decision.<sup>73</sup> Summary Notification does not contain these strictures. In addition, Summary Notification imposes a minimal burden on researchers and manufacturers.<sup>74</sup> The Council's Proposal for Directive 90/220 provides that the notification should consist of information already available to businesses.<sup>75</sup> Moreover, the Proposal states that "notifications will not be required of the final users of the product, i.e. farmers, environmental clean-up companies, etc."<sup>76</sup> It would seem, therefore, that compliance with Summary Notification is comparatively limited in scope and is less burdensome than a complete environmental assessment.

#### B. *The Anticipated Effects of Decision 91/596*

Most industry experts and participants agree that some controls are necessary, and even beneficial, in assessing the effects of releasing GMOs.<sup>77</sup> Decision 91/596 is the equivalent of codifying risk evaluation, which is normally undertaken by researchers and manufacturers.<sup>78</sup> The Summary Notification format, at best, facilitates what might otherwise be a complex and time-consuming process. Yet industry reaction to Decision 91/596 is divided; some company officials are relieved to have new rules to eliminate the growing confusion of national standards, whereas others fear such regulatory controls in biotechnology will undermine the

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<sup>70</sup> Directive 85/337, *supra* note 26.

<sup>71</sup> Compare Council Decision 91/596, *supra* note 10, at ANNEX, with Directive 85/337, *supra* note 26.

<sup>72</sup> Directive 85/337, *supra* note 26.

<sup>73</sup> *Id.*

<sup>74</sup> See Proposal for a Council Directive, *supra* note 55, at 57.

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> See, e.g., *Directives Could Cripple*, *supra* note 46.

<sup>78</sup> See Coopers & Lybrand, *Pharmaceuticals*, *supra* note 8, at \*17.7.

ability of biotechnology products to compete with similar products.<sup>79</sup>

A major concern of industry participants is the full-disclosure requirement of Decision 91/596, because the researchers must reveal details of the development of the microorganism and its intended use.<sup>80</sup> The Commission has made it clear, however, that confidential information supplied to authorities will be kept secret to protect the competitive position of the notifier.<sup>81</sup> Nonetheless, depending on how confidential information is defined, an important question is whether the public will have the right to obtain detailed biotechnology information under a new Directive on public access to environmental information.<sup>82</sup>

The most important question, of course, is whether Decision 91/596 will effectively accomplish its intended purpose. There are at least two incentives for Member States to enact measures to enforce the Decision. The first is that the Community's environmental laws can be enforced by local and national courts, as well as by the ECJ.<sup>83</sup> Accordingly, the ECJ has the authority to sanction Member States for failure to comply.<sup>84</sup>

The second reason Member States will want to comply with Decision 91/596 is the ability of private citizens to complain directly to the Commission about violations of environmental law.<sup>85</sup> This is an important motivation given the belief, widely held by biotechnology industry officials, that the most critical issue facing biotechnology in Europe is public perceptions.<sup>86</sup> Thus, in view of

<sup>79</sup> *Id.*

<sup>80</sup> See Council Decision 91/596, *supra* note 10, at 7-12.

<sup>81</sup> See Council Decision 92/146, 1992 O.J. (L 60) 1.

<sup>82</sup> Directive 90/313 is modelled on the U.S. Freedom of Information Act and establishes a common standard for public access to government files for all citizens in the Community. Individuals will have a right to obtain environmental information on the state of air, water, soil, flora, fauna, and natural areas. The Directive will come into effect January 1, 1993. 1990 O.J. (L 158) 35. Its terms do not exclude biotechnology or genetically engineered products. Coopers & Lybrand, *Environment*, *supra* note 7, at \*3.2.

<sup>83</sup> *Id.* at 2.1.

<sup>84</sup> EEC TREATY art. 171. The ECJ recently held that the failure to adopt measures needed to implement a Community directive constituted an infringement of article 171 of the EEC Treaty for which the Member States could be ordered to pay damages. *Joined Cases 227-230/85, Commission of the European Communities v. Kingdom of Belgium*, 1 CEC(CCH) 626, 632-33 (1990). The court imposed costs under article 69(2) of the Rules of Procedure.

<sup>85</sup> See *id.*

<sup>86</sup> Arnst, *supra* note 9. One may only speculate why industry officials are convinced that the public plays a more important role in Europe than in the United States or Japan. It may be that the public in Europe is generally more aware of, and concerned with,

the serious potential threat to the environment, the very real threat of sanctions by the ECJ for non-compliance, and the veiled threat of consumer dissatisfaction, the Summary Notification established by Decision 91/596 will likely be implemented and enforced by the Member States.<sup>87</sup>

### CONCLUSION

Decision 91/596 demonstrates that the EC is again leading other countries in managing environmental risks. Although the United States and Japan have chosen to ignore the necessity of regulating the rapidly developing biotechnology sector, the EC has enacted comprehensive preventive legislation. The potential drawbacks of the Decision reflect the need to enact threshold standards which will be enforceable and effective. Any shortcomings of Summary Notification will be addressed when Community-wide standards are adapted to the needs of individual Member States. This flexibility is consistent with the EC's environmental objectives and its goal of internal harmonization. Overall, Summary Notification for the deliberate release of GMOs is a unique and potentially expeditious way of handling the complex issues raised by sophisticated technologies.

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environmental issues due to Europe's traditional overcrowding and limited resources—problems which have finally come to the forefront in other countries in the last decade.

<sup>87</sup> The 1990 biotechnology directives, Directive 90/219 and 90/220, required implementation by the Member States by October 23, 1991. *UK: Department of the Environment—Regulations on Genetically Modified Organisms Delayed*, Reuter Textline, May 13, 1992, available in LEXIS, Europe Library, Alleur File, at \*2. Germany was among the first of the Member States, along with the Netherlands and Denmark, to ratify the two directives. *Implementation of Biotech Rules Reassures Companies—Germany Leads the Way*, Apr. 24, 1992, available in LEXIS, Europe Library, Alleur File, at \*2.

As of mid-1992, other Member States were still in the process of enacting the 1990 directives. Italy has yet to implement either of the directives, and industry representatives there believe that this absence of legislation has delayed product development. *Implementation of Biotech Rules Reassures Companies—Italy Lacks Legislation*, Apr. 24, 1992, available in LEXIS, Europe Library, Alleur File, at \*2. The UK recently published its revised proposals for new regulations to implement the directives; they are intended to be more "user-friendly" than the EC format in Decision 91/596. *UK: Department of the Environment—Proposals for New Regulations on Genetically Modified Organisms*, Reuter Textline, Aug. 18, 1992, available in LEXIS, Europe Library, Alleur File, at \*1, \*3. Finally, Spain has enacted the directives and taken the additional step of reforming its Penal Code to include prison sentences of two to six years for unethical genetic manipulation. *Implementation of Biotech Rules Reassures Companies—Spain at Work on Ethics*, Apr. 24, 1992, available in LEXIS, Europe Library, Alleur File, at \*2.