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# An Agricultural Law Research Article

# Genetically Modified Crops in the Philippines: Can Existing Biosafety Regulations Adequately Protect the Environment

by

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# GENETICALLY MODIFIED CROPS IN THE PHILIPPINES: CAN EXISTING BIOSAFETY REGULATIONS ADEQUATELY PROTECT THE ENVIRONMENT?

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Abstract: Global concern persists about the use of genetically modified crops ("GM crops"). This concern originates from the divergent perspectives of nations with a stake in either the production or consumption of GM crops. Proponents of GM crops in developing countries claim that the crops could increase food supply by improving plant resistance to pesticides, thereby alleviating the need for farmers to purchase chemicals that are frequently expensive or unavailable. However, many organizations and countries are hesitant or outright opposed to GM crops, particularly regarding their potentially undesirable ecological and agricultural consequences.

As one of the first Asian nations to approve and commercialize a GM crop, the Philippines serves as a useful case study for evaluating a developing nation's strategy for regulating the environmental impacts of agricultural biotechnology in the face of international pressures. Though among the first of the Asian nations to enact biosafety regulations, the Philippines' existing regulations do not adequately protect the environment because they lack enforcement power and leave gaps in coverage. Legislation that would create a more streamlined regulatory process and endow the regulating agencies with stronger enforcement authority should be enacted.

#### I. INTRODUCTION

The application of biotechnology to agricultural crops, a development known as "agro-biotechnology," has been promoted as an innovative advance in the worldwide endeavor to improve food security.<sup>1</sup> It has simultaneously been criticized for its potential to bring about significant disruption to the environment.<sup>2</sup> A genetically modified ("GM") crop<sup>3</sup> contains a gene from a different species that gives the crop new traits such as

<sup>&</sup>lt;sup>†</sup> The author would like to thank Professor Sean O'Connor as well as the editors of the *Pacific Rim* Law & Policy Journal for their guidance, suggestions, and assistance in the development of this Comment.

<sup>&</sup>lt;sup>1</sup> See, e.g., U.N. Conference on Trade & Dev. [UNCTAD], Policy Issues in Int'l Trade and Commodities Study Series No. 29, International Trade in GMO and GM Products: National and Multilateral Legal Frameworks, at 1, U.N. Doc. UNCTAD/ITCD/TAB/30, U.N. Sales No. E.04.II.D.41 (2005) (prepared by Simonetta Zarrilli) [hereinafter UNCTAD GMO Trade Study].

<sup>&</sup>lt;sup>2</sup> See, e.g., Miguel A. Altieri, Genetic Engineering in Agriculture: The Myths, Environmental Risks, and Alternatives 35-43 (2004).

<sup>&</sup>lt;sup>3</sup> Such crops are referred to as GM crops, GE crops, transgenic crops, biotech crops, or simply genetically modified organisms ("GMOs"). All terms refer to the concept in which a crop had been modified through biotechnological processes to contain a gene that confers new characteristics. This Comment will use the descriptor "GM crop."

resistance to certain insects or herbicides, increased drought tolerance,<sup>4</sup> or enhanced nutritional value.<sup>5</sup> Supporters of agro-biotechnology argue that it could reduce the amounts of pesticide, fertilizer, and water needed to produce foods, potentially leading to greater crop yields and improvements in food security.<sup>6</sup> Critics of the technology warn of potential dangers, including threats to the ecosystems in which GM crops are introduced, decreased genetic biodiversity of crops, and unknown effects to humans from consuming GM foods.<sup>7</sup>

The environmental dangers from releasing GM crops have captured the world community's attention. In particular, scientists and community organizations have been concerned that engineered genes<sup>8</sup> could escape into the environment and be incorporated into the genomes of their wild relatives<sup>9</sup> through "outcrossing."<sup>10</sup> The impacts of such incorporation could lead to the inadvertent evolution of new strains of viruses or pathogenic bacteria, as well as the development of herbicide-resistant "superweeds" and insecticide-resistant "superbugs."<sup>11</sup> A separate threat to the environment is the possibility that genetic engineering may lead to genetically uniform crop systems (monocultures),<sup>12</sup> a danger because intra-species genetic diversity is important in agriculture.<sup>13</sup>

Asia is poised to play a crucial role in determining how widely GM crops will be accepted on an international scale.<sup>14</sup> As a region, Asia is home

<sup>&</sup>lt;sup>4</sup> WORLD HEALTH ORGANIZATION, TWENTY QUESTIONS ON GENETICALLY MODIFIED FOODS, http://www.who.int/foodsafety/publications/biotech/20questions/en/ (last visited Mar. 31, 2006) [hereinafter WHO].

<sup>&</sup>lt;sup>3</sup> Gregory N. Mandel, Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals, 45 WM. & MARY L. REV. 2167, 2171 (2004).

<sup>&</sup>lt;sup>6</sup> See, e.g., Sean D. Murphy, Biotechnology and International Law, 42 HARV. INT'L L. J. 47, 55 (2001); Haley Stein, Intellectual Property and Genetically Modified Seeds: The United States, Trade and the Developing World, 3 NW. J. TECH, & INTELL. PROP. 160, 175 (2005).

See, e.g., Murphy, supra note 6, at 56-59; ALTIERI, supra note 2, at ix, 27-33.

<sup>&</sup>lt;sup>8</sup> Engineered genes are also known as transgenes.

<sup>&</sup>lt;sup>9</sup> Norman C. Ellstrand, Dangerous Liaisons? When Cultivated Plants Mate With Their Wild Relatives 171 (2003).

<sup>&</sup>lt;sup>10</sup> See WHO, supra note 4.

<sup>&</sup>lt;sup>11</sup> Murphy, supra note 6, at 59.

<sup>&</sup>lt;sup>12</sup> Id. One of the most significant dangers of monocultures is that the crops lack the "necessary ecological defense mechanisms" to successfully fight off pests. Consequently, in order to grow the crop, farmers must add agrichemical inputs. ALTIERI, *supra* note 2, at xi-xii.

<sup>&</sup>lt;sup>13</sup> Clive Stannard et al., Agricultural Biological Diversity for Food Security: Shaping International Initiatives to Help Agriculture and the Environment, 48 How. L. J. 397, 403-04 (2004).

<sup>&</sup>lt;sup>14</sup> See, e.g., Mark McCord, Opinion, Asia Heads Toward Use of GMO Foods Despite Activist Protests, THE MANILA TIMES, Aug. 28, 2004; John Feffer, Asia Holds the Key to the Future of GM Food, YALEGLOBAL ONLINE, Dec. 2, 2004, http://yaleglobal.yale.edu/display.article?id=4956 (asserting that Asia "holds the key to the future of GM food," and analogizing that if the decision whether to use GM crops were an election, then Asia would be the swing state between the United States and the European Union).

to many developing countries struggling to feed their populations.<sup>15</sup> Asia also currently contains the world's largest consumer base, is home to the greatest number of farmers,<sup>16</sup> and is a net grain importer.<sup>17</sup> These factors combine to create high potential for Asia both as a consumer market<sup>18</sup> and as a potential agricultural production area. Many Asian countries have also been particularly active in developing and using agro-biotechnology.<sup>19</sup>

Within Asia, the Philippines is on the front lines of the agrobiotechnology movement and was one of the first Asian countries to endorse commercialization of GM crops.<sup>20</sup> The Philippines has embraced agrobiotechnology as one method to improve national food security.<sup>21</sup> In 2004, the Philippines grew 0.1 million hectares of GM crops.<sup>22</sup> The International Service for the Acquisition of Agri-Biotech Applications classifies the Philippines as one of fourteen "biotech mega-countries," which are countries that grow 50,000 hectares or more of GM crops annually.<sup>23</sup> The Philippine population, estimated at 85 million in 2005, is growing rapidly at a rate of 2.4 % annually.<sup>24</sup> This population growth, in combination with the shrinking area available for farming,<sup>25</sup> has led the Philippines to be a net importer of

 See McCord, supra note 14.
 Neil D. Hamilton, Forced Feeding: New Legal Issues in the Biotechnology Policy Debate, 17 WASH. U. J.L. & POL'Y 37, 39 (2005).

<sup>20</sup> In December 2002, the Philippines approved Monsanto's application for the commercialization of "Bt com," which is corn that has been engineered to include genetic material of the Bacillus thuringiensis bacteria. The result is corn that resists the Asiatic corn borer, an insect pest. See DEP'T OF AGRIC., GMA CORN PROGRAM, BT CORN . . . WHAT YOU NEED TO KNOW, FACT SHEET (May 2003), available at http://www.da.gov.ph/cornprogram/profile/BtCorn/btcorn.html; see also Roderick T. de la Cruz, UNCTAD Calls on RP, Other Countries to Balance Impact of GMO, MANILA STANDARD TODAY, May 17, 2005, http://www.manilastandardtoday.com/?page=business06\_may17\_2005.

<sup>21</sup> See DEP'T OF AGRIC., ADMINISTRATIVE ORDER NO. 8, SERIES OF 2002, pmbl. (Apr. 3, 2002), available at http://www.da.gov.ph/agrilaws/AO2002/AO\_08.html [hereinafter ADMINISTRATIVE ORDER No. 8] ("WHEREAS, on July 16, 2001 Her Excellency President Gloria Macapagal-Arroyo approved the Policy Statement on Modern Biotechnology, reiterating the government policy of promoting the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development . . . .").

Clive James, International Service for the Acquisition of Agri-Biotech Applications [ISAAA], ISAAA Briefs No. 32. Preview: Global Status of Commercialized Biotech/GM Crops: 2004. Executive Summary, at 4, available at http://www.isaaa.org (follow hyperlink "ISAAA Briefs 34-2005: Global Status of Commercialized Biotech/GM Crops: 2005").

<sup>23</sup> Id.

<sup>&</sup>lt;sup>15</sup> McCord, supra note 14.

<sup>&</sup>lt;sup>16</sup> Feffer, supra note 14.

<sup>&</sup>lt;sup>17</sup> Sambit Mohanty, Opinion, Asian Nations May Have To Be Cautious About GMO Rice, MANILA TIMES, Oct. 28, 2004.

<sup>&</sup>lt;sup>24</sup> Perfecto G. Corpuz U.S. Dep't of Agric. Service, Global Agric. Info. Network Report, Philippines Biotechnology Annual 2005 (Jul. 25, 2005), http://www.fas.usda.gov/gainfiles/200506/146130020.pdf. 25 Id.

grains.<sup>26</sup> Adding to the country's food supply challenges, the average Filipino spent about 54% of his or her income on food as of 2002.<sup>27</sup> Faced with these facts, the government supports agro-biotechnology as a method to improve Philippine agricultural productivity.<sup>28</sup>

As a heavily agrarian developing nation embracing agrobiotechnology, the Philippines serves as a useful case study of the challenges developing nations must address when regulating agro-biotechnology. The Philippine government encourages the use of biotechnology in a manner that enhances the "integrity of the environment" and prevents or reduces risks to biological diversity and human health.<sup>29</sup> Accordingly, it has developed administrative measures regulating the field release of GM crops. This Comment will focus on the environmental impacts of agro-biotechnology, a field whose domain intersects with technology, development, food security, environmental protection, and international trade agreements.

The Philippine regulations that seek to protect the nation's ecosystems and agricultural resources from the dangers associated with GM crops lack enforcement mechanisms, but could be improved by strengthening compliance requirements and implementing a centralized authority to avoid regulatory gaps.<sup>30</sup> Part II of this Comment details the potential harms posed by releasing GM crops into the environment and how regulation of agrobiotechnology implicates international obligations. Part III describes international and Philippine regulatory schemes regarding the release of GM crops into the environment. Part IV critiques the enforcement and compliance mechanisms in Philippine biosafety regulations, and contrasts them with both Australia's more robust enforcement regulatory scheme and the gap-ridden United States biotechnology regulatory framework. Part V argues that the Philippines should enact congressional legislation creating a more streamlined, centralized regulatory process and providing the

<sup>&</sup>lt;sup>26</sup> Food and Agriculture Organization, Food and Agriculture Indicators: Philippines, FAOSTAT, World Bank—World Development Indicators (July 2004), http://www.fao.org/es/ess/compendium\_2004/ pdf/ESS\_PHI.pdf [hereinafter FAO, Food and Agriculture Indicators].

<sup>&</sup>lt;sup>27</sup> Augusto de Leon et al., The Cost Implications of GM Food Labeling in the Philippines: A Socioeconomic Impact Study Conducted for the Bureau of Food and Drugs, Feb. 2004, at 80 (on file with The Pacific Rim Law & Policy Journal).

<sup>&</sup>lt;sup>28</sup> See ADMINISTRATIVE ORDER NO. 8, supra note 21; Press Release, Office of the President, Republic of the Philippines, Lawmakers, Scientists Bat for Legislation on Biotechnology (May 7, 2005), http://www.op.gov.ph/news.asp?newsid=9149 [hereinafter Lawmakers, Scientists Bat for Legislation on Biotechnology].

<sup>&</sup>lt;sup>20</sup> See ADMINISTRATIVE ORDER NO. 8, *supra* note 21, pmbl.; *accord* Lawmakers, Scientists Bat for Legislation on Biotechnology, *supra* note 28.

<sup>&</sup>lt;sup>30</sup> Issues of labeling and the safety of GM foods as consumables for humans and animals are beyond the scope of this paper. For a study of GM food labeling in the Philippines, see de Leon et al., *supra* note 27, at 10-11.

regulating agencies with stronger enforcement authority. Such legislation would bring the Philippines into compliance with the Cartagena Protocol on Biosafety,<sup>31</sup> which the Philippine Congress need not formally ratify, as the factors for and against doing so balance each other out.

II. CRITICS OF GM CROPS ARE CONCERNED ABOUT ENVIRONMENTAL IMPACTS OF FIELD RELEASE

Groups opposed to GM crops cite the potential for harm to the environment as one reason not to cultivate GM crops in fields.<sup>32</sup> GM crops also present developing countries with complicated international trade challenges.<sup>33</sup>

## A. Field Release of GM Crops Triggers Environmental Concerns

Cultivation of GM crops poses risks to the environment.<sup>34</sup> One prominent risk is "gene flow," which is the possibility that the engineered genes ("transgenes") from GM crops might escape and be incorporated into wild populations.<sup>35</sup> Gene flow is a natural part of evolution and occurs with conventional crops<sup>36</sup> as well as engineered crops. However, in the biotechnology realm, gene flow refers to the possibility that GM crops will hybridize with their wild relatives, resulting in the transfer of the transgenes from the GM crops to their wild counterparts.<sup>37</sup> For this reason, GM organisms have been identified as a potential vector through which "foreign and potentially invasive genes may be introduced into a new environment."<sup>38</sup>

<sup>&</sup>lt;sup>31</sup> Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027, *available at* http://www.biodiv.org/biosafety/protocol.asp (last visited Mar. 31, 2006) [hereinafter Cartagena Protocol].

<sup>&</sup>lt;sup>32</sup> The prospect of detriment to the environment is only one of numerous reasons critics of GM crops oppose agro-biotechnology. However, this Comment focuses on the regulations governing the environmental impacts of growing GM crops in the field.

<sup>&</sup>lt;sup>33</sup> UNCTAD GMO Trade Study, supra note 1, at 2.

<sup>&</sup>lt;sup>34</sup> National Research Council of the National Academies, Biological Confinement of Genetically Engineered Organisms 48-49 (2004) [hereinafter National Research Council].

<sup>&</sup>lt;sup>35</sup> Michael P. Healy, Information Based Regulation and International Trade in Genetically Modified Agricultural Products: An Evaluation of the Cartagena Protocol on Biosafety, 9 WASH. U. J.L. & POL'Y 205, 210-12 (2002).

<sup>&</sup>lt;sup>36</sup> See ELLSTRAND, supra note 9, at 15-18.

<sup>&</sup>lt;sup>37</sup> ELLSTRAND, supra note 9, at 172.

<sup>&</sup>lt;sup>38</sup> International Plant Genetic Resources Institute, Issues in Genetic Resources No. 10, International Law of Relevance to Plant Genetic Resources: A Practical View for Scientists and Other Professionals Working with Plant Genetic Resources 68 (2004) (Susan Bragdon, ed.), available at http://www.ipgri.cgiar.org/publications/pubfile.asp?ID\_PUB=937 [hereinafter IPGRI]. It should also be noted that the rationale for treating GM crops differently stems from the recognition that, while some biotechnological processes can bring about genome changes that *could* have occurred through natural mutations or directed breeding but *actually* occur in one generation rather than hundreds (e.g., improved

There are four specific environmental dangers that gene flow may produce.<sup>39</sup> First, transgenes might confer a competitive benefit to the GM crop species' wild relatives, leading to the evolution of "superweeds" that have the potential to disrupt natural ecosystems.<sup>40</sup> For example, if a transgene that confers pest or herbicide resistance is incorporated into a weedy relative of the GM crop, then the transgene would contribute to the evolution of increased weediness.<sup>41</sup> Second, the possibility exists that hybridization between GM crops and their wild relatives will increase the risk of extinction among the wild relatives.<sup>42</sup> Third, the genetic diversity of wild populations may be harmed.<sup>43</sup> Finally, the introduction of genetically engineered genes could be considered "genetic pollution" of natural ecosystem diversity.<sup>44</sup> Many of these possible effects of gene flow apply for conventionally cultivated agricultural crops,<sup>45</sup> but the risks from genetic movement have become more pronounced because agro-biotechnology introduces genes that otherwise would not exist in plants.

Other environmental concerns about GM crops are the potential for the transgene's product to affect other organisms in the ecosystem (e.g., genetically engineered pesticides that harm non-target insects);<sup>46</sup> increased use of chemicals in agriculture;<sup>47</sup> and the possibility that targeted pests and pathogens will evolve resistance to pesticides or diseases.<sup>48</sup> A final danger is "genetic erosion," a situation where farmers' reliance on GM crops results in reduced diversity in the gene pool for that species.<sup>49</sup> This occurs when the ecosystem changes in response to the GM organisms or when farmers limit the range of crops they grow.<sup>50</sup>

44 ELLSTRAND, supra note 9, at 172.

<sup>45</sup> See David J. Schnier, Genetically Modified Organisms & the Cartagena Protocol, 12 FORDHAM ENVTL. L.J. 377, 395 (2001); ELLSTRAND, supra note 9, at 172.

<sup>46</sup> NATIONAL RESEARCH COUNCIL, *supra* note 34, at 49.

yield or drought-resistance), there are other applications of biotechnology that never could have occurred naturally (e.g., resistance to a specific commercial pesticide).

<sup>&</sup>lt;sup>39</sup> ELLSTRAND, *supra* note 9, at 172.

<sup>&</sup>lt;sup>40</sup> Id.

<sup>41</sup> NATIONAL RESEARCH COUNCIL, supra note 34, at 49.

<sup>&</sup>lt;sup>42</sup> ELLSTRAND, *supra* note 9, at 172; NATIONAL RESEARCH COUNCIL, *supra* note 34, at 49-50.

<sup>&</sup>lt;sup>43</sup> ELLSTRAND, supra note 9, at 172; NATIONAL RESEARCH COUNCIL, supra note 34, at 49-50.

<sup>47</sup> WHO, supra note 4.

<sup>&</sup>lt;sup>48</sup> NATIONAL RESEARCH COUNCIL, *supra* note 34, at 49.

<sup>&</sup>lt;sup>49</sup> Healy, *supra* note 35, at 211-12.

<sup>&</sup>lt;sup>50</sup> Id.; see also ALTIERI, supra note 2, at 36.

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### B. GM Crops Present Developing Countries with International Trade Dilemmas

Developing nations face difficult choices in setting policy regarding GM crops because of their position on the international scene.<sup>51</sup> Given the ease with which plant materials can cross national boundaries—the common example being air-borne pollen—international agreements about the movement of plant materials are highly relevant to national decisions about the regulation of agro-biotechnology.

While developed nations create agro-biotechnology policies based on domestic concerns (e.g., labeling for GM products stemming from a purported "right to know"), developing nations may feel pressure to establish "national regulatory schemes based on the requests and expectations of their main trade partners."<sup>52</sup> Critics of GM crops assert that weak regulatory systems in developing nations allow international agribusinesses to promote agro-biotechnology without regard for its impacts.<sup>53</sup> Within Asia, critics of the agro-biotech industry claim that, in general, governments acquiesce to pressure from GM crop exporters despite significant popular opposition.<sup>54</sup>

Developing nations may also be caught in the middle when their trading partners have divergent policies regarding agro-biotechnology.<sup>55</sup> For example, major GM crop exporters, such as the United States, Canada, and Argentina, have authorized most GM products for production and consumption.<sup>56</sup> In contrast, many European Union countries have adopted a "no risk" approach to regulating GM products and impose strict import measures that guarantee importing countries maintain a high level of health and environmental protection.<sup>57</sup> Countries that trade with both the United States and the European Union will be forced to alienate one or the other.

<sup>&</sup>lt;sup>51</sup> UNCTAD GMO Trade Study, supra note 1, at 2.

<sup>&</sup>lt;sup>52</sup> *Id.* at iii.

<sup>&</sup>lt;sup>53</sup> McCord, supra note 14.

<sup>&</sup>lt;sup>54</sup> GRAIN, Whither Biosafety?: In These Days of Monsanto Laws, Hope for Real Biosafety Lies at the Grassroots, AGAINST THE GRAIN (Oct. 2005), available at http://www.grain.org/articles/?id=9.

<sup>55</sup> See UNCTAD GMO Trade Study, supra note 1, at 7.

<sup>&</sup>lt;sup>56</sup> Id. at 4.

<sup>57</sup> Id. at 7.

### III. REGULATING AGRICULTURAL BIOTECHNOLOGY POSES UNIQUE CHALLENGES

International governmental organizations and individual nations face unique challenges when determining the most effective approach to regulate agro-biotechnology because it is an interdisciplinary issue spanning "trade, intellectual property, environment, health, and agriculture."<sup>58</sup> As a catch-all issue, GM crops have become increasingly implicated in international trade conflicts because in regulating agro-biotechnology, developing nations must take into consideration economic development, food security, and environmental protection—all against the backdrop of international trade agreements.<sup>59</sup> The following section describes how international and national instruments attempt to regulate the environmental impacts of GM crops.

## A. The Two Major International Biosafety Instruments Offer Different Approaches to Regulating Agricultural Biotechnology

The two international treaties that regulate GM crops—the Cartagena Protocol on Biosafety<sup>60</sup> ("Cartagena Protocol") and the World Trade Organization's ("WTO") Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement")—reflect different philosophical approaches to regulating agro-biotechnology and exemplify the tensions that make GM crops a controversial international trade issue.<sup>61</sup>

The Cartagena Protocol grew out of the Convention on Biological Diversity ("CBD").<sup>62</sup> The CBD, which the Philippines has signed and ratified,<sup>63</sup> is a framework treaty that contains primarily aspirational provisions regarding biodiversity. It includes generalized guidance on the handling of biotechnology and the distribution of its benefits, directing the parties to develop a protocol outlining procedures for the "safe transfer, handling, and the use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and

<sup>&</sup>lt;sup>58</sup> Murphy, supra note 6, at 139.

<sup>&</sup>lt;sup>59</sup> UNCTAD GMO Trade Study, supra note 1, at iii.

<sup>&</sup>lt;sup>60</sup> Cartagena Protocol, *supra* note 31.

<sup>&</sup>lt;sup>61</sup> The Philippines joined the WTO in 1995. WTO, Member Information: Philippines and the WTO, http://www.wto.org/english/thewto\_e/countries\_e/philippines\_e.htm (last visited Mar. 31, 2006).

<sup>&</sup>lt;sup>62</sup> Convention on Biological Diversity, art. 19, June 5, 1992, 31 I.L.M. 818 (1992), available at http://www.biodiv.org/doc/legal/cbd-en.pdf [hereinafter CBD].

<sup>&</sup>lt;sup>63</sup> Parties to the Convention on Biological Diversity/Cartagena Biosafety Protocol, http://www.biodiv.org/world/parties.asp (last visited Mar. 31, 2006) [hereinafter Parties to the CBD/Cartagena Protocol].

sustainable use of biological diversity."<sup>64</sup> Accordingly, a working group of parties to the CBD spent the next several years negotiating such procedures, resulting in a final version of the Cartagena Protocol in 2000.65

The Cartagena Protocol, which entered into force on September 11, 2003.<sup>66</sup> provides a framework for ensuring protection of biological diversity and human health from the potential risks posed by the international movement and use of living modified organisms ("LMOs").<sup>67</sup> The Philippines has signed, but not ratified, the Cartagena Protocol.<sup>68</sup>

Two of the key provisions in the Cartagena Protocol are the "precautionary principle"<sup>69</sup> and the concept of notice and consent through an advanced informed agreement.<sup>70</sup> The precautionary principle is an emerging concept in international law that permits countries to take actions to prevent harm to humans or the environment, even in the face of scientific uncertainty.<sup>71</sup> It reflects "international recognition of the need for and legitimacy of applying precaution" in situations of low scientific certainty<sup>72</sup> and places the burden of proving the safety of a new technology on the producer of the technology, rather than on critics.<sup>73</sup> The advanced informed agreement requires exporters to seek consent from an importing country before introducing LMOs into the environment.<sup>74</sup>

<sup>64</sup> CBD, supra note 62, art. 19.

<sup>&</sup>lt;sup>65</sup> Cartagena Protocol, supra note 31.

<sup>&</sup>lt;sup>66</sup> Cartagena Protocol on Biosafety, Status of Ratification and Entry into Force, http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt (last visited Apr. 2, 2006).

<sup>&</sup>lt;sup>67</sup> Notably, the Cartagena Protocol excludes living modified organism ("LMO") commodities that will be directly used as foods, feed or processing, LMOs in transit, and LMOs bound for contained use (e.g., organisms intended for scientific research in a laboratory). IPGRI, *supra* note 38, at 72. <sup>68</sup> Parties to the CBD/Cartagena Protocol, *supra* note 63. The Philippines Constitution states that the

Philippines "adopts the generally accepted principles of International Law as part of the laws of the land." CONST. (1987) § 2, art. II, (Phil.). Treaties must receive a two-thirds approval vote from the Senate in order to be valid and effective. Id. § 21, art. VII (Phil.).

Cartagena Protocol, supra note 31, pmbl.

<sup>&</sup>lt;sup>70</sup> Id. arts. 7-10.

<sup>&</sup>lt;sup>71</sup> See, e.g., Philippe Sands, Introduction to GREENING INTERNATIONAL LAW xxxiii (Philippe Sands ed., 1994); Schnier, supra note 45, at 412; Jonathan B. Wiener, Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems, 13 DUKE J. COMP. & INT'L L. 207, 211

<sup>(2003).</sup> <sup>72</sup> Laurence Graff, The Precautionary Principle, in The Cartagena Protocol on Biosafety: <sup>74</sup> Development? 410 (Christoph Bail et al. eds., <sup>75</sup> Development? 410 (Christoph Bail et al. eds., <sup>76</sup> Development? 410 (Christoph Bail et al. eds., <sup>77</sup> Development? 410 (Christoph Bail et al. eds., <sup>78</sup> Development? 410 (Christoph Bail et al. eds., <sup>79</sup> Development? 410 (Christoph Bail et al. eds., <sup>70</sup> Development? 410 (Christoph Bail et al. eds., <sup>71</sup> Development? 410 (Christoph Bail et al. eds., <sup>72</sup> Development? 410 (Christoph Bail et al. eds., <sup>73</sup> Development? 410 (Christoph Bail et al. eds., <sup>74</sup> Development? 410 (Christoph Bail et al. eds., <sup>75</sup> Development? 410 (Christoph Bail et al. eds.) 2002) [hereinafter Reconciling Trade].

 <sup>&</sup>lt;sup>73</sup> ALTTERI, supra note 2, at 55.
 <sup>74</sup> See, e.g., Elizabeth Duall, A Liability and Redress Regime for Genetically Modified Organisms Under the Cartagena Protocol, 36 GEO. WASH. INT'L L. REV. 173, 182-85 (2004); de Leon et al., supra note 27, at 10-11; U.S. DEP'T OF STATE, BUREAU OF OCEANS & INT'L ENVT'L AND SCIENTIFIC AFFAIRS, FACT SHEET: CARTAGENA PROTOCOL ON BIOSAFETY, Mar. 8, 2004. available at http://www.state.gov/g/oes/rls/fs/2004/28621.htm.

In contrast to the precautionary approach of the Cartagena Protocol, the WTO's SPS Agreement is a more substantial threshold because it relies on the need for scientific proof in risk assessments.<sup>75</sup> The SPS Agreement focuses on preventing the misuse of phytosanitary regulations as a barrier to trade.<sup>76</sup> While it encourages members to be consistent with international standards, it does allow higher phytosanitary standards if there is scientific justification for the higher standard, which requires members to perform risk assessments.<sup>77</sup> Thus, the SPS Agreement "threatens to preclude developing countries from banning or restricting the importation of genetically modified seeds."<sup>78</sup> It does not single out GMOs as an item to be regulated, but if they pose a scientifically-justified threat to biosafety in an importing country, then the SPS Agreement would apply to any relevant national sanitary or phytosanitary measures.<sup>79</sup> Major exporters of GM crops, such as the United States, Canada, and Argentina, apply conventional, science-based risk assessments to GM products.<sup>80</sup> In contrast, many European Union countries have adopted a "no risk" approach, which entails strict import measures that guarantee that importing countries maintain a high level of health and environmental protection.<sup>81</sup>

A fundamental, philosophical conflict exists between the SPS Agreement and the Cartagena Protocol.<sup>82</sup> The SPS Agreement requires scientific justification for imposing higher standards on imported items, such as GM plant material, while the Cartagena Protocol only relies on the precautionary principle, which does not require scientific justification.<sup>83</sup> Further, the Cartagena Protocol takes socio-economic considerations into

Denise M. Lietz, Comment, A Precautionary Tale: The International Trade Implications of Regulating Genetically Modified Foods in Australia and New Zealand, 10 PAC. RIM L. & POL'Y J. 441, 423-24 (2001).

Phytosanitary regulations aim to: (1) protect agricultural crops from disease vectors such as viruses, bacteria, and fungi, and (2) prevent alien invasive species from disrupting natural ecosystems. Before the application of biotechnology to agricultural products, nations protected their crops from these concerns with phytosanitary laws, which generally operate to reduce risks by regulating the transfer of plant materials and imposing quarantines. IPGRI, supra note 38, at 69.

<sup>&</sup>lt;sup>7</sup> Anais K. Laidlaw, Is It Better to Be Safe than Sorry? The Cartagena Protocol Versus the World Trade Organization, 36 VICT. U. WELLINGTON L. REV. 427, 446 (2005).

<sup>&</sup>lt;sup>78</sup> Carmen G. Gonzalez, Trade Liberalization, Food Security, and the Environment: The Neoliberal Threat to Sustainable Rural Development, 14 TRANSNAT'L L. & CONTEMP. PROBS. 419, 461 (2004).

<sup>&</sup>lt;sup>79</sup> Food and Agriculture Organization of the U.N. Legal Office, Law and Modern Biotechnology: Selected Issues of Relevance to Food and Agriculture, FAO Legislative Study 78, at 36 (2003) (prepared by Lyle Glowka) [hereinafter FAO Legal Office].

 <sup>&</sup>lt;sup>80</sup> UNCTAD GMO Trade Study, supra note 1, at 4.
 <sup>81</sup> Id. at 7.

<sup>&</sup>lt;sup>82</sup> Laidlaw, supra note 77, at 466.

<sup>&</sup>lt;sup>83</sup> Id. at 423-24.

account,<sup>84</sup> while the SPS Agreement does not.<sup>85</sup> The major GM exporting countries have expressed apprehension that countries relying on the precautionary principle will use socio-economic reasons to justify a ban on GM products, an action that could lead to a trade conflict.<sup>86</sup>

#### The Philippines Regulates GM Crops Through Executive and R. Administrative Regulations

The Philippines' rules and policies that specifically address the potential effects of agro-biotechnology on the environment are: (1)Executive Order No. 430,<sup>87</sup> which created the National Committee on Biosafety of the Philippines ("NCBP"), and (2) the Department of Agriculture's Administrative Order No. 8 ("Administrative Order No. 8"), which is titled the "Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology,"88

#### The National Committee on Biosafety of the Philippines Provides 1. Technical Recommendations Regarding Biotechnology

The National Committee on Biosafety of the Philippines ("NCBP") is a technical advisory body with a central role in regulating biotechnology. Created in 1990 by Executive Order No. 430, the NCBP was the Philippine government's earliest effort to regulate biotechnology.<sup>89</sup> The NCBP is a multi-disciplinary, inter-agency body attached to the Philippine government's Department of Science and Technology.<sup>90</sup> Its functions include identifying potential hazards involved in genetic engineering experiments, formulating and reviewing national policies and guidelines on

<sup>&</sup>lt;sup>84</sup> Cartagena Protocol, supra note 31, art. 26.

<sup>&</sup>lt;sup>85</sup> See Laidlaw, supra note 77, at 446. The SPS Agreement states that "sanitary and phytosanitary measures should be based on an assessment of the risks to human, animal or plant life or health." UNCTAD GMO Trade Study, supra note 1, at iii.

<sup>&</sup>lt;sup>36</sup> See Thomas P. Redick, Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence, 44 JURIMETRICS J. 5, 12-13 (2004).

<sup>&</sup>lt;sup>87</sup> Constituting the National Committee on Biosafety of the Philippines (NCBP) and for Other Purposes, Exec. Ord. No. 430 (Oct. 15, 1990) (Phil.) [hereinafter Exec. Ord. No. 430].

ADMINISTRATIVE ORDER NO. 8, supra note 21.
 <sup>89</sup> Dep't of Env't & Natural Resources—Protected Areas and Wildlife Bureau, The National Biosafety Framework of the Philippines 5 (2004), available at http://www.pawb.gov.ph/WEBnbfp/index.htm [hereinafter National Biosafety Framework].

<sup>90</sup> National Committee on Biosafety of the Philippines, About NCBP. http://www.dost.gov.ph/ncbp/about.htm (last visited Jan. 29, 2006) (unpublished Web page formerly on the Philippine Department of Science and Technology website, on file with The Pacific Rim Law & Policy Journal) [hereinafter About NCBP].

biosafety and risk assessments, developing working arrangements with the NCBP-member government agencies, developing technical expertise and facilities, and holding public deliberations on proposed national policies.<sup>91</sup> The NCBP is chaired by the Undersecretary for Research & Development of the Department of Science and Technology, and is composed of: one biological scientist, one environmental scientist, one physical scientist, one social scientist, two "respected members of the community," and one representative each from the Departments of Agriculture, Environment and Natural Resources, and Health.<sup>92</sup>

The NCBP has developed risk assessment guidelines for contained use (laboratory or greenhouse use) and field tests of genetically modified plants. The first version of the Philippine National Biosafety Guidelines was published in 1991 and established that the NCBP must review and approve any work covered by the Guidelines.<sup>93</sup> In 1998, the NCBP released a second edition of the Guidelines ("NCBP Guidelines"), which divided the Guidelines into three monographs, one of which specifically addresses the planned release of GMOs and potentially harmful exotic species.<sup>94</sup> Under these guidelines, all institutions engaged in genetic engineering must establish an Institutional Biosafety Committee ("IBC"), which will evaluate and monitor the biosafety aspects of their activities.<sup>95</sup> An IBC must be composed of at least five members, at least three of which must be "scientist-members" not affiliated with the institution.<sup>96</sup>

### 2. The Philippine Department of Agriculture's Bureau of Plant Industry Regulates the Release of GM Crops

Regulatory authority over field release of GM crops is split between the Philippine Department of Agriculture, the Department of Environment and Natural Resources, and the Department of Health.<sup>97</sup> In 2002, the Department of Agriculture promulgated Administrative Order No. 8,<sup>98</sup> which

<sup>&</sup>lt;sup>91</sup> Exec. Ord. No. 430, supra note 87, § 4.

<sup>92</sup> Exec. Ord. No. 430, supra note 87, § 1.

<sup>&</sup>lt;sup>93</sup> FAO LEGAL OFFICE, supra note 79, at 32.

<sup>&</sup>lt;sup>94</sup> National Committee on Biosafety of the Philippines, Guidelines for Planned Release of Genetically Modified Organisms and Potentially Harmful Exotic Species (May 15, 1998), *available at* http://binas.unido.org/binas/country.php?id=17 (unpublished Web page formerly on the Philippine Department of Science and Technology website, on file with The Pacific Rim Law & Policy Journal) [hereinafter NCBP Guidelines].

<sup>95</sup> Id. § 3.2.

<sup>&</sup>lt;sup>96</sup> Id. § 3.2.1.

<sup>97</sup> Id.

<sup>&</sup>lt;sup>98</sup> ADMINISTRATIVE ORDER NO. 8, supra note 21.

requires a risk assessment before releasing any plant or plant products derived from the use of modern biotechnology<sup>99</sup> into the environment<sup>100</sup> and establishes guidelines for using GM crops for contained use, field testing. propagation, and for feed, food, or processing. Administrative Order No. 8 also represents the Department of Agriculture's attempt to conform to the risk assessment principles in the Cartagena Protocol on Biosafety.<sup>101</sup>

A sub-division of the Department of Agriculture, the Bureau of Plant Industry ("BPI"), is responsible for acting on the risk assessment guidelines outlined in Administrative Order No. 8. The BPI's authority derives from the Philippine Plant Quarantine Law of 1978,<sup>102</sup> which includes a penalty clause that subjects violators to fines not in excess of 20,000 pesos or imprisonment or both.<sup>103</sup> The BPI assures GM product safety through review by its Scientific and Technical Research Panel, which conducts a risk assessment prior to release of the product into the environment in order to determine whether the product poses significant risks to human health and the environment.<sup>104</sup> If the regulated article passes the risk assessment, the BPI issues a biosafety permit, which could be for (1) import for contained use; (2) field testing; (3) propagation; or (4) import for direct use as food, feed, or processing.<sup>105</sup>

IV. THE PHILIPPINES' EXISTING BIOSAFETY REGULATIONS LACK ENFORCEMENT MECHANISMS AND FAIL TO COVER THE RANGE OF PROBLEMS POSED BY GM CROPS

The Philippines currently relies on biosafety regulations and guidelines that lack enforcement power and do not cover the range of situations impacted by GM crops. These deficiencies demonstrate the weakness of the Philippines' existing biosafety regulatory framework.

<sup>&</sup>lt;sup>99</sup> Id. § 2(A).

<sup>100</sup> Id. § 3.

<sup>&</sup>lt;sup>101</sup> See id. ("WHEREAS, the Philippines, as a signatory to the Cartagena Protocol on Biosafety, is committed to ensuring that the development, handling, transport, use, transfer and release of genetically modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health ...."). <sup>102</sup> Philippine Plant Quarantine Law, Pres. Dec. No. 1433 (June 12, 1978) (Phil.).

<sup>103</sup> Id. § 23.

<sup>&</sup>lt;sup>104</sup> ADMINISTRATIVE ORDER NO. 8, *supra* note 21, § 3(A).

<sup>105</sup> United Nations Environment Programme and Global Environment Facility, Project on Development of National Biosafety Frameworks, Philippines: National Progress Report Submitted to the Third Series of Subregional Workshops (2003/2004), available at http://www.unep.ch/biosafety/ development/countryreports/PHprogressrep.pdf [hereinafter UNEP-GEF] (last visited Mar. 31, 2006).

#### The Philippines' Biosafety Regulations Lack Adequate Enforcement Α. Mechanisms

The Philippines' existing regulatory regime for biosafety-the NCBP Guidelines and Administrative Order No. 8-lacks enforcement power. As an entity created by executive order rather than Congressional law, the NCBP itself has no regulatory function. Acknowledging this limitation, the NCBP "deems itself a technical evaluation body; it reviews proposals for biotechnology application for the benefit of final approving bodies . . ." (e.g., the Department of Agriculture for agro-biotechnology applications).<sup>106</sup> The NCBP can impose sanctions and penalties for violators only through existing rules and regulations in the relevant regulatory agencies.<sup>107</sup> The member agencies, in turn, do not have any laws or regulations that directly address agro-biotechnology.<sup>108</sup> Further, penalties for violations are weak. For example, the Department of Agriculture's Bureau of Plant Industry relies on the Plant Quarantine Law of 1978<sup>109</sup> to regulate the field release of agricultural crops.<sup>110</sup> The Plant Quarantine Law penalties include fines or imprisonment, at the court's discretion.<sup>111</sup> The fine cannot exceed 20,000 pesos, which is only about US\$370 and would not likely serve as a deterrent to transnational corporations. The weak enforcement mechanisms and penalties of the Philippines' existing regulatory regime for biosafety make it difficult for authorities to ensure GM crop cultivators are adequately protecting the environment.

For each applicant who seeks to release GM crops into the environment, the NCBP Guidelines require an Institutional Biosafety Committee ("IBC") to oversee compliance with the regulatory process.<sup>112</sup> The NCBP developed the IBC concept as a way to retain NCBP oversight over applicants in the face of limited NCBP funding.<sup>113</sup> An IBC is responsible for evaluating project proposals; supervising, monitoring and reporting project progress to the NCBP; ensuring that the environment and

<sup>&</sup>lt;sup>106</sup> National Committee on Biosafety of the Philippines, Department of Science and Technology, Recent Actions of the National Committee on Biosafety of the Philippines to Clarify its Understanding of its Mandate (unpublished Web page formerly on the Philippine Department of Science and Technology website, on file with The Pacific Rim Law & Policy Journal) [hereinafter NCBP Actions to Clarify].

About NCBP. supra note 90.

<sup>&</sup>lt;sup>108</sup> NATIONAL BIOSAFETY FRAMEWORK, supra note 89, at 24.

<sup>&</sup>lt;sup>109</sup> Philippine Plant Quarantine Law, supra note 102.

<sup>&</sup>lt;sup>110</sup> Philippine Bureau of Plant Industry website, http://bpi.da.gov.ph/AUs/AUs.html (last visited Mar. 31, 2006).

 <sup>&</sup>lt;sup>111</sup> Philippine Plant Quarantine Law, *supra* note 102.
 <sup>112</sup> NCBP Guidelines, *supra* note 94, § 3.2; NCBP Actions to Clarify, *supra* note 106.

<sup>&</sup>lt;sup>113</sup> About NCBP, supra note 90.

human health are protected; and informing surrounding communities of plans for environmental release of GM crops.<sup>114</sup> Although an IBC has the "power to draft rules and regulations" to supplement the 1998 NCBP Guidelines,<sup>115</sup> an IBC has no more enforcement authority than the NCBP, so such rules would merely support the purely advisory powers of the NCBP. Thus, any rules or regulations that an IBC develops would not provide adequate deterrence against possible violators.

In a similar vein, although a majority of an IBC must endorse the project to the NCBP,<sup>116</sup> the NCBP itself has no authority to halt a project, so the recommendations of an IBC are of little practical consequence. The NCBP may withdraw its approval from a project,<sup>117</sup> but it is the government agency that granted any applicable permit or license, and not the NCBP, that has the power to revoke the permit/license and destroy the GM crops.<sup>118</sup>

When enforcing Administrative Order No. 8, the BPI does not have adequate regulatory authority to prevent violations. The penalties available under Administrative Order No. 8 are revocation of the license or permit.<sup>119</sup> Further, much of the monitoring and reporting is voluntary for both the BPI and the parties growing GM crops.<sup>120</sup> The BPI's Plant Quarantine Officer "may inspect at any time the site where the regulated article is field tested,"121 but there are reports that such biosafety is not taken seriously122 and that inspections are rare.<sup>123</sup>

#### The Absence of a Single Regulatory Body with Enforcement Authority R. Hinders Compliance

Two of the most common approaches to regulating biotechnology are to have specific legislation on GMOs or to expand the interpretation of existing laws.<sup>124</sup> Australia uses specific legislation, while the United States uses administrative regulations adapted to address GMOs through existing

<sup>&</sup>lt;sup>114</sup> NCBP Guidelines, supra note 94, § 3.2.

<sup>115</sup> Id. § 3.2,3,

<sup>116</sup> Id. § 4.4.

<sup>117</sup> Id. § 6.

<sup>118</sup> Id. § 6.3.

<sup>&</sup>lt;sup>119</sup> ADMINISTRATIVE ORDER NO. 8, supra note 21, § 8(P). The NCBP Guidelines state that in the event of revocation, the NCBP "may order the proponent or any government authority to destroy" the GM crops. NCBP Guidelines, supra note 94, § 6.3.

See, e.g., id. §§ 5(D)(9), 8(J)(9), 10(G)(4).
 ADMINISTRATIVE ORDER NO. 8, supra note 21, § 8(N).

<sup>&</sup>lt;sup>122</sup> Governments Pushing GM Crops Despite Lack of Knowledge, NEW STRAITS TIMES, Feb. 24, 2004, at 8.

<sup>&</sup>lt;sup>123</sup> GRAIN, supra note 54.

<sup>124</sup> FAO LEGAL OFFICE, supra note 79, at 4.

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laws.<sup>125</sup> The Philippines' current regulatory framework contains elements of both the United States and Australian approaches, but it should be remodeled to more closely match the Australian model.

#### The Current Structure of the Philippine Agencies with a Role in 1. **Regulating GM Crops Impedes Compliance**

Lack of a single regulatory body to regulate biotechnology in the Philippines allows gaps in regulatory coverage and makes compliance By cobbling together existing agencies to regulate the problematic. environmental release of GM crops, the Philippines' current biosafety regulatory regime presents administrative challenges that leave many gaps in coverage and results in a decreased likelihood of compliance with the NCBP Guidelines. Given the interdisciplinary nature of genetic modification of food products, it is inevitable that there will be jurisdictional overlap among the agencies involved.

The sheer number of governmental agencies involved in attaining approval to release a GM crop presents dramatic administrative and coordination challenges. The Philippine Departments of Agriculture, Health, Environment, Science and Technology, Trade and Industry, Economic Planning, and Foreign Affairs all have a role in the oversight of issues related to biosafety.<sup>126</sup> Each department is composed of several bureaus, many of which have a role in regulating agro-biotechnology. For example, when Monsanto, a major transnational agricultural business based in the United States, applied for a commercial permit for distribution of Bt corn, the following agencies within the Department of Agriculture were involved: the Bureau of Plant Industry, the Bureau of Animal Industry, the Bureau of Agricultural and Fisheries Products Standards, and the Fertilizer and Pesticide Authority.<sup>127</sup> Under the NCBP Guidelines, the IBC for a project is responsible for ensuring "that all relevant regulatory agencies have been consulted" and that the "necessary permits, licenses or approvals have been obtained before any planned release is made."<sup>128</sup> While Monsanto's IBC presumably fulfilled its duties, the regulatory structure unwisely relies on IBCs to ensure that GM crop cultivators obtain all the necessary permits. As discussed in Part IV.A. the NCBP Guidelines implemented by an IBC have

<sup>125</sup> Id.

 <sup>&</sup>lt;sup>126</sup> de Leon et al., supra note 27, at 10.
 <sup>127</sup> Louie Alonso Belmonte, Genetically Modified Food Requires Testing, MANILA TIMES, Sept. 12, 2005.

<sup>&</sup>lt;sup>128</sup> NCBP Guidelines, supra note 94, § 3.2.2(g).

no enforcement authority other than that provided by the mandates of the NCBP member agencies.

Another problem with regulating GM crops through a network of existing agencies is that gaps in regulatory coverage will inevitably result. A striking gap in the Philippines' existing biosafety regulatory regime is that there are no specific roles for the Department of Environment and Natural Resources and the Department of Health to monitor impacts to the environment and human health during field release of GM crops.<sup>129</sup> The NCBP Guidelines specify that the Department of Environment and Natural Resources is responsible for monitoring environmental impacts<sup>130</sup> and that the Department of Health is responsible for monitoring the effects on human health,<sup>131</sup> yet neither agency has regulatory authority or funding to conduct such monitoring.<sup>132</sup>

Gaps in regulatory coverage are a particularly acute problem with biotechnology, because technology develops faster than the laws governing For example, the Philippines' existing regulatory scheme for agroit. biotechnology appears to have been designed only for situations in which GM crops are grown for consumption. However, the "next wave" in agrobiotechnology is "biopharming," which is the genetic engineering of plants pharmaceuticals, antibodies, and industrial enzymes.<sup>133</sup> to grow Biopharming poses more serious risks to human health and the environment than crops intended for consumption.<sup>134</sup> Consequently, regulation of biopharming in the Philippines would require much more involvement from the Department of Environment and Natural Resources and the Department of Health. The Department of Health would need to evaluate the adverse health impacts that could result from human consumption of plants growing biopharm products. However, the existing biosafety framework does not provide for such extensive participation from the Department of Health. If an organization intended to pursue biopharming in the Philippines, such gaps in the regulatory regime would be exposed and could lead to harmful results.

<sup>&</sup>lt;sup>129</sup> NATIONAL BIOSAFETY FRAMEWORK, supra note 89, at 24.

<sup>&</sup>lt;sup>130</sup> NCBP Guidelines, supra note 94, § 5.1(b)(ii).

<sup>&</sup>lt;sup>131</sup> Id. § 5.1(b)(iii).

<sup>&</sup>lt;sup>132</sup> NATIONAL BIOSAFETY FRAMEWORK, supra note 89, at 24.

<sup>&</sup>lt;sup>133</sup> Rowena C. Seto, Selling the Pharm: The Risks, Benefits, and Regulations of Biopharmaceuticals, 27 ENVIRONS ENVTL. L. & POL'Y J. 443, 445 (2004).

<sup>&</sup>lt;sup>134</sup> See id. at 454; John Mason, Scientists Warn of Danger of GMO Contamination, FINANCIAL TIMES, Feb. 24, 2004, at 11.

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### 2. The Philippines' Approach to Regulating Biotechnology Shares Key Flaws with the United States' Regulatory Framework and Should Be Modified to More Closely Resemble the Australian Regulatory Model

The Australian "specific legislation" model for regulating biotechnology is more effective than the "existing legislation" approach the United States utilizes. The United States' biotechnology regulatory framework does not have a single regulatory authority with enforcement authority.<sup>135</sup> and simultaneously has been heavily criticized for its ineffectiveness.<sup>136</sup> In the United States, regulatory authority over GM crops is shared mostly by three federal agencies, the Environmental Protection Agency ("EPA"), the Department of Agriculture ("USDA"), and the Food and Drug Administration ("FDA").<sup>137</sup> In 1986, the Office of Science and Technology Policy drafted the Coordinated Framework for the Regulation of Biotechnology.<sup>138</sup> This framework is based on the philosophy that GM crops are substantially similar to conventional crops,<sup>139</sup> and thus their safety can be assured by existing regulations.<sup>140</sup> Accordingly, the EPA and USDA are involved before GM crops can be produced commercially, and thus regulate the environmental release of plants derived from agro-biotechnology.<sup>141</sup> Separate from the EPA and the USDA, the FDA regulatory authority only applies to the marketing of GM crops as food for humans and animals.<sup>142</sup> Each agency regulates under the authority of other relevant federal statutes, each with its own mission and regulatory structure, none of which were enacted to address biotechnology.<sup>143</sup> The United States' overlapping approach has been criticized for being convoluted and ineffective.<sup>144</sup> Relying on separate regulations for the agricultural and the environmental aspects of biotechnology increases the complexity of the regulatory systems<sup>145</sup> and allows the agencies to divide regulation of GM crops in an

<sup>&</sup>lt;sup>135</sup> FAO LEGAL OFFICE, supra note 79, at 4.

<sup>&</sup>lt;sup>136</sup> See, e.g., Jan-Peter Nap et al., The Release of Genetically Modified Crops into the Environment, 33 PLANT J. 1, 10 (2003); Rebecca M. Bratspies, Consuming (F)ears of Corn: Public Health and Biopharming, 30 AM. J. L. & MED. 371, 390 (2004) [hereinafter Bratspies, Consuming (F)ears of Corn]; ROBERT L. PAARLBERG, THE POLITICS OF PRECAUTION: GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES 22 (2001).

<sup>&</sup>lt;sup>137</sup> Rebecca Bratspies, The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops, 10 N.Y.U. ENVTL. L.J. 297, 311 (2002) [hereinafter Bratspies, Illusion of Care].

<sup>&</sup>lt;sup>138</sup> Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

<sup>&</sup>lt;sup>139</sup> Nap et al., *supra* note 136, at 9.

<sup>&</sup>lt;sup>140</sup> See, e.g., Mandel, supra note 5, at 2216-17.

<sup>&</sup>lt;sup>141</sup> Nap et al., *supra* note 136, at 9.

<sup>&</sup>lt;sup>142</sup> Id.

<sup>&</sup>lt;sup>143</sup> Bratspies, Illusion of Care, supra note 137, at 312.

<sup>&</sup>lt;sup>144</sup> Id. at 310; see also Mandel, supra note 5, at 2228-42.

<sup>&</sup>lt;sup>145</sup> Stannard et al., supra note 13, at 424-25.

illogical manner.<sup>146</sup> In sum, despite the existence of the Coordinated Framework to encourage coordination, the United States' regulations have proven to be under-inclusive.

In contrast, Australia has one agency that oversees all GMO-related issues,<sup>147</sup> an approach that is more efficient and comprehensive than the United States' system. The Australian Gene Technology Act consolidates all regulation of GMOs and GM products and established the Office of the Gene Technology Regulator ("OGTR") to oversee implementation of the law.<sup>148</sup> The OGTR issues GMO licenses, prepares risk assessment and risk management plans, develops policies and codes of practice, and provides advice to the public, other regulatory agencies and the Ministerial Council.<sup>149</sup> The Gene Technology Act establishes a scientific committee, a community committee, and an ethics committee to provide advice upon request to the OGTR and Ministerial Council.<sup>150</sup> Funneling all regulatory functions through the OGTR decreases potential problems regarding coordination and confusing overlaps in jurisdiction.

The Philippines' NCBP is a step toward having a centralized regulator like the Australian OGTR, but the current Philippine administrative framework is too weak to be effective because the NCBP lacks enforcement authority over the agencies with legal authority over biotechnology matters. Such reliance on existing authority to regulate biotechnology is similar to the United States' system, and should be strengthened.

V. STRONG BIOSAFETY LAWS WILL ENABLE THE PHILIPPINES TO BETTER PROTECT ITS ENVIRONMENT FROM THE DANGERS POSED BY GM CROPS

The Philippines should strengthen its domestic biosafety laws in order to better protect the environment from transgenes that could escape from GM crops. Legislation from the Philippine Congress is necessary to provide the adequate enforcement authority and funding to the agencies that must implement biosafety laws. Such legal authority would bring the Philippines into compliance with the Cartagena Protocol, although the country may not benefit by formally ratifying the Protocol due to the potential adverse effects on trade and economic issues.

<sup>&</sup>lt;sup>146</sup> Rebecca M. Bratspies, Myths of Voluntary Compliance: Lessons from the Starlink Corn Fiasco, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 615 (2003) [hereinafter Bratspies, Myths of Voluntary Compliance].

<sup>&</sup>lt;sup>147</sup> FAO LEGAL OFFICE, supra note 79, at 4, 151-52.

<sup>&</sup>lt;sup>148</sup> Australian Government, Department of Health and Ageing, Office of the Gene Technology Regulator, About the OGTR, http://www.ogtr.gov.au/about/index.htm (last visited Mar. 31, 2006).

<sup>&</sup>lt;sup>149</sup> FAO LEGAL OFFICE, supra note 79, at 152; Nap et al., supra note 136, at 12.

<sup>&</sup>lt;sup>150</sup> FAO LEGAL OFFICE, supra note 79, at 152.

## A. The Philippines Should Enact Congressional Legislation to Centralize and Strengthen Enforcement for Regulation of GM Crops

As a long-term strategy, the Philippines should enact legislation that centralizes and strengthens regulatory authority over GM crops. A statutory mandate in the form of a Republic Act (Philippine Congressional legislation) is necessary in order to provide enforcement power and funding for the agencies tasked with regulating GM crops.

As an initial matter, enacting congressional legislation specific to biosafety—rather than regulating through existing authority—represents tacit acceptance of the philosophy that products of biotechnology should be regulated differently than identical products created through conventional means.<sup>151</sup> Although some biotechnological processes alter genomes in ways that could have occurred without biotechnology,<sup>152</sup> it is only the applications that could not have occurred naturally that warrant specialized legislation.<sup>153</sup> However, because this distinction would be burdensome to assess in practical applications, regulation of crops created through genetic modifications will necessarily be over-inclusive.

A centralized agency with enforcement authority over biosafety would minimize gaps in regulatory coverage and increase compliance. The Philippines already has a central biosafety entity—the National Committee on Biosafety of the Philippines—but as discussed *supra* in Part IV.B, the NCBP has only advisory authority. Currently the NCBP merely indicates its approval of a project; bestowing actual permit-issuing authority would give its assessments more weight. The NCBP should also have the power to halt projects.

One gap that should be closed is the possibility that a thorough analysis of environmental impacts will not be taken prior to field release of GM crops. In the United States, the Department of Agriculture's Animal and Plant Health Inspection Service rarely requires preparation of an Environmental Impact Statement prior to approving a biopharm field,<sup>154</sup> indicative of the regulatory gap critics have identified regarding environmental impacts of biopharming.<sup>155</sup> Analogously, there is currently no

<sup>&</sup>lt;sup>151</sup> See FAO LEGAL OFFICE, supra note 79, at 4 ("Perhaps the most obvious distinction is that a country can have specific laws on GMOs or it can rely on existing non-specific laws that apply through an expanded interpretation.").

<sup>152</sup> See supra Part II.A.

<sup>&</sup>lt;sup>153</sup> For a discussion of the philosophical bases for regulating the products of biotechnology, see Less Livodow & Susan Carr, Normalizing Novelty: Risk Regulation at the U.S. EPA, 11 RISK: HEALTH, SAFETY, AND ENV'T 9, 12-14 (2000).

<sup>&</sup>lt;sup>154</sup> Seto, *supra* note 133, at 463.

<sup>&</sup>lt;sup>155</sup> Id. at 463; Bratspies, Consuming (F)ears of Corn, supra note 136, at 390-91.

regulatory trigger for the Philippine Department of Environment and Natural Resources ("DENR") to conduct an environmental impact assessment for the field release of GM crops.<sup>156</sup> The NCBP Guidelines establish that DENR "shall be responsible for monitoring the environmental effects of the planned release."<sup>157</sup> However, DENR itself has no explicit mandate to be involved with GM crops,<sup>158</sup> as crops are deemed to be an agricultural issue within the purview of the Department of Agriculture.<sup>159</sup> A related assurance that environmental impacts were being adequately addressed could be provided by more robust public participation requirements, which could be enforced by a central agency but performed at the local level. Public participation supported by the threat of penalty would be an improvement over the minimum requirements currently dictated by the NCBP Guidelines and Administrative Order No. 8.<sup>160</sup>

To improve the likelihood of compliance, the legislation should include stricter penalties than merely revoking a permit or license. Lessons from countries, such as the United States, that have been growing GM crops for longer than the Philippines reveal the flaws of relying on voluntary compliance.<sup>161</sup>

Inclusion of a provision in the biosafety legislation establishing liability for environmental harms is unnecessary and would drastically reduce the likelihood of the legislation's enactment. Given the Philippine Congress' reluctance to ratify the Cartagena Protocol, it is doubtful it would pass any laws establishing liability for environmental harms caused by GM crops. Countries with well-established GM crop sectors, such as the United States, rely on common law civil liability to remedy harms.<sup>162</sup> Legal

<sup>&</sup>lt;sup>156</sup> UNEP-GEF, supra note 105.

<sup>&</sup>lt;sup>157</sup> NCBP Guidelines, supra note 94, § 5.1(b)(ii).

<sup>&</sup>lt;sup>158</sup> NATIONAL BIOSAFETY FRAMEWORK, supra note 89, at 24.

<sup>159</sup> See id. at 23.

<sup>&</sup>lt;sup>160</sup> Administrative Order No. 8 and the NCBP Guidelines merely compel public notice through postings in public town areas and publication in local newspapers; public hearings are necessary only upon the recommendation of the IBC that the project may significantly pose risks to human health and the environment. See ADMINISTRATIVE ORDER NO. 8 supra note 21, §§ 8(G), 10(E); NCBP Guidelines, supra note 94, § 4.7.

<sup>&</sup>lt;sup>161</sup> The most infamous example of the failure of voluntary compliance in the United States was the entry into the human food supply of a variety of GM corn called StarLink, which had only been approved for animal feed use, not human consumption. See generally Bratspies, Myths of Voluntary Compliance, supra note 146 (analyzing the StarLink corn incident and proposing regulatory improvements); Donald Uchtmann, Professor at University of Illinois at Urbana-Champaign, Panel Remarks, Liability Issues: Lessons from StarLink, in 10 RICH. J.L. & TECH. 23 (2004) (using the StarLink incident to explore liability options in the food biotechnology field).

<sup>&</sup>lt;sup>162</sup> Uchtmann, *supra* note 161, at 13-14.

theories that might apply include negligence, negligence per se, strict liability in tort, trespass, private nuisance, and public nuisance.<sup>163</sup>

### B. The Factors For and Against Philippine Ratification of the Cartagena Protocol on Biosafety Balance Each Other

The Philippines is under pressure from international and domestic forces to ratify the Cartagena Protocol on Biosafety, but on balance, the considerations supporting and opposing ratification are roughly equal. Enacting domestic biosafety legislation is the most important action the Philippines should take to protect its environment from the potential dangers of GM crops. Doing so will bring the Philippines closer into compliance with the Cartagena Protocol, but not threaten the foreign trade or investment interests that the Philippines depends on to improve its national economy.

A factor supporting ratification of the Cartagena Protocol is the likelihood that doing so would help the Philippines strengthen human and institutional capacities in biosafety. Article 22 of the Protocol describes the methods through which parties can improve their capacity.<sup>164</sup> Capacity-building is an important aspect of improving compliance, as penalties cannot be imposed unless the implementing agency has the capacity to discover violations and enforce fines.<sup>165</sup>

Further, the Philippines already appears to partially support the Cartagena Protocol. During negotiations of the Cartagena Protocol, the Philippines belonged to the "Like-Minded Group" negotiating bloc, which comprised most of the developing countries.<sup>166</sup> The Like-Minded Group sought a broad scope for the Cartagena Protocol and wanted it to supersede other international agreements.<sup>167</sup> They were also concerned that "unregulated use of GMOs would threaten the sustainable use of their biodiversity."<sup>168</sup> In addition, the Philippines' executive agencies claim that the existing Philippine biosafety guidelines are consistent with the risk

<sup>163</sup> Id. at 10.

<sup>&</sup>lt;sup>164</sup> Cartagena Protocol, supra note 31, art. 22.

<sup>&</sup>lt;sup>165</sup> See also Benjamin J. Richardson, Is East Asia Industrializing Too Quickly? Environmental Regulation in Its Special Economic Zones, 22 UCLA PAC. BASIN L.J. 150, 175 (2004) ("[N]ew environmental legislation is not so valuable unless 'accompanied by a substantial increase in each nation's capability for policy development, institutional structures, administrative competence, and ability to train management, monitoring, and enforcement personnel.").

<sup>&</sup>lt;sup>166</sup> Bernaditas C. Muller, Like-Minded Group: Philippines, in RECONCILING TRADE, supra note 72, at 138.

<sup>&</sup>lt;sup>167</sup> Duall, *supra* note 74, at 180.

assessment procedure provided in the Cartagena Protocol<sup>169</sup> (although statements from agency officials indicate that in practice the agencies act on science-based risk assessment principles,<sup>170</sup> more similar to the SPS Agreement). The government has stated that it believes GM crops to be safe.<sup>171</sup> thus not requiring additional regulation.

On the other hand, the Philippines faces the possibility that ratification of the Cartagena Protocol may jeopardize economic development opportunities from international corporations.<sup>172</sup> A key factor is that the United States, the Philippines' most important trading partner, is not bound by the Cartagena Protocol;<sup>173</sup> this is very likely a contributing reason why the Philippine Senate has not yet ratified the Protocol. In addition, it does not seem likely that the Philippines will ratify the Cartagena Protocol in the near future.<sup>174</sup> There are reports that the Philippines' Senate Committee on Foreign Affairs has not vet deliberated on the Protocol's ratification<sup>175</sup> and that the Chairman of the Philippine Senate Committee on Agriculture believes the Philippines should not ratify the Cartagena Protocol because the United States has not done so.<sup>176</sup>

Understandably, the Philippine government's priority is economic development and it is unlikely to take any actions that might threaten international investment in the Philippine economy.<sup>177</sup> The government views GM crops as an approach to improving domestic food security and the livelihoods of farmers.<sup>178</sup> However, in setting domestic policies regarding the regulation of agro-biotechnology, the Philippines, like many other

<sup>&</sup>lt;sup>169</sup> See, e.g., Emmanuel S. Borlongan, Public Affairs Director, Monsanto Philippines, Letter to the Editor, PHILIPPINE DAILY INQUIRER, May 11, 2003 (recounting the risk assessments Monsanto's Bt corn underwent before receiving approval for commercialization by the Department of Agriculture).

<sup>&</sup>lt;sup>170</sup> Belmonte, supra note 127.

<sup>&</sup>lt;sup>171</sup> ld.

<sup>&</sup>lt;sup>172</sup> See Lawmakers, Scientists Bat for Legislation on Biotechnology, supra note 28 (describing Philippine government officials' consideration of the competitive advantage pro-biotechnology national policies could bring).

<sup>&</sup>lt;sup>173</sup> See Parties to the CBD/Cartagena Protocol, supra note 63.

<sup>174</sup> CORPUZ, supra note 24; Neth Dano, RESIST Agrochemical TNCs!, GMO Updates, Nov. 12, 2004, http://resistagrochem.blogspot.com/2004/11/gmo-updates.html (on file with The Pacific Rim Law & Policy Journal). <sup>175</sup> CORPUZ, supra note 24.

<sup>176</sup> Dano, supra note 174.

<sup>&</sup>lt;sup>177</sup> See generally, David G. Scalise & Patricia J. de Guzman, Foreign Investment in the Philippines, 29 GEO. WASH. J. INT'L L. & ECON. 145, 146 (1995).

<sup>&</sup>lt;sup>178</sup> In a May 2003 speech to hunger strikers protesting Bt corn, then-Secretary of the Department of Agriculture, Luis P. Lorenzo, explained that the Department of Agriculture was trying to be careful of safety; that Bt corn was worth pursuing because it reduced the use of pesticides and increased yield; and that the Philippine government was "under tremendous pressure to help improve the income of . . . rural folk," and Bt corn was "just one approach in reaching that goal." Luis P. Lorenzo, Agriculture Secretary, Letter to the Editor, PHILIPPINE DAILY INOUIRER, May 11, 2003.

developing countries, is heavily influenced by its foreign trading partners.<sup>179</sup> The United States, in particular, wields significant influence on the Philippines. From 1898 until 1946, the United States controlled the Philippines, and subsequently the countries maintained close economic ties.<sup>180</sup> Today, the United States makes its wishes known on the economic front, as it is the Philippines' most important trading partner and largest foreign investor.<sup>181</sup> In turn, the United States is the Philippines' top export market; approximately one-third of all Philippine exports are to the United States.<sup>182</sup> Further, the United States is the world's most significant exporter of GM crops (accounting for 59% of the global production), and in 2004, the Philippines was the United States' 16th largest export market for agricultural products.<sup>183</sup> Thus, the United States has an economic interest in ensuring the openness of markets for its agricultural products, which increasingly comprise GM foods, and the Philippines is one of those markets. From the Philippines' perspective as a net importer of grains,<sup>184</sup> it is reluctant to alienate its trading partners that supply those grains. The Philippines is also reluctant to jeopardize international investment,<sup>185</sup> as the nation faces significant domestic economic challenges, including a national debt constituting 78% of the GDP.<sup>186</sup> The government is attempting to increase revenue, but domestic political uncertainty has hampered those efforts, resulting in one of the lowest economic growth rates in the region and decreases in foreign investment.<sup>187</sup> The Philippines is pursuing Bt corn to meet the shortfall in corn and corn substitutes, which the Philippine feed industry depends on.<sup>188</sup> Thus, the Philippines has compelling economic reasons for following the United States' lead on GM policies.

However, the Philippines has other trading partners as well, many of which are parties to the Cartagena Protocol. As of April 2, 2006, 132

<sup>&</sup>lt;sup>179</sup> UNCTAD GMO Trade Study, supra note 1, at 45.

<sup>180</sup> Scalise & Guzman, supra note 177, at 146.

<sup>&</sup>lt;sup>181</sup> Thomas Hubbart, Acting Assistant Secretary of State for East Asian and Pacific Affairs, U.S. Dept. of State, Speech to Subcommittee on East Asian and Pacific Affairs, Senate Foreign Relations Committee, U.S.-Philippine Relations: Opportunities to Enhance Our Enduring Partnership (Mar. 6, 2001), http://www.state.gov/p/eap/rls/rm/2001/1129.htm.

<sup>&</sup>lt;sup>182</sup> Id.
<sup>183</sup> CORPUZ, supra note 24.
<sup>183</sup> CORPUZ, Supra note 24. <sup>184</sup> FAO, FOOD AND AGRICULTURE INDICATORS, supra note 26.

<sup>&</sup>lt;sup>185</sup> See Lawmakers, Scientists Bat for Legislation on Biotechnology, supra note 28.

<sup>&</sup>lt;sup>186</sup> Carlos H. Conde, Philippines Pinching Pesos to Fight a Huge and Worsening Deficit, N.Y. TIMES,

Sept. 4, 2004, § A. <sup>187</sup> Carlos H. Conde, 6% Growth Surprises Government in Philippines, N.Y. TIMES, Nov. 30, 2004, § W.

<sup>&</sup>lt;sup>188</sup> Lorenzo, supra note 178.

countries were parties to the Protocol,<sup>189</sup> including many of the United States' current trading partners. The Protocol states that trade of living modified organisms between parties and non-parties must be consistent with the Protocol.<sup>190</sup> The United States Department of State acknowledges that non-parties who wish to export to parties must abide by the importing country's domestic regulations<sup>191</sup> and the United States purports to be support practical and effective implementation of the Cartagena Protocol.<sup>192</sup> There is strength in numbers and the more countries that accede to the Protocol, the closer the international community will be to having binding standards for minimizing the environmental risks posed by GM crops.<sup>193</sup> Harmonization over standards and terms in legislation is an important step in resolving potential trade disputes.<sup>194</sup>

In analyzing whether the Philippines should ratify the Cartagena Protocol, it would be helpful to examine the economic ramifications of other developing nations and island countries in the Pacific Rim with economic similarities to the Philippines that have either signed or not signed the Cartagena Protocol. However, given the Philippines' colonial history with Spain and later the United States, the Philippines is unique. It is also too early to see economic ramifications of other countries' decisions regarding the Cartagena Protocol, as the Protocol entered into force so recently (in 2003). Yet, Thailand's experience with GM crops may be instructive. In 2005, Monsanto threatened to halt its GM corn production in Thailand unless the Thai government lifted its ban on open field trials and the commercialization of transgenic crops.<sup>195</sup> Thailand is a party to the Cartagena Protocol, and this incident reveals that taking too cautious a stance on GM crops can jeopardize foreign investment.

The precautionary principle, a critical feature of the Cartagena Protocol, has resulted in an unexpected phenomenon among many developing countries' policies regarding GM crops.<sup>196</sup> Given the lower priority developing countries usually assign to environmental protection and

<sup>&</sup>lt;sup>189</sup> Parties to the CBD/Cartagena Protocol, supra note 63.

<sup>&</sup>lt;sup>190</sup> Cartagena Protocol, supra note 31, art. 24.

<sup>&</sup>lt;sup>191</sup> U.S. DEP'T OF STATE, supra note 74.

<sup>&</sup>lt;sup>192</sup> See U.S. Dep't of State, Bureau of Oceans & Int'l Envt'l and Scientific Affairs, Frequently Asked Ouestions on the Cartagena Protocol on Biosafety (CPB), Feb. 23, 2004, available at http://www.state.gov/ g/oes/rls/or/2004/29751.htm.

<sup>&</sup>lt;sup>193</sup> Commentators have noted that countries may conform to the European Union's level of precaution regarding biosafety. See Redick, supra note 86, at 12-13.

 <sup>&</sup>lt;sup>194</sup> Nap et al., supra note 136, at 15.
 <sup>195</sup> Kultida Samabuddhi, Thailand: Monsanto May Drop GE Corn Investment, BANGKOK POST, June 13, 2005, available at http://www.corpwatch.org/article.php?id=12414.

<sup>&</sup>lt;sup>196</sup> PAARLBERG, supra note 136, at 4.

their simultaneous need to increase food production, one would expect developing countries to have relatively permissive biosafety policies, but that is not the case.<sup>197</sup> Professor Robert Paarlberg has attributed the cautious GM crop policies in developing countries to an array of international influences, including non-governmental organizations from industrial countries objecting to GM crops as part of an agenda against globalization and the prospect of consumer skepticism toward GM crops in export markets in other countries.<sup>198</sup> He further attributes cautious GM crop policies to the Cartagena Protocol, which encourages caution on biosafety approvals and "implicitly likens the transboundary shipment of GM organisms to the international shipment of hazardous waste."199 Other critics of the precautionary principle observe that it does not consider the benefits of a complete array of risks, thus rendering incomplete the comparison between the new technology and the current practice.<sup>200</sup> In so doing, the precautionary principle prevents a technology from steadily progressing toward the reduction of risks by halting it if the first uses of the technology are "not perfect."<sup>201</sup> Since the Philippines is pursuing GM crops to benefit national food security, an overly cautious policy regarding biosafety may delay the expected benefits of GM crop technology, thus defeating the purpose.

#### The Philippines Should Adopt the Draft National Biosafety С. Framework As a Temporary Measure to Improve Biosafety

The Protected Areas and Wildlife Bureau of the Philippines' Department of Environment and Natural Resources has drafted a National Biosafety Framework ("Draft Framework")<sup>202</sup> that would improve environmental protection by increasing coordination between the agencies that regulate GM crops. With the assistance of the United Nations Environment Programme, the Protected Areas and Wildlife Bureau

<sup>&</sup>lt;sup>197</sup> *Id.* at 24. <sup>198</sup> *Id.* at 151-55. <sup>199</sup> *Id.* at 154.

<sup>200</sup> Deborah Katz, Note, The Mismatch Between the Biosafety Protocol and the Precautionary Principle, 13 GEO. INT'L ENVTL. L. REV. 949, 966 (2001).

<sup>&</sup>lt;sup>201</sup> Id.; see also Wiener, supra note 71, at 223 ("More precautionary policies are not always superior to policies chosen by cost-benefit balancing. Precaution may avoid the harms of inaction on false negatives (risks thought to be minor that turn out to be serious) but incur the harms of overreaction to false positives (risks thought to be serious that turn out to be minor).").

<sup>202</sup> Dep't of Env't and Natural Resources-Protected Areas and Wildlife Bureau, Project on Development of the National Biosafety Framework Philippines Terminal Report, GF/2716-02-4529 (2004), available at http://www.pawb.gov.ph/WEB-nbfp/index.htm (last visited Mar. 31, 2006) [hereinafter National Biosafety Framework Terminal Report].

conducted a multi-year project to determine how the Philippines could best prepare to conform its domestic laws with the Cartagena Protocol on Biosafety<sup>203</sup> should the nation choose to ratify the Protocol.<sup>204</sup> The end product was a draft Executive Order prescribing guidelines for the implementation of the Framework and strengthening the NCBP.<sup>205</sup>

The Draft Framework consolidates existing "policies, laws, and administrative issues related to modern biotechnology and biosafety" into an integrated framework that increases "clarity, transparency, and predictability [in] decision-making," seeks to avoid jurisdictional conflicts, and facilitates public consensus.<sup>206</sup> For instance, the Draft Framework lays out which administrative agency shall take the lead on enumerated GMO scenarios and it also directs the NCBP to designate an agency when a GMO does not fall under the jurisdiction of one of the enumerated agencies.<sup>207</sup> Further, it seeks to ensure that agencies other than the Department of Agriculture also participate in monitoring and enforcement when necessary; the Framework proposes to accomplish this by attaching monitoring conditions to approvals and authorizations.<sup>208</sup>

The Southeast Asia Regional Initiatives for Community Empowerment ("SEARICE"), a non-profit group based in the Philippines, has criticized the Draft Framework for not designating the Department of Environment and Natural Resources as the sole lead agency responsible for implementation of the Draft Framework. SEARICE recommends that the Department of Environment and Natural Resources manage the Draft Framework, since it is already the lead agency for the Convention on Biodiversity.<sup>209</sup> SEARICE also argues that the Framework does not resolve the problems in administrative efficiency and flexibility inherent in the existing biosafety regulations, noting that coordination between the NCBP

<sup>&</sup>lt;sup>203</sup> United Nations Environment Programme Council of the Global Environment Facility, Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety, GEF/C.16/4/Rev.1 (Oct. 17, 2000), *available at* http://www.gefweb.org/Documents/ Council\_Documents/ GEF\_C.16/4\_Rev.1.pdf.

<sup>&</sup>lt;sup>204</sup> The project team evaluated "existing national policies on modern biotechnology/biosafety," and sought "to integrate and update and/or revise these policies to come up with [a National Biosafety Framework] that is consistent with the relevant provisions of the Protocol." NATIONAL BIOSAFETY FRAMEWORK TERMINAL REPORT, supra note 202.

<sup>&</sup>lt;sup>205</sup> NATIONAL BIOSAFETY FRAMEWORK, supra note 89, at 10.

<sup>&</sup>lt;sup>206</sup> Id.

<sup>&</sup>lt;sup>207</sup> Id. at 20-21.

<sup>&</sup>lt;sup>208</sup> Id. at 24.

<sup>&</sup>lt;sup>209</sup> Southeast Asia Regional Initiatives for Community Empowerment (SEARICE), Comments on the Working Draft [of] [t]he National Biosafety Framework of the Philippines, http://www.scarice.org.ph/pdf/nbf.pdf (last visited Mar. 31, 2006).

and the Bureau of Plant Industry ("BPI") is particularly troublesome.<sup>210</sup> However, it is unclear why coordination between the NCBP and the Department of Environment and Natural Resources would be smoother. The NCBP is better situated to coordinate the regulatory agencies. It occupies a more independent position as it is attached to the Department of Science and Technology. Further, retaining the BPI in an important role makes sense because, as a bureau within the Philippine Department of Agriculture, it is better equipped to balance hypothetical biosafety risks from GM crops against the Philippines' actual food production needs.<sup>211</sup>

The drafters of the Draft Framework correctly acknowledge its limitations as a long-term solution.<sup>212</sup> However, despite the criticisms from SEARICE, the Draft Framework is worth implementing for the clarification it provides regarding the roles of the various administrative agencies in regulating agro-biotechnology, which helps fill some of the gaps left by the existing regulatory regime.

## D. Enacting Stronger Biosafety Laws Would Contribute to Building Public Support for GM Crops

Ensuring strong environmental protection is one aspect of improving public confidence in GM crops, which are currently beleaguered by volatile protests. Further, increasing public confidence in the Philippine government's ability to regulate the environmental impacts of GM crops is an important step toward building the acceptance GM crops need in order to have any kind of impact on food security, which is the Philippine government's purpose for embracing the technology.

There are groups that oppose GM crops for reasons other than their potential to disrupt ecosystems through the flow of transgenes.<sup>213</sup> Several farmers' groups and non-governmental organizations do not want the Philippines to become dependent on foreign transnational companies for

<sup>&</sup>lt;sup>210</sup> Id.

<sup>&</sup>lt;sup>211</sup> China's GM crop biosafety review process occurs in the agriculture ministry for this reason. See PAARLBERG, supra note 136, at 156 ("Nations seeking to balance real production needs more effectively against hypothetical biosafety risks would be well advised to strengthen the agricultural ministry links to their approval committee.").

<sup>&</sup>lt;sup>212</sup> NATIONAL BIOSAFETY FRAMEWORK, supra note 89, at x.

<sup>&</sup>lt;sup>213</sup> See, e.g., Beau Baconguis, Genetic Engineering Campaigner, Biosafety First!, Greenpeace Southeast Asia, Opinion, http://www.cyberdyaryo.com/opinion/op2004\_0223\_01.htm (Feb. 23, 2004) (on file with The Pacific Rim Law & Policy Journal); Roberto Verzola, We Need a Moratorium on Bt Corn Planting Now, PHILIPPINE DAILY INQUIRER, May 11, 2003 (listing the health, environmental, safety, and economic concerns that motivated a hunger strike against Bt corn).

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seeds and other agricultural needs.<sup>214</sup> Improving environmental protection would do little to sway these groups that GM crops should be embraced. However, public opinion polls indicate that the majority of consumers in Asia are open-minded, albeit cautious, about GM crops.<sup>215</sup> A precautionary approach to regulating GM crops would appeal to those populations who might otherwise support GM crops. Commentators have noted that with the introduction of new technologies, "low-certainty, low-consensus" risk situations can be expected, but as time passes those situations have the potential to move into higher levels of consensus.<sup>216</sup> In low-certainty, low-consensus situations, public input "assumes even greater social and scientific importance."<sup>217</sup>

A challenge in building public approval of GM crops is that a public relations battle is being fought by both sides. An infamous example is how frequently anti-GMO groups cite the 2000 discovery of transgenes from GM maize in the genomes of traditional maize varieties in Mexico. However, the scientific method from the original test was suspect, and when the confirming survey was conducted in 2004, the scientists found no transgenes.<sup>218</sup> Within the Philippines, there have been conflicting reports about the success of Bt corn.<sup>219</sup> The Philippine government frequently touts Bt corn as an example of how the existing biosafety guidelines are functioning properly. However, even if Bt corn is safe, that does not mean all GM crops in the future will be. Each genetic transformation event and each modified species will behave differently in the field.<sup>220</sup> Thus, it is

<sup>&</sup>lt;sup>214</sup> Mindoro Town Farmers Uproot Bt Corn Plants, PHILIPPINE DAILY INQUIRER, Sept. 16, 2005 (reporting that farmers backed by Greenpeace International and the municipal government uprooted Bt corn plants after the provincial government passed an environmental code banning GMOs; farmers were also motivated by a desire to achieve "sustainable agriculture where the farmers are the focal point of development and not mere beneficiaries of the so-called modern technology").

<sup>&</sup>lt;sup>215</sup> Philippines Now Requires All GM Foods to Undergo Testing, ASIA PULSE, Northern Territory Regional, Sept. 9, 2005.

<sup>&</sup>lt;sup>216</sup> David Winickoff et al., Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law, 30 YALE J. INT'L L. 81, 105 (2005).

<sup>&</sup>lt;sup>217</sup> Id.

<sup>&</sup>lt;sup>218</sup> Emma Marris, Four Years On, No Transgenes Found in Mexican Maize, 436 NATURE 760 (Aug. 11, 2005).

<sup>&</sup>lt;sup>219</sup> See CORPUZ, supra note 24, at 7 ("Local Bt corn farmers are generally happy as a result of higher income derived from a reported 40 percent increase in yields."). But see id. at 8 (discounting those criticisms of biotechnology arising from the higher price of Bt corn seed compared to traditional corn seed and the fact that some anti-biotech groups report that Bt corn farms performed below expectations).

<sup>&</sup>lt;sup>220</sup> Erik Stokstad & Gretchen Vogel, *Mixed Message Could Prove Costly for GM Crops*, 302 SCIENCE 542 (Oct. 24, 2003) (reporting that the results of three-year field tests of genetically modified beets, maize, and oilseed rape revealed that GM beets and oilseed rape "clearly had deleterious effects on wildlife and native plants" while GM maize was more "environmentally friendly than its non-GM counterpart").