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Case Studies of African Agricultural Biotechnology Regulation: Precautionary and Harmonized Policy-Making in the Wake of the Cartagena Protocol and the AU Model Law

R. Nelson Godfrey
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R. NELSON GODFREY*

I. INTRODUCTION

In spite of increased, targeted investment in agricultural development across the African continent, production levels continue to lag and approximately one third of sub-Saharan Africa's population is still chronically hungry.[1] The reasons are numerous. Limited technical and scientific research capacity for crop improvement, skilled labor shortages, pricing and distribution problems, and environmental stresses all contribute to the problem. The stakes are high. As Malawi's President, Bingu wa Mutharika, said on accepting the position of Chairman of the Africa Union (AU) Assembly in 2010: "One challenge we all face is poverty, hunger and malnutrition of large populations. . . . I would therefore request the AU Assembly to share the dream that five years from now no child in Africa should die of hunger and malnutrition. No child should go to bed hungry."[2]

"Biotechnology"[3]-based crop technologies have long been lauded as having the potential to help make agricultural production cheaper and easier on farmers,[4] and have enjoyed a widespread and rapid rise. In

* B.Sc.Hons., University of Saskatchewan 2007; JD, University of British Columbia 2011. The author is affiliated with the UBC Intellectual Property & Policy Research Group and has written extensively on intellectual property issues, as well as Canadian and international governance problems. The author would like to thank Emily Marden for her helpful comments.

1. Kevin J.A. Thomas & Tukufu Zuberi, *Demographic Change, the IMPACT Model, and Food Security in Sub-Saharan Africa* 1 (U.N. Dev. Programme, Working Paper No. 003, 2012), *available at* http://web.undp.org/africa/knowledge/WP-2012-003-thomas-zuberi-impact.pdf.

2. Dr. Bingu Wa Mutharika, President of the Republic of Malawi, Acceptance Speech on his election as the Chairman of the Assembly of the African Union 18−19 (Jan. 31, 2010); *Demographic Change*, *supra* note 1.

3. "Biotechnology" is defined in *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity,* art. 3, 39 L.L.M. 1027 (Jan. 29, 2000) [hereinafter Protocol], for instance, as the application of techniques that "overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection." *Id.* art. 3(i).

4. *See* Marion Motarim, et al., *South Africa – Blazing a Trail for African Biotechnology*, 22 NATURE BIOTECHNOLOGY 37, 39 (2004); Emily Waltz, *Plant Genomics' Ascent,* 28 NATURE

2009, 14 million farmers planted 134 million hectares of crops derived through biotechnology, up almost 10 million hectares from 2008.[5] Thirteen million of those farmers reside in emerging and developing countries.[6] Widely used crops include those modified to express broad-spectrum insecticidal proteins present in *Bacillus thuringiensis* (*Bt*) bacteria,[7] and crops modified to be resistant to common herbicides.[8] While most commentators agree that the crops may offer significant productivity advantages to the African farmer,[9] some critics claim that the current generation of commercialized agricultural biotechnology products "was designed to supplement the capital- and input-intensive farming methods of commercial agriculture, not the low-input techniques employed by smallholder farmers in Southern Africa."[10] Efforts are underway to change this, however. Collaborative projects are in progress to develop crops resistant to drought and other abiotic stresses.[11] Biotechnology is also being leveraged to improve the

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BIOTECHNOLOGY 10 (2010) (The emergence of genomics-based characterization and mapping techniques have been widely recognized as having the potential to further influence and accelerate the impact of biotechnology-based techniques); Joel I. Cohen*, Harnessing Biotechnology for the Poor: Challenges Ahead for Capacity, Safety and Public Investment*, 2(2) J. OF HUM. DEV. 239, 240 (2001). ("[M]olecular characterization and genomics expand our knowledge of plant and livestock genomes, making new genes available that could not have been isolated before.").

5. *See Crop Biotech Update Special Edition: Predicted Second Wave of Biotech Growth and Development Begins*, ISAAA (2009), *available at* http://isaaa.org/kc/ [hereinafter Biotech Update].

6. *See id*. Among the top seven producers of biotech crops worldwide, five of them (Brazil, Argentina, India, China, and Paraguay) are classified as "emerging and developing" economies in the International Monetary Fund's 2010 World Economic Outlook Report.

7. For an early paper discussing this invention, see M. Vacek, A. Reynaerts & H. Hofte, *Transgenic Plants Protected From Insect Attack,* 328 NATURE 33 (1987), *available at* http://www.nature.com/nature/journal/v328/n6125/abs/328033a0.html.

8. *See* Video: Global Status of Commercialized Biotech/GM Crops, International Service for the Acquisition of Agri-Biotech Applications, 2011, *available at* http://www.isaaa.org/resources/videos/globalstatusreport2011/default.asp, for a discussion of how herbicide resistance (particularly to Monsanto's Roundup) is present in approximately 80% of genetically modified crops currently in the ground.

9. For opinions and data supporting the widespread adoption of *Bt* varieties in developing countries, see Biotech Update, *supra* note 5; Matin Qaim & David Zilberman, *Yield Effects of Genetically Modified Crops in Developing Countries*, 299 SCIENCE 900 (2003); *see* P.N. Mwangi & A. Ely, *Assessing Risks and Benefits: Bt Maize in Kenya*, 48 BIOTECHNOLOGY AND DEV. MONITOR 6 (2001) *and* Marnus Gouse, et al., *A GM Subsistence Crop in Africa: The Case of Bt White Maize in South Africa*, 7 INT'L J. BIOTECHNOLOGY 84 (2005).

10. *See* NOAH ZERBE, AGRICULTURAL BIOTECHNOLOGY RECONSIDERED: WESTERN NARRATIVES AND AFRICAN ALTERNATIVES, 81, 95–103 (2005); *see* VANDANA SHIVA, SOIL NOT OIL: ENVIRONMENTAL JUSTICE IN AN AGE OF CLIMATIC CRISIS (2008).

11. *See* Ani Grover et al., *Understanding Molecular Alphabets of the Plant Abiotic Stress Responses,* 80 CURRENT SCI. 206 (2001); *see also* Biotechnology and Food Security, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, http://www.fao.org/worldfoodsummit/english/fsheets/biotech.pdf; *see also* T. Umezawa, et. al, *Engineering Drought Tolerance in Plants: Discovering and Tailoring Genes to Unlock the Future*, 17 CURRENT OP. IN BIOTECH. 113 (2006); *see also* Y. Wang, *et al.*, *Molecular Tailoring*

nutritional characteristics of numerous staple food crops.[12] Commercial varieties of such crops "remain on the distant horizon"[13] (with a few exceptions, such as vitamin A-enriched Golden Rice),[14] but research efforts have been promising. In the right policy environment,[15] this next generation of agricultural biotechnology products could make a world of difference, not only for impoverished farmers, but also, critically, for Africa's malnourished and vitamin-deficient populations.

"Precautionary"[16] attitudes have traditionally had a heavy influence on African participation in international and regional biosafety negotiations.[17] The Cartagena Protocol on Biosafety and the African

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of Farnesylation for Plant Drought Tolerance and Yield Protection, 43 PLANT J. 413 (2005); *see also* S.G. Mundree, et al., *Prospects for Using Genetic Modification to Engineer Drought Tolerance in Crops, in* PLANT BIOTECH: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS 193, 193 (Nigel G. Halford ed., 2006); *see also* Water Efficient Maize for Africa, PROGRESS REPORT MARCH 2008-MARCH 2011 (African Agricultural Technology, Nairobi, Kenya); *see also Pocket K No. 3L: Biotechnology for the Development of Drought Tolerant Crops*, ISAAA, *available at* http://www.isaaa.org/resources/publications/pocketk/32/default.asp.

12. *See* Dietrich Rein & Karin Herbers, *Enhanced Nutritional Value of Food Crops, in* PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS 91, 91−93 (2006) (discussing possible applications including modifications that would increase the bioavailable portion of nutrients such as Vitamin E, Vitamin A, iron, and zinc).

13. Zerbe, *supra* note 10, at 77.

14. *See* Xudong Ye, et al*., Engineering the Provitamin A (Beta-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*, 287 SCIENCE 303 (2000); Ingo Potrykus, *Golden Rice and Beyond*, 125 PLANT PHYSIOLOGY 1157 (2001).

15. *See generally* R. Zimmermann & M. Qaim, *Potential Health Benefits of Golden Rice: a Philippines Case Study*, 29 FOOD POL'Y 147 (2004) (noting that stable commercial lines of Golden Rice have been developed and that critics have suggested that its widespread adoption could make a significant impact in developing nations, but also that the technology has yet to be widely adopted due to biosafety, trade, and other constraints); *see also* Kym Anderson, et al., *Genetically Modified Rice Adoption: Implications for Welfare and Poverty Alleviation*, 20 J. ECON. INTEGRATION 771 (2004); *see also* Baorong Lu, Zhiping Song, & Jiakuan Chen, *Can Transgenic Rice Cause Ecological Risks Through Transgene Escape?*, 13 PROGRESS IN NATURAL SCIENCE 17 (2003); *see also* Harry A. Kuiper et al., *Assessment of the Food Safety Issues Related to Genetically Modified Foods,* 27 THE PLANT JOURNAL 503 (2001); *see also* Kent J. Bradford, et al., *Regulating Transgenic Crops Sensibly: lessons from Plant Breeding, Biotechnology and Genomics*, 22 NATURE BIOTECHNOLOGY 439, 442 (2005).

16. The most widely cited iteration of the precautionary principle is found in the Rio Declaration on Environment and Development, "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The application of "precautionary" approaches to regulating biotechnology products have been discussed at great length in the literature; while this article confines its discussion of "precaution" to provisions that limit the trade or use of biotechnology products in favor of health and biosafety interests, many commentators have persuasively noted that "precautionary" conceptions of biotechnology and GMOS must take into account the "risks" of *not* permitting trade or research in biotechnology and of closing one's borders to its products. *See* Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol,* 35 TEX. INT'L L.J. 173 (2000); *see also* CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE 13−34 (2d ed., 2005).

17. Protocol, *supra* note 3; *see also* African Union, *African Model Law on Biosafety*, AU

Union Model Law on Biosafety are two agreements concluded in the context of such negotiations that are notable for their emphasis on precaution and socioeconomic considerations as acceptable bases for the rejection of imported crops.[18] To what extent have these instruments affected the development of existing biotechnology sectors on the continent, and to what extent will they affect the development of new regulatory policies in nations with emerging or nonexistent biosafety regimes?[19] Have their purported harmonizing aims been achieved? This paper presents an overview of the agri-biotechnology regulatory schemes of South Africa, Kenya, and Burkina Faso—and discusses how the emergence of these three nations as leaders in African plant biotechnology, in the context of the Cartagena Protocol and the Model Law, contrasts with the way these international instruments have been characterized as reifying forces of precautionary, harmonized policy-making in biotechnology.

This paper is divided into five sections. Following the introduction, section I discusses the Cartagena Protocol and AU Model Law as instruments that purport to harmonize regulatory policies and institutionalize precautionary decision-making vis-à-vis biotechnology. Section II discusses the South African regulatory approach to biotechnology, as a case study of the oldest and most successful biotechnology sector on the continent. Section III discusses the lengthy commercialization delays experienced in Kenya, and the eventual passage of the *Kenya Biosafety Act* as aspects of a second case study of African agricultural biotechnology policy. Section IV examines the regulatory approach underpinning the recent explosion of *Bt* cotton as a commercial crop in Burkina Faso. The paper concludes in Section V with a discussion of the net impacts of attempts to harmonize precautionary policy in the existing agri-biotechnology regulatory landscape.

II. PRECAUTIONARY AND HARMONIZING INFLUENCES ON BIOTECHNOLOGY REGULATION IN AFRICA: THE CARTAGENA PROTOCOL AND THE AU MODEL LAW

The early success and rapid rise of agricultural biotechnology in

BIOSAFETY PROJECT (1999), *available at* http://www.africa-union.org/root/au/auc/departments/hrst/biosafety/AU_Biosafety_2b.htm/.

18. Protocol, *supra* note 3; *see also African Model Law on Biosafety*, *supra* note 17.

19. *See* Status of Crop Biotechnology in Africa, Table 1: Status of Genetically Modified (GM) Crops in Africa, NEPAD, *available at* http://www.nepadbiosafety.net/subjects/biotechnology/status-of-crop-biotechnology-in-africa [hereinafter NEPAD Biotech]. According to the African Biosafety Network of Expertise (ABNE), there are over 20 African nations whose National Biosafety Frameworks may be characterized as "works in progress" and approximately 10 nations that have no National Biosafety Frameworks at all.

North American markets has been well-documented. Policymakers, farmers, and consumers in many less developed countries, by contrast, have responded to the technology with far more reticence.[20] Three reasons are worth briefly mentioning: first, the general safety of biotechnology-based crops and their impact on biodiversity have been a subject of much debate amongst farmers and regulators in many developing nations;[21] second, modified crops have historically been subject to significant trade barriers (relative to conventionally-bred varieties) in important trading partners of many African nations;[22] and third, many first-generation agri-biotech products were developed by companies accused of pursuing broad international intellectual property protections to the purported detriment of entities, including the seed-saving farmer[23] and agricultural research centers that rely upon the ready availability of plant germplasm.[24]

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20. Doreen Mnyulwa & Julius Mugwagwa, *Agricultural Biotechnology in Southern Africa: A Regional Synthesis, in* BIOTECHNOLOGY, AGRIC., AND FOOD SECURITY IN S. AFR. 13, 29 (Steven Were Omano & Klaus von Grebmer eds., 2005).

21. A short list of commonly-listed fears about the safety of plant biotech products includes: long-term consumption by humans or animals (particularly as a dietary staple) could have deleterious effects on them; proliferation of agricultural products with relative fitness advantages could out-compete traditional varieties or breed with them via cross pollination; engineered genes could spread to related species with deleterious consequences; and resistance to herbicides (Roundup) and pesticides (*Bt* toxin) could develop in response to their increased environmental presence. For early and influential articles discussing these risks and others, *see* Paul Berg, *et al.*, *Potential Biohazards of Recombinant DNA Molecule*, 185 SCIENCE 303 (1974); *see also* James Tiedje, et al., *The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations*, 70(2) ECOLOGY 297, 299 (1989); *see also* Philip J. Dale, *Spread of Engineered Genes to Wild Relatives*, 100 PLANT PHYSIOLOGY 13, 15 (1992); *but see* A.B. Salifu, *The Role of Biotechnology in Meeting the Biodiversity Conservation Challenge of Africa,* ASPECTS OF AFRICAN BIODIVERSITY 58 (Jacob Midiwo ed., 2010), where the author notes that biotechnology could be used as a tool to help preserve biodiversity, if the appropriate scientific capacity is in place.

22. *See* Mnyulwa & Julius Mugwagwa, *supra* note 20, at 29. As a result, many farmers and regulators have held the view that the appearance of potential "contamination" of traditional varieties by transgenic seed could disproportionately affect the trade prospects of those traditional varieties; *see also* S. Herrera, *Syngenta's Gaff Embarrasses Industry and White House*, 23 NATURE BIOTECHNOLOGY 755 (2005). A prominent and well-publicized example is the StarLink™ case, where modified corn approved solely as animal feed was detected in US shipments destined for human consumption; *see also* J.L. Fox, *Puzzling Industry Response to PodiGene Fiasco*, 21 NATURE BIOTECHNOLOGY 3 (2003).

23. *See Monsanto v. Schmeiser,* [2004] S.C.C. 34 (Can.) (the Canadian patent infringement case); *see also* VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE (1997); A.G. Gold, *Vanishing Seeds' Cyclicality*, 8(3) J. OF MATERIAL CULTURE 255 (2003).

24. For more details on the relevance of IP to open sharing of technical property in and among agricultural research centers, s*ee* Emily Marden & R. Nelson Godfrey, *Intellectual Property and Sharing Regimes in Agricultural Genomics: Finding the Right Balance for Innovation*, 17(2) DRAKE J. AGRIC. L. 369 (2012); *but see* Joel I. Cohen & Robert Paarlberg, *Explaining Restricted Approval and Availability of GM Crops in Developing Countries*, 4 AGBIOTECHNET 1–3 (2002), for a compelling argument that the enforcement of intellectual property rights alone cannot explain the slow uptake of biotechnological crops in developing nations.

These considerations resonated with policymakers in numerous African nations, many of whom adopted precautionary policies in the 1990s and early 2000s governing the importation and development of biotechnology products.[25] Some such nations—according to several commentators, particularly those heavily influenced by NGOs and European trade policy[26]—implemented regulatory strategies that characterized biotechnology products as inherently hazardous, subject to quarantine, post-import milling, or outright rejection.[27] To this day, restrictive policies and suspicious attitudes towards biotechnology remain deeply ingrained in some nations.[28]

These same hesitations and suspicions are arguably reflected in regional and international negotiations on the subject of modified organisms and in international instruments on the subject such as the Cartagena Protocol on Biosafety and the African Union's Model Law on Biosafety.

A. The Cartagena Protocol on Biosafety

The Cartagena Protocol—a product of the Convention on Biological Diversity's explicit focus on "living modified organisms"[29]—is the most authoritative international agreement on the subject of biosafety and living biotechnology products.[30] The Protocol is a non-mandatory agreement that supplies model policies for policymakers,

25. *See generally* The Need for Biosafety Regulatory Systems, NEPAD (2010), http://www.nepadbiosafety.net/about/need-for-biosafety-regulatory-systems.

26. *See* ROBERT PAARLBERG, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA Ch. 4 (2008).

27. In the midst of a 2002–2003 famine, for example, the governments of Zambia and Zimbabwe rejected food aid from the United States as "genetically altered" and "toxic" because GM seed in the shipments could not be distinguished from non-GM seed. *See generally* Jennifer A. Thomson, *Regulatory Regimes for GE Crops in Africa, in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGIS. 265 (Iain Taylor ed., 2007); *see also* Declan Walsh, *America Finds Ready Market for Genetically Modified Food: The Hungry*, THE INDEPENDENT, Mar. 30, 2000.

28. *See* Al-Amani Mutarubukwa, *Strict Bio-Safety Law Stalls GM Maize Trials*, AATF, *available at* http://www.aatf-africa.org/. Zambia maintains its ban on products of agricultural biotechnology, to this day.

29. Convention on Biological Diversity of the United Nations Conference on the Environment and Development, U.N. Doc. ST/DPI/1307 (June 5, 1992) (entered into force Dec. 29, 1993) *reprinted in* 31 I.L.M. 818 [hereinafter CBD], Article 8(g), at 6. ("Each party shall, as far as possible and where appropriate . . . [e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity.").

30. Protocol, *supra* note 3. As of February 2013, 166 nations are party to the Protocol, including many large producers of biotechnology products. *See* Cartagena Protocol on Biosafety, *Parties to the Protocol and Signature and Ratification of the Supplementary Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY (last visited Mar. 23 2013), *available at* http://bch.cbd.int/protocol/parties/.

and while it leaves decisions on appropriate safety standards to national discretion, it represents an attempt to codify international consensus on "living modified organisms" ("LMOs") and their impact on biosafety.[31] The regulatory provisions of the Cartagena Protocol are triggered by LMOs[32] that "*may* have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."[33] The focus on LMOs distinguishes the Protocol from other relevant international instruments (including, e.g., the CBD and WTO agreements), and has the effect of separating plant biotechnology from traditional techniques as an area that "countries have decided needs collective actions on a global scale."[34]

The Protocol focuses on two categories of LMOs, those intended for unconfined environmental release, governed by the advanced informed agreement ("AIA") procedure, and those intended for consumption as food or feed products ("LMOs-FFP").[35] The AIA procedure is intended to ensure that importing countries are informed of the potential risks associated with the proliferation of LMOs and that they have the opportunity to refuse their entry.[36] It mandates that exporters notify importers of impending trans-boundary movement of LMOs prior to the first instance of that movement and provide them with all relevant and available information on their safety.[37] The provisions dealing with LMOs-FFP are similarly worded, differing mainly in procedural steps for the transboundary movement of LMOs.

The establishment of national risk assessment standards for LMOs is left to the sovereign discretion of parties, but generally, assessments must be performed "in a scientifically sound manner . . . and [take] into account recognized risk assessment techniques."[38] Importantly, regulators may take relevant socio-economic

31. *See* G. Jaffe, *Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory Systems: An Analysis of Key Unresolved Issues,* 5 J. OF PUB. AFF. 299, 304 (2005).

32. Defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology," Protocol, *supra* note 3, art. 3(g). "Living organism," in this context, refers to "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids" and "biotechnology" is defined as stated in note 3.

33. *Id.* art. 4 (emphasis added).

34. Jaffe, *supra* note 31, at 301.

35. *Id.*

36. *Id.*

37. Protocol, *supra* note 3, Annex 1. These include the characteristics of the organism and parental or donor organisms, centers of origin and genetic diversity, intended use of the organisms or products thereof, suggested methods for handling and use, and the regulatory status of the product in the country of export.

38. *Id.* art. 15(1). LMOs should also be assessed on a case-by-case basis, *id.* at Annex III.6, and risks should be evaluated in the context of the likely receiving environment, *id.* at Annex III.5.

considerations into account in making regulatory decisions at their discretion.[39] The Protocol also contains novel, broad expressions of the precautionary principle within its operational sections, particularly when compared with the imprecise provisions of the Convention on Biological Diversity and other relevant agreements.[40] Article 10 of the Protocol states that "[l]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects . . . shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects."[41]

Due to the potential breadth of provisions that may be engaged in the absence of factual justification (i.e., taking decisions to mitigate *potential adverse effects* when compared with, for example, *threats of serious or irreversible damage*, which is the standard used in Principle 15 of the Rio Declaration and the Preamble of the CBD) and the inclusion of the aforementioned expressions of the precautionary principle, numerous commentators concluded that the Protocol's provisions support the adoption of harmonized, precautionary measures unique to regulating living biotechnology products.[42] Commentators also worried that widespread adoption of the Protocol could result in potential consumer risks being emphasized over trade interests and the progress of biotechnology research.[43] Because the "African Group" of countries from the continent collectively emphasized the uncertainties associated with biotechnology at the negotiating table and argued vociferously in favor of national biosafety interests, it is understandable that many such commentators feared that precautionary stances (and iterations of the precautionary principle) would continue to define African national approaches to biotechnology in the wake of the

39. *See id.* art. 26(1).

40. *See* Protocol, *supra* note 3; *see also* Laurence Graff, *The Precautionary Principle, in* THE CARTAGENA PROTOCOL ON BIOSAFETY: RECONCILING TRADE AND BIOTECHNOLOGY WITH ENVIRONMENT AND DEVELOPMENT? 410, 410–11, 17 (Christoph Bail, Robert Falkner & Helen Marquard eds., 2002).

41. Protocol, *supra* note 3, art. 10(6). Article 11 of the Protocol uses virtually identical language but focuses instead on LMO-FFPs. *See also id.* at Annex III.4: "Lack of scientific knowledge or . . . consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."

42. *See*, *e.g.*, Graff, *supra* note 40, at 410. *See also* Adler, *supra* note 16, at 175; PAARLBERG, *supra* note 26. On the harmonizing goals of the Protocol, *see, e.g.*, Jaffe, *supra* note 31; *see generally* John Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207 (2001).

43. *See* PETER ANDRÉE, GENETICALLY MODIFIED DIPLOMACY (2007), at 212–13; *see also* W. De Greef, *The Biosafety Protocol and the Future of Agbiotech*, 22(7) NATURE BIOTECHNOLOGY 811 (2004).

Protocol's agreement.[44]

B. The African Union's Model Law on Biosafety

The Model Law on Biosafety of the African Union ("Model Law")[45] was first drafted in 1999, during a lull in the Cartagena Protocol negotiations, to provide a basis for a "harmonized approach towards biosafety in Africa [and serve] as a model legal instrument for developing national biosafety legislations."[46] A first version of the Model Law was agreed upon by representatives from 28 African governments in 2001 (subsequent revisions followed in 2006 and 2008) to, among other things, specifically address organisms and products not regulated by the Protocol.[47]

The Model Law contains non-mandatory provisions that provide a model for policy-makers to adopt into national legislation at their discretion. The regulatory focus of the Model Law is similar to that of the Protocol—genetically modified organisms (GMOs) are defined therein as "any organism that possesses any novel combination or expression as a trait of genetic material obtained through the use of modern biotechnology."[48] The Model Law is not limited to *living* modified organisms, and also includes material not regulated by the Cartagena Protocol including non-living food and feed products of biotechnology and material developed by a broader class of modification techniques.[49] The Model Law contains noteworthy provisions on public consultation and education,[50] GMO and derivative labeling (a particularly contentious issue in the Cartagena Protocol negotiations),[51] and also states that competent authorities should develop

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44. *See generally* The Secretariat of the Convention on Biological Diversity, *The Cartagena Protocol on Biosafety: A Record of the Negotiations* (2004); African Ministerial Conference on Science and Technology (AMCOST III) Steering Committee Meeting, *Context for Revising the AU Model Law on Safety in Biotechnology*, 7–8 AU/EXP/STEERING/ST/6(III) (June 6–7, 2007) [hereinafter Context for Revising AU Model Law].

45. *African Model Law on Biosafety, supra* note 17; *see also* African Union, *Revised African Model Law on Biosafety* (Jan. 2008), *available at* http://www.africa-union.org/root/au/auc/departments/hrst/biosafety/DOC/level2/DraftRevAMLBS_Jan08_EN.pdf [hereinafter 2008 Revised Model Law].

46. *Id*.

47. *Id.; see also* 2008 Revised Model Law, *supra* note 45.

48. 2008 Revised Model Law, *supra* note 45, art. 2. "Organism" is defined therein as "any biological entity capable of transferring or replicating genetic material including sterile biological entities, viruses, viroids and *plasmids*" (emphasis added) and "modern biotechnology" is defined as (a) *in vitro* or *in vivo* modification of DNA, (b) *in vitro* or *in vivo* modifications of DNA or RNA so as to change any trait of an organism, or (c) cell fusion techniques that "overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection" (emphasis added).

49. *Id*. art. 11.

50. *See id.* art. 7.

51. *See id.* art. 14.

measures to create and protect "GMO free zones."[52] The focus here, however, will be on the Model Law's unique risk assessment and evidentiary standards. For example, Article 8.5 reads that "[n]o approval shall be given by the Competent Authority *unless there is firm and sufficient evidence* that the genetically modified organism or the product of a genetically modified organism poses *no significant risks* to the environment, biological diversity or human health."[53]

Even more striking are the provisions related to non-biosafety factors to be considered in regulating GMOs. The Model Law states that:

> No approval shall be granted for the making, import, use or release of a GMO unless the Competent Authority determines that the GMO will:
> (a) benefit the country without causing any significant risk to the environment, biological diversity or human health;
> (b) contribute to sustainable development;
> (c) not have adverse socioeconomic impacts; and
> (d) accord with the ethical values and concerns of communities and does not undermine local community or indigenous knowledge and technologies.[54]

These provisions extend the mandate for regulators far beyond the strict biosafety role envisioned by the World Trade Organization and beyond even the more generally precautionary provisions of the Cartagena Protocol. The language used in the Model Law permits the imposition of measures that require concrete evidence of an *absence* of risk in an area where uncertainty and some degree of potential risk are almost always the norm.[55] Furthermore, these provisions engage broad, subjective concepts (e.g., "benefit", "significant risk", "sustainable development") that may be difficult to predictably define for product developers and regulators alike. These provisions are noteworthy because of the breadth and strength of language included to protect African biosafety interests;[56] indeed, some commentators have found

52. *See id.* art. 19.

53. *Id.* art. 8 (emphasis added).

54. *Id.* art. 8.7. "Socio-economic conditions" are defined as "the economic, social or cultural conditions, livelihoods, knowledge, innovations, practices and technologies of indigenous and local communities including the national economy"; *id.* art. 2.

55. *See generally* Robin Gregory & Timonthy McDaniels, *Improving Environmental Decision Processes,* DECISION MAKING FOR THE ENV'T 175 (Garry D. Brewer & Paul C. Stern eds., 2005); *see also* Joyce Tait & Les Levidow, *Proactive and Reactive Approaches to Risk Regulation: The Case of Biotechnology*, 24(3) FUTURES 219 (1992).

56. *See* 2008 Revised Model Law, *supra* note 45, Preamble ("Whereas, with the potential risks posed by genetic modification it is consistent with the precautionary principle to regulate any undertaking for the making, import, contained use, release or placing on the market of genetically modified organisms and products of genetically modified organisms.") (emphasis omitted).

that the Model Law's provisions regulate biosafety in a "stringent and precautionary" manner.[57]

The extent to which the model provisions of the Protocol and Model Law impact national regulation is difficult to assess in the abstract. The general impact of these instruments as reifying forces of precautionary policy-making, however, may be approximated by reference to established biosafety frameworks concluded or modified since their introduction. In the sections that follow, this article examines the national regulatory approaches of three leaders in the African biotechnology sector, namely: South Africa, Kenya, and Burkina Faso, as case studies of agri-biotech policy-making in the wake of these agreements. All three of these nations have introduced (or, in the case of South Africa, updated) relevant biosafety regulatory frameworks since the conclusion of the subject agreements. Furthermore, all three nations have signed and ratified the CBD, are contracting parties to (and were involved in the negotiation of) the Protocol, and representatives of all three nations have contributed to the discussions leading to the agreement and subsequent revisions of the Model Law. Thus, South Africa, Kenya, and Burkina Faso are well placed to serve as case studies of regulatory policy-making and biotechnology research and development endeavors in the context of the Protocol and Model Law.

III. SOUTH AFRICA

South Africa prioritized investment in agricultural development in the wake of apartheid, forming the Agricultural Research Council (ARC) and investing heavily in its projects. Due to consistently high poverty levels[58] and other pressing needs, however, the government shifted its focus away from scientific investment and lowered financial support for the ARC and other agricultural research institutions in the early 2000s.[59] While government support for general agricultural research has faltered, funding for domestic biotechnology projects has increased.[60] Public research institutions, joined by a fairly robust private sector and regional entities, conduct the majority of the biotechnology

57. Context for Revising AU Model Law, *supra* note 44, at 25; MEREDITH MARIANI, THE INTERSECTION OF INTERNATIONAL LAW, AGRICULTURAL BIOTECHNOLOGY, AND INFECTIOUS DISEASE, 201 (2006) ("[T]he provisions of the African Model Law are arguably more protective than those of the Biosafety Protocol.").

58. *See* Frikkie Liebenberg & Johann Kirsten, *South Africa: Coping with Structural Changes, in* AGRIC. R&D IN THE DEVELOPING WORLD: TOO LITTLE, TOO LATE? 195, 196 (Phillip G. Pardey, Julian M. Alston, & Roley R. Pigott eds., 2006).

59. While government financial support of scientific research and development has increased, there has been a decrease in government funding to the ARC from R337 million in 1998 to R262 million in 200. *See id.* at 214.

60. *See* Michael Gastrow, *Great Expectations: The State of Biotechnology Research and Development in South Africa*, 7 AFR. J. OF BIOTECHNOLOGY 342, 345 (2008).

research performed in the country.[61]

As an early leader in African biotechnology, South Africa was also the first African nation to establish regulatory policies on biotechnology. Biosafety requirements for biotechnology products were first established in 1979 by the South African Committee for Genetic Engineering, focusing primarily on laboratory safety.[62] The first formal field trials on genetically modified agricultural products were not conducted until the early 90s, however, and consisted of applications to the Department of Agriculture roughly outlining hazards potentially associated with the trials.[63] Due to a steadily increasing volume of applications and the multidimensional concerns involved, the Departments of Health, Agriculture, and Environment collaborated to formalize the application process and collectively drafted the Genetically Modified Organisms Act 1997,[64] which was implemented in 1999 and later updated to its current version in 2007.[65]

The lead agency under the *GMO Act* is the Department of Science and Technology (DST) and the prescribed Scientific Advisory Committee (SAC), which advises a multidisciplinary Executive Committee. The Executive regulates the approval and supervision of the development, testing, production, and use of "genetically modified organisms,"[66] including the testing and approval of GMOs for release or importation, for which the Act suggests (but does not mandate) an environmental risk (or impact) assessment may be appropriate.[67] The Act does not elaborate on the content of risk assessments or mandate unique analytical steps with respect to GMOs beyond imposing a general obligation on users to "ensure that appropriate measures are taken to avoid an adverse impact on the environment which may arise from the use of genetically modified organisms."[68]

The Environment Conservation Act 73 of 1989,[69] provides some guidance on environmental risk assessments, requiring very generally that a proposed action (in this case, the release of a GMO) be compared

61. *See id.* at 348.

62. *See* Muffy Koch, *Institutional Capacity in the South African Biosafety System, in* PROCEEDINGS OF A WORKSHOP ON BIOSAFETY CAPACITY BUILDING IN E. AND S. AFR. 48, 48 (2002).

63. *Id*.

64. Genetically Modified Organisms Act of 1997 (S. Afr.) [GMO Act].

65. *See* Genetically Modified Organisms Amendment Act of 2006 (S. Afr.).

66. "Genetically modified organisms" are defined in the GMO Act, *supra* note 64, § 1.xiii, as organisms "the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both," where "organism" is defined as "a biological entity, cellular or non-cellular, capable of metabolism, replication, reproduction or of transferring genetic material and includes a micro-organism." *Id.* § 1.xx.

67. *See* GMO Act *supra* note 64, § 5(a).

68. *Id.* § 17(1).

69. Environment Conservation Act 73 of 1989 (S. Afr.).

to available alternatives in terms of the extent and significance of identified environmental impacts.[70] The National Environmental Management: Biodiversity Act, 2004 (the NEMA),[71] pursuant to the Protocol, requires that the release of a GMO that "may pose a threat to any indigenous species or the environment" not be permitted, unless an environmental assessment has been conducted.[72] By their inclusion in Schedule 1 of the NEMA's prescribed categories, GMOs can be approved on the strength of merely a "basic" risk assessment.[73] This includes generally considering the particularities of the environment in question, the potential impact and cumulative effects of the release, measures to mitigate those effects, and information on ongoing monitoring and impact-management efforts.[74]

Set against this framework, South Africa has the most advanced agricultural biotechnology sector on the continent.[75] South Africa is the eighth largest grower of biotechnological crops worldwide, with 2.1 million hectares of commercially grown transgenic crops currently under cultivation.[76] *Bt* cotton was the first biotech crop to receive regulatory approval in 1997, and today, more than 75 percent of cotton grown in South Africa is *Bt* cotton.[77] Among the other *Bt* crops that have been researched is white maize, which was adapted from yellow maize varieties and is generally more consistent with South African diets.[78] Furthermore, while all varieties of biotechnological crops currently under cultivation were developed off-continent, recent transformation events include the transformation of maize to tolerate the maize streak virus—the first GM plant developed entirely "by Africans, for Africa."[79]

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70. *Id.* § 22. The Regulation also notes that the application must include a consideration of the environment in question, the activity, and whether and how the public was consulted. *Id*.

71. National Environmental Management: Biodiversity Act of 2004 (S. Afr.).

72. *Id.* § 78(1).

73. National Environmental Management Act of 1998 (S. Afr.).

74. *Id.* § 24(7).

75. *See* Mohohlo Molatudi & Anastassios Pouris, *Assessing the Knowledge Base for Biotechnology in Southern Africa*, 68 SCIENTOMETRICS 97, 106 (2006). Many different measures are commonly used to evaluate such a claim, but one widely cited fact is that South African researchers regularly account for approximately 40 percent of the biotechnology-related publications on the continent.

76. *See* Biotech Update, *supra* note 5, at 2.

77. *See* R.J. Hillocks, *GM Cotton for Africa*, 38(4) OUTLOOK ON AGRIC. 311, 313 (2009). Approximately 95 percent of South African cotton is produced by 300 large landholding farmers, while the other five% is grown on small farms of two hectares or less. The author notes that 75 percent of South African smallholder cotton farmers were growing *Bt* cotton as of the year 2000.

78. *See* Gouse, *supra* note 9, at 87. Gouse suggests that yellow *Bt* maize was adopted rather slowly by South African farmers in part because it was developed from a variety adapted to the US environmental and social context, reducing its marketability within South Africa.

79. *See* Sinha Gunjan, *GM Technology Develops in the Developing World*, 315 SCI. 182 (2007).

While it has thus enacted provisions corresponding to the Protocol's focus on "potential adverse effects," South Africa, via the NEMA, explicitly treats genetically modified plants as products that generally exhibit low environmental risk.[80] The *GMO Act* and *Biodiversity Act* mandate unique bureaucratic processes with respect to GMOs, but those bureaucratic processes do not appear to subject the products to more stringent standards than those employed with respect to other products. While some crops may be subject to rejection or quarantine due to their particular characteristics as revealed by environmental risk assessment, a product's transgenic or modified character does not make it inherently more hazardous than products developed by other means.[81] By equating GMOs with traditionally bred crops and generally eschewing process-based regulation, the South African government has adopted a position on biosafety that arguably supports the nascent biotechnology industry instead of following the "precautionary" tone of the Protocol and Model Law.[82]

IV. KENYA

The Kenyan economy, like that of many African nations, is dominated by its agricultural sector. Due in part to consistently low productivity rates,[83] agricultural technology and biosafety policy development have remained priorities for the Kenyan government over the past several decades,[84] and have developed in concert as researchers and policymakers have recognized the role that biotechnology could play in intensifying agricultural production and alleviating poverty.[85]

In the late 1990s and early 2000s, well before the introduction of statutory biosafety policies, Kenyan researchers attempted to import and evaluate biotechnological crops (including trials of sweet potato, *Bt*

80. National Environmental Management Act, *supra* note 73, § 24(7).

81. Indeed, once the safety of a particular engineered trait has been ascertained by environmental assessment, that trait can be freely backcrossed into other varieties without further regulation: *See* Gouse, *supra* note 9, at 86.

82. As an example of commentary supporting this view, *see* Context for Revising AU Model Law, *supra* note 44, at 30, where the author notes that "[i]n its broadest contours, South African biosafety legislation has tended to follow the *permissive* regulatory approach of the United States" (emphasis added); *see also* M.O. Makinde, et al., ROLE OF AGRICULTURAL BIOTECHNOLOGY IN HUNGER AND POVERTY ALLEVIATION FOR DEVELOPING COUNTRIES 1–2 (2007).

83. For example, critics note that Kenyan farmers produce 1.6 tons of dry, refined product per hectare of farmland whereas one hectare of farmland in the United States produces nine tons of product. *See* Cohen & Paarlberg, *supra* note 24, at 81.

84. *See* Republic of Kenya, *A National Biotechnology Development Policy* 5–6 (2006).

85. *See* Matthew Harsh, *Formal and Informal Governance of Agricultural Biotechnology in Kenya: Participation and Accountability in Controversy Surrounding the Draft Biosafety Bill*, 17 J. OF INT'L DEV. 661, 661–70 (2005).

cotton, and, most notably, *Bt* maize crops) on several occasions.[86] Applications for field trials of *Bt* maize were originally subject to interim biosafety guidelines established in 1998 by the National Council of Science and Technology for confined trials and research on GMOs.[87] These regulations were enforced by regulators generally unfamiliar with biotechnology and its products.[88] In the end, due to delays in the processing of the application, field trials for *Bt* maize did not actually commence until a full decade after the initial application, which exemplifies some of the inefficiencies of the early system as well as the hazards of a "reactive" approach to biotechnology regulation.[89]

The Kenyan *Biosafety Act*[90] (implementing the National Biotechnology Policy of 2006) was introduced in 2009; the legislation was developed by the National Council of Science and Technology with the aid of the IFPRI's Program for Biosafety Systems and the UNEP Global Environment Facility.[91] Kenya was the first country to sign the Cartagena Protocol at the fifth negotiating Conference of Parties in May 2000, and was heavily involved in its negotiation.[92] It is no surprise then, that the provisions of the *Biosafety Act* closely mirror those of the Protocol. Introduced to "establish a transparent, science-based and predictable process for reviewing and making decisions on the transfer, handling and use of GMOs,"[93] the *Biosafety Act* mandates that GMOs may not be imported (nor may GMOs developed within Kenya be released from confinement) without first undergoing a multidisciplinary safety assessment by the National Biosafety Committee (NBC) and the National Council for Science and Technology.[94] The NBC assesses and evaluates the potential adverse effects (and the likelihood of the effects being realized) associated with the release or importation of any new

86. *Id.* at 663–64.

87. *Id.*

88. *See* STEVEN WERE OMAMO, BIOTECHNOLOGY, AGRICULTURE, AND FOOD SECURITY IN SOUTHERN AFRICA 252 (Klaus von Grebmer ed., 2005).

89. *See* Jenna Kryszczun & Steven Were Omano, *Workshop Proceedings for the FANRPAN-IFPRI Regional Policy Dialogue on Biotechnology, Agriculture, and Food Security in Southern Africa, in* BIOTECHNOLOGY, AGRIC., AND FOOD SECURITY IN S. AFR., (Klaus von Grebmer, ed. 2005). *Id.* at 251; *see also* Joel I. Cohen, *Poor Nations Turn to Publicly Developed GM Crops*, 23 NATURE BIOTECHNOLOGY 27, 29 (2005) [hereinafter *Poor Nations Turn*].

90. *Kenya Biosafety Act*, No. 2 (2009), KENYA LAW REPORT § 2.

91. *See PBS Helps Set the Stage for Biosafety Legislation*, PBS KENYA (2008), *available at* http://pbs.ifpri.info/files/2011/09/pbsfs_kenya.pdf.

92. *See* Zachary Mankanya, *Grounding Biosafety Regulations in Developing Countries, in* PROCEEDINGS OF A WORKSHOP ON BIOSAFETY CAPACITY BUILDING IN E. AND S. AFR. 23, 23 (2002).

93. *Kenya Biosafety Act*, *supra* note 90, § 4(c). "Genetically modified organism" is defined therein as "any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques", including recombinant DNA techniques and fusion of cells beyond the taxonomic family that are not used in traditional breeding. *Id.* § 2.

94. *Id.* § 20(1).

GMO, taking into account considerations such as phytosanitary data from exporting countries, the characteristics of recipient and parental organisms, the insert and its modification, and information relating to the receiving environment and intended use.[95] Different regulatory standards exist for products destined for confined trials as compared with unconfined release,[96] and exemptions exist where experience or information exist to conclude that the product does not pose a significant risk.[97]

Imported GMOs are subject to multi-stage regulation in Kenya; in addition to the *Biosafety Act*, they are also subject to the provisions of the *Plant Protection Act*, administered by the Kenya Plant Health Inspectorate Service (KEPHIS).[98] KEPHIS regulations prescribe a product-focused system with risk assessment and containment procedures that vary significantly and which depend expressly on the characteristics, species, and intended use of the particular product.[99]

Set against this evolving regulatory environment is a growing agri-biotechnology research community. While commercial crops have not yet made their way to African farmers, confined field trials have begun for several major crops, including: two trials of cassava transformation events; *Bt* cotton; sorghum; and three events of maize transformation, including one developed under the auspices of the Water Efficient Maize for Africa project.[100] Other recent developments include expanded research efforts into tissue culture and marker-assisted breeding technology, and concerted efforts to develop national research and technology capacity.[101]

In spite of its uncertain beginnings, Kenya has established a biosafety system that some regard as an exemplary "role model" of

95. *Id*. fifth schedule, § 5. These include phytosanitary data from the exporting country, the characteristics of recipient and parental organisms, the relevant vector, the insert and its modification, the receiving environment, and information relating to its intended use.

96. *See id.* third schedule, § 18(2).

97. *See id*. § 28. These exemptions have been the source of significant criticism from biosafety proponents and some NGOs, which note that the provisions could be used to circumvent environmental risk assessment without an adequate assessment of the product's potential impact on the Kenyan environment specifically. *See* Mariam Mayet, *Comments on the Kenyan Biosafety Bill of 2008, of Kenya*, AFR. CENTRE FOR BIOSAFETY (2009).

98. *See* Ann Kingiri & Selfe Ayele, *Towards a Smart Biosafety Regulation: The Case of Kenya*, 8 ENVTL. BIOSAFETY RES. 133, 134 (2009); *see also Kenya Biosafety Act*, *supra* note 90, § 3(1), which notes that the requirements of the *Act* apply in addition to the requirements of other relevant Acts.

99. *See Plant Protection Act*, (2012), LAWS OF KENYA Cap. 324 § 8(2)(a); *see also* Legal Notice on the Plant Protection Import Regulation, KENYA PLANT HEALTH INSPECTORATE SERVICE (last visited Mar. 14, 2013), *available at* http://www.kephis.org/plant-import-requirements-mainmenu-86.html.

100. Global Status of Commercialized Biotech/GM Crops, *supra* note 8, at 7.

101. *Id.*

regulatory development.[102] Indeed, some Kenyan biotechnology proponents, including scientists and policymakers, consider the *Biosafety Act* and workable biosafety policies implemented thereby, as "the key for advancing adoption of biotechnology" in the country, particularly amongst farmers.[103] The uncertainty and lengthy delays associated with early biotechnology products exemplify the importance of rapid implementation of formal biosafety policies and a continued focus on capacity-building research and regulatory expertise at a grassroots level.[104] Further observations may be drawn from the fact that, though Kenya has adopted policies which closely mirror the Cartagena Protocol, its national biotechnology strategy cannot be viewed as particularly "precautionary"; government reports have emphasized the importance of biotechnology in Kenya's agricultural research strategy[105] and some commentators (including numerous anti-GMO lobbyists) have found that the resultant *Biosafety Act* provisions are fairly permissive and favor the interests of Kenyan biotechnology researchers (or at least do not subject research interests to those of biosafety proponents).[106]

V. BURKINA FASO

Burkina Faso's economy is heavily dependent on the agricultural sector, with approximately 80% of the population employed therein.[107] Burkina Faso is the largest sub-Saharan producer and exporter of cotton,[108] in addition to a variety of staple food crops. Regulators, farmers, and scientists alike have generally reacted eagerly to the possible incorporation of biotechnological crops into Burkina Faso's agricultural framework. Farmers had *Bt* cotton test crops in the ground in 2003, well before the establishment of legislated regulatory policies in 2006.[109] Even more troubling to proponents of strong national

102. *See* Harsh, *supra* note 85, at 661.

103. *See* Kingiri & Ayele, *supra* note 98, at 137.

104. *See id.* at 136–37; Harsh, *supra* note 85, at 661.

105. *See generally A National Biotechnology Development*, *supra* note 84.

106. *See Whither Biosafety? In these days of Monsanto laws, Hope for Real Biosafety Lies at the Grassroots,* GRAIN (Oct. 11, 2005), *available at* http;//www.grain.org/article/entries/153-whither-biosafety-in-these-days-of-monsanto-laws-hope-for-real-biosafety-lies-at-the-grassroots [hereinafter Whither Biosafety?}; *see also* Mayet, *supra* note 97, at 4.

107. *See* Food and Agric. Org., *AGORA: Helping Burkina Faso's Researchers Develop Innovative Agricultural Solutions*, AGORA (Sept. 2010), http://www.aginternetwork.org/en/free_access_resource_gallery/2010_Sept_15_INERA_case_study.pdf.

108. *See Cotton,* HARVEST CHOICE (last visited Apr. 10, 2013), *available at* http://harvestchoice.org/commodities/cotton.

109. Elfrieda Pschorn-Strauss, *Bt Cotton in South Africa: The Case of the Makhathini Farmers*, GRAIN (Apr. 26, 2005), http://www.grain.org/article/entries/492-bt-cotton-in-south-africa-the-case-of-the-makhathini-farmers.

biosafety measures, *Bt* crops were in the ground some months even before *temporary* measures had been formally introduced.[110] These temporary regulations were concluded by Ministerial Decree, and introduced an arguably de-regulatory stance on *Bt* cotton and other biotechnological crops in the interests of promoting scientific capacity development and foreign investment. Formal biosafety policies, developed by the Ministers of the Environment, Agriculture, Commerce, Health, and others,[111] followed soon thereafter.

The current policy for biotechnology products in Burkina Faso, which operates under the auspices of the National Framework, include "Biosafety Rules" regulating the testing of *Bt* products. Burkina Faso's biotechnology policies also implicate environmental, health and trade legislation. The National Biotechnology Agency, created through the National Biosafety Rules, is tasked with regulating the development and transboundary movement of "genetically modified organisms" defined simply as organisms with genetic material modified other than by means of natural recombination or multiplication.[112] The Rules prescribe that confined field trials are required for all new uses of GMOs, including those intended for research, teaching, or preliminary evaluation purposes,[113] and that an environmental safety assessment must be completed prior to the unconfined release of any GMO in a manner consistent with the precautionary principle.[114] Environmental safety assessments involve the case-by-case classification of GMOs in one of three levels according to their potential level of risk as defined in regulations.[115]

As discussed above, environmental, health, and other legislation in place prior to the establishment of the National Biosafety Rules was updated thereafter with the express purpose of bringing those enactments to bear upon biotech products in Burkina Faso. As such, the provisions of the 2006 *Loi portant réglementation des semences végétales au Burkina Faso*, which generally regulates intellectual

110. *See* Ronald J. Herring, *Stealth Seeds: Bioproperty, Biosafety, Biopolitics*, 43(1) J. DEV. STUD. 130, 133–34 (2007), for a discussion on the difficulty of controlling the transboundary movement of agri-biotech crops (so-called "stealth seeds") in and amongst groups of farmers in Brazil and India.

111. Comité National de Biosecurité, *Cadre National Pour la Prevention des Risques Biotechnologiques au Burkina Faso,* ch. 1.2.3 (Ouagadougou: CNB, 2005) [hereinafter National Framework].

112. *Id*. ch. 5.2.

113. Règles Nationales en matière de Sécurité en Biotechnologie, 2004-262/PRES/PM/MECV/MAHRH/MS, June 18, 2004, ch. 4 [National Biosafety Rules] ("Elle s'effectue obligatoirement après les travaux menés en milieu confiné et après évaluation des risques."). Confined trial conditions are delineated by regulation, and the exact specifications are beyond the scope of this article.

114. *Id.* ch. 1.7.

115. *Id.* ch. 1.5.1 (describing confined field trial risk categories).

property and biosafety issues associated with the production and use of seeds, explicitly include biotechnology products within their ambit.[116] The Act distinguishes between "traditional" and "improved" varieties in a product-based manner,[117] and mandates that before any new improved variety may be released or imported it must first meet regulatory standards of nutritional and phytosanitary quality.[118] While all other pieces of coordinate legislation (including the Seeds Regulations) are expressly subordinate to the National Biosafety Rules,[119] these provisions introduce interesting elements of product-based regulation to a system that otherwise expressly subjects biotechnology products of biotechnology to process-based scrutiny.

After five years of evaluation through confined trials, in 2008, Burkina Faso became the second African country (after South Africa) to approve the commercialization of a crop developed via biotechnology—*Bt* cotton was the approved crop in both cases.[120] Other biotech crops with confined trial approval in Burkina Faso include nutrient-enriched sorghum and insect-resistant cowpea,[121] but the post-approval adoption rate of *Bt* cotton perhaps best illustrates Burkina Faso's national excitement for biotechnology. The planted area of *Bt* cotton in Burkina Faso rose from 8,500 hectares in 2008 to 125,000 hectares in 2009, and further increased to 360,000 hectares (or 70 percent of the total national planted area of cotton) in 2010.[122]

To contrast Kenya's experience, Burkina Faso's example illustrates the potentially pro-biotechnology consequences of interim biosafety policies, if concluded in the context of de-regulatory policy models and in the interest of improving scientific capacity. The relevant statutory provisions exemplify process-focused biosafety regulation in the model of the Cartagena Protocol,[123] but neither those process-

116. *Loi Portant Réglementation des Semences Végétales au Burkina Faso,* 2006–10, art. 4 [Seeds Regulations] ("Les activités relatives aux semences issues des biotechnologies modernes sont régies par la législation en vigueur.").

117. *See id.* arts. 2, 3.

118. *See id.* arts. 5, 27.

119. The National Biosafety Rules explicitly occupy a preferred position with respect to biotechnology products and the many policy instruments that govern their development and use. *See* National Framework, *supra* note 111, ch. IV ("Parmi ces outils, les Règles Nationales en matières de sécurité en Biotechnologie occupent actuellement une place privilégiée.").

120. Clive James, *BRIEF 41 - Global Status of Commercialized Biotech/GM Crops: 2009*, ISAAA BRIEFS 129, 131 (2009), *available at* http://www.isaaa.org/resources/publications/briefs/41/download/isaaa-brief-41-2009.pdf.

121. *See* NEPAD Biotech, *supra* note 19, at 12.

122. *See Biosafety in Burkina Faso: Ensuring the Safe Rollout of Genetically-Modified Cotton,* USAID (2010); *see also* Biotech Update, *supra* note 5.

123. *See Whither Biosafety?*, *supra* note 106. Critics note that, in spite of the process-focused nature of the regime, the provisions do not support a full analysis of the unique risks associated with biotechnology and its products, and that the balance in Burkina Faso's regulatory system is shifted too far in favor of innovation.

focused provisions nor the explicit incorporation of the precautionary principle within the framework result in a particularly "precautionary" approach to biotechnology. To the contrary, the current policy environment contains elements of product-based regulation that have served to underpin a dramatic and rapid rise in the uptake and use of biotechnological crops in Burkina Faso.

VI. CONCLUSIONS

The last decade has seen some significant changes in policy and public opinion with respect to biotechnology in Africa—crops are being more widely tested and planted across the continent,[124] negative biosafety consequences have been rare (where reported at all),[125] and countries are increasingly moving towards formal biosafety policies. As a consequence of this movement, proponents generally recognize that "[f]unctional biosafety systems are key to maximizing the benefits from biotechnology while demonstrating to stakeholders and the public that attendant environmental and health issues are addressed by scientific risk assessments."[126] The stakes on regulatory policy decisions are extremely high. On the one hand, much ink has been spilled on the possible health and biodiversity concerns associated with biotechnology-based products. On the other hand, critics suggest that African agriculture must grow by five to six percent each year to be a major factor in reducing poverty,[127] a monumental task. Furthermore, regulatory issues can delay the release of new crop varieties by up to nine years and increase costs for transgenic crop approval by up to five to eight times more than for conventional crops (between $6 million and $15 million for insect-resistant maize and herbicide-tolerant maize, for instance).[128]

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124. *See* NEPAD Biotech, *supra* note 19, at 1–2. It bears mentioning that, in addition to the case studies presented herein, Egypt also has one of the leading biotechnology sectors on the continent; researchers have *Bt* maize in the ground and are approaching commercialization of transgenic varieties of squash, white maize, and cotton.

125. *See Poor Nations Turn*, *supra* note 89, at 29; *see also* Phillip J. Dale et al., *Potential for the Environmental Impact of Transgenic Crops*, 20 NATURE BIOTECHNOLOGY 567 (2002). An excellent example of the changing opinions on transgenic seed is that of the government of Zimbabwe, which famously rejected modified food aid as "toxic" in the midst of a famine in 2002; and at present day, is one of fourteen African nations that has reached the level of confined research on agri-biotech products and established laws and regulatory policies specifically for monitoring their impact.

126. *See Harnessing Biotechnology for the Poor*, *supra* note 4, at 244; *see also* Unesu Ushewokunze-Obatolu, *Biosafety Policy, in* BIOTECHNOLOGY, AGRIC., AND FOOD SECURITY IN S. AFR. 157, 160–61 (Steven Were Omano & Klaus von Grebmer eds., 2005).

127. *See* Victor. O. Chude, *Links Between Soil Management and Food Security in West Africa*, FAO 2 (Dec. 5–7, 2012), *available at* http://www.fao.org/fileadmin/user_upload/GSP/docs/WS_managinglivingsoils/Chunde_West_Africa.pdf.

128. *See* Peter Beyer, *Golden Rice and 'Golden' Crops for Human Nutrition*, 27(5) NEW

African nations were heavily involved in the negotiations leading to the Cartagena Protocol; the "African Group" of parties at the Cartagena negotiations argued in favor of a broad expression of the precautionary principle and broad protections for biosafety interests.[129] Furthermore, participation in the resultant framework for regulating LMOs has been widespread; over 45 African countries have ratified the Protocol.[130] As for the AU Model Law, while few countries have adopted its model provisions wholesale, its provisions have informed and influenced the national approaches of many African countries.[131] While the agreements play a significant role in decision-making on multiple levels, the case studies contained herein demonstrate that they do not necessarily serve as reifying forces of either precautionary or harmonized policy-making.

The impact of instruments such as the Protocol and Model Law on national policy depends on numerous factors including: histories of use of and trade in GMO/LMOs; the policies of neighbors and close-trading partners; the character of national policy goals;[132] as well as early regulatory experiences and the identity of the crops subject to regulation.[133] These considerations, among many others, contribute to the wide breadth of regulatory approaches that define the existing global regulatory environment for agri-biotechnology.

To compare, while Kenya and Burkina Faso explicitly evaluate GMOs in a category distinct from other plant products and subject GMOs to risk assessment provisions based on their genetically modified

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BIOTECHNOLOGY 478, 479 (2010); *see also* Nicholas Kalaitzandonakes et al., *Compliance Costs for Regulatory Approval of New Biotech Crops*, 25 NEW BIOTECHNOLOGY 509 (2007); *see also* Thomson, *supra* note 27, at 265. Thomson notes that in circumstances where regulatory oversight is disproportionate and informational requirements are extensive, "regulatory costs might exceed the costs of research and experimentation to develop a given GE crop."

129. Context for Revising AU Model Law, *supra* note 44, at 7–8.

130. NEPAD Biotech, *supra* note 19, at 2.

131. *See* Context for Revising AU Model Law, *supra* note 44*,* at 14. For example, Kenya's 1999 legal framework adopted the Model Law's provisions on liability, redress, rehabilitation, and cleanup.

132. *See A National Biotechnology Development Policy*, *supra* note 84, at 6. There are, of course, a variety of other international biosafety and trade agreements that may affect policy decisions with respect to biotechnology products (including the GATT, TBT, and SPS Agreements of the WTO, and the Convention on Biological Diversity) as well as bilateral and regional trade agreements that may further complicate matters.

133. *See* Motarim et al., *supra* note 4, at 41. The contrast is clear between early regulatory experiences in South Africa and Burkina Faso, where interim and statutory policies were concluded in the context of applications for approval of *Bt* cotton (and its associated regulatory experience and approvals in other nations), and in Kenya, where regulators were initially faced with applications for approval of *Bt* maize (which had struggled to receive regulatory approval in other nations due to uncertainty about its safety for human consumption). These examples illustrate to some extent the importance of prioritizing investment and conducting research on varieties that are well-adapted to national agricultural and social conditions (and well-targeted to consumers' preferences).

character, South Africa's GMO Act mandates unique bureaucratic processes for GMOs but equates risk assessment procedures for biotechnology products to those of traditionally-bred crops. Kenya and Burkina Faso are further distinguishable by subtle differences in their respective approaches to process-based regulation—in Kenya, new crops are subject to coordinate legislative provisions including the *Biosafety Act* and the product-focused KEPHIS regulations; however, in Burkina Faso, elements of product-based regulation are likewise brought to bear by supporting pieces of legislation, but are expressly subordinate to the National Biosafety Rules.[134]

While there are significant differences between the three regimes analyzed herein, they are similar in that, although all three are parties to the Cartagena Protocol and have adopted at least some measures consistent with its provisions, none of the three nations have fully embraced the "precautionary" tone of its provisions as envisioned by early commentators.[135] Indeed, some stakeholders have drawn a contrary conclusion, that the "permissive" natures of these countries' respective policy frameworks may emphasize biotechnology research and development at the expense of biosafety interests.[136] The same holds true for the Model Law's espousal of socioeconomic considerations and its risk assessment standards (requiring an "evidence of absence" of risk).[137] The anticipated impacts of these instruments as models of "precautionary" biosafety policy-making have largely not been borne out in any of the three nations assessed. The non-restrictiveness of the three regimes examined herein generally underscores the broad discretion afforded countries to prioritize national policy goals under the rubric of agreements such as the Protocol and Model Law.

Furthermore, while the Cartagena Protocol and Model Law frameworks represent attempts to harmonize biosafety policy-making on an international and regional scale,[138] the policy models of the three

134. *See* Kingiri & Ayele, *supra* note 98, at 134.

135. Walter S. Alhassan, *Presenting the Sabina Project at the Forum for Agricultural Research in Africa*, ACCRA 7 (Oct. 5, 2011). It should be noted that the regulatory approaches discussed herein comprise three of the most successful biotechnology sectors on the continent, to specifically illustrate the possible permissiveness of regulations that are textually in line with the Protocol (and elements of the Model Law). They may be contrasted with national approaches concluded in line with the Protocol and Model Law that are decidedly *non*-permissive, and equate biotechnology products with highly precautionary, "inherent" conceptions of risk. See, for example, the policies implemented in the West African nation of Mali, one of the few regimes directly based on the Model Law, and the interim framework implemented in the nation of Togo.

136. *See id. (*presented at the Forum for Agricultural Research in Africa, Accra, 5 October 2011, specifically identifying Kenya and Burkina Faso as having "permissive" biosafety systems at 7).

137. Context for Revising AU Model Law, *supra* note 44, 11–12.

138. *See* UNEP/GEF BUILDING CAPACITY FOR THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY 13 (2002). Recognizing the importance of effective biosafety

nations examined herein (all of whom are parties to the Protocol and have contributed to the Model Law negotiations) take very different approaches to implementing their rather inexact provisions. Indeed, as non-mandatory instruments that provide policy-making models rather than strict standards, the Protocol and the Model Law introduce the potential for choice. The resulting diversity of national regimes constituting ratified or acceded provisions of the Protocol belies its usefulness as an instrument promoting international consistency. The same may be said for regionally harmonized African biosafety policy and the AU Model Law.

Finally, these conclusions may contribute to broader discussions on the role of harmonization in the context of international and/or regional biosafety policy. There is a widespread belief that the harmonization of regional biosafety policy (where possible) is appropriate and necessary, in the interest of less confusing and less expensive (for nations and product developers alike) regulatory burdens that will better and more safely control the spread and use of GMOs.[139] While such appeals are undoubtedly well-intentioned and persuasive, national appeals for harmonization often propose a particular iteration or approach to the issue as "appropriate" or "correct," be it precautionary, permissive, or something unique to an individual country.[140] Such appeals not only give too little weight to the distinctive environmental and agricultural conditions of other nations, they are also arguably inconsistent with the general principles of national sovereignty and self-determination emphasized in both the Protocol and the CBD.[141] While capitalizing on the regulatory experience of neighboring nations

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provisions to agricultural development, the United Nations Environment Program Global Environment Facility (UNEP-GEF) developed broad guidelines to help countries establish biosafety systems in line with the Protocol's provisions and in the interests of regional harmonization; *see generally* PAARLBERG, *supra* note 4, at 129–31. Indeed, the UN-GEF spent $74 million dollars between 2000 and 2006 to promote the establishment of biotech-oriented biosafety policies and the development of scientific capacity in the developing world, "much of it in Africa."

139. General proponents of harmonized approaches include the UNEP, *id.*, the Common Market for Eastern and Southern Africa (COMESA), and the Economic Community of West African States (ECOWAS); *see also* Samuel E. Timpo, H*armonizing Biosafety Regulations in Africa: Surmounting the Hurdles, in* AFR. UNION/NEPAD POL'Y BRIEF SERIES (2011); *see also* Munyaradzi Makoni, *Africa's Long Walk to Biosafety*, AFR. FILES (Dec. 14, 2009), *available at* http://www.africafiles.org/article.asp?ID=22494; *see also* Julius Mugwagwa, *To Harmonize or Not to Harmonize? The Case of Cross-Nat'l. Biotechnology Governance in S. Afr.* 6(3) J. OF TECH. MGMT. & INNOVATION 2 (2011).

140. *See* Makoni, *supra* note 139, where the author quotes Jocelyn Webster, the executive director of AfricaBio, stating that "[i]f there were harmonized laws, it would become cheaper and much better for a region like the SADC as regional countries will accept standards that are already set in South Africa."

141. Protocol, *supra* note 3, at Preamble; CBD, *supra* note 29, at Preamble. *See also* A *Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects,* GEF BIOSAFETY UNIT 3 (2006).

and model policies, such as those of the Protocol and Model Law, can be useful (and is often necessary) for nations with emerging biosafety systems and limited budgets, parties to international agreements must be afforded the latitude to adopt their provisions to national political and environmental contexts without having them dictated by other parties—particularly when the legislated issue is one as contentious as agricultural biotechnology.