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Financing of Regional Biotechnology Regulations: Lessons from West Africa

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Access to agricultural technology is important for increasing food security and promoting development in many low-income countries. Increasingly, donor agencies and development institutions are supporting the creation of regional capacity for the assessment and approval of genetically modified organisms as a way to promote agricultural development. In this article we examine the regulatory design risks associated with developing sustainable financing for regional implementations of the Cartegena Biosafety Protocol, which provides an international framework for the regulation of transboundary movements of genetically modified organisms. West Africa provides considerable insight into the potential design risks associated with providing sustainable financing of regional regulation. In West Africa, development institutions are increasingly providing financial support for the development of regional regulatory frameworks to facilitate the introduction of Bt cotton. The regional approach is supported by market-levy-based financing initiatives; however, a market does not currently exist for Bt cotton in West Africa. Our results show that using the market levy may create financial incentives for the regulatory agencies to approve and promote the adoption of Bt technology without appropriate processes being followed. Alternative funding mechanisms are evaluated suggesting that a suitably designed financial guarantee may be a prudent approach to mitigate any risks that may arise from financial short falls in the early years of a regional regulatory system.

Key words: food security, regulation, risk, sustainability, environment, biodiversity, GMO, biosafety, public policy, finance.

Introduction

Access to agricultural technology is seen as important for increasing food security and promoting development in many low-income countries (Clarke, 1997; Islam, 1995; Mitchell, Ingco, & Duncan, 1997; Pinstrup-Andersen, Pandya-Lorch, & Rosegrant, 1999). The green revolution provides some evidence to support a technology-led solution to the problem of feeding people (Trewavas, 1999). Therefore, as a way to promote agricultural development and address capacity constraints, donor agencies and development institutions are financing regional environmental regulatory frameworks for the use of genetically modified organisms (GMOs).[1] To date, few attempts have been made to systematically analyze the development of regional approaches to the regulation of biotechnology. Birner and Linacre (2007) provide an overview of the design options available to countries. In this article, we examine one of the design issues identified by Birner and Linacre (2007), namely the design of sustainable financing systems for regional implementations of the Cartagena Biosafety Protocol.[2]

Many developing countries are currently in the process of developing regulatory frameworks for biotechnology. More than 120 countries are signatories to the Cartagena Protocol on Biosafety and participate in the "Development of National Biosafety Frameworks" project of the United Nations Environment Program and the Global Environmental Facility (UNEP-GEF). Eight countries have moved to the UNEP-GEF project on the "Implementation of National Biosafety Frameworks."[3] Concerns about the costs associated with biotechnology regulation, technical capacity constraints, and potential problems to control transboundary movements of

1. *For a discussion of risks, see Ellstrand and Hoffman (1990); Ellstrand, Prentice, and Hancock (1999); and Linacre et al. (2006).*

2. *Convention on Biological Diversity, Cartagena Biosafety Protocol (see http://www.cbd.int/biosafety)*

3. *See http://www.unep.org/biosafety/national%20Biosafety%20frameworks.aspx.*

GMOs across neighboring countries have led to a strong interest in regional collaboration for biotechnology regulation throughout the developing world and among donor agencies (UNEP-GEF, 2006).

The development of regionalization of biotechnology regulation in West Africa provides considerable insight into the potential design risks associated with providing sustainable financing of regional regulation. In West Africa, development institutions are increasingly providing financial support for the development of regional regulatory frameworks to facilitate the introduction of Bt cotton. Cotton is a major revenue source for a large part of the rural population and a major source of export earnings (US Department of Agriculture, Foreign Agricultural Service [USDA FAS], 2006). West Africa has several initiatives underway to establish a regional system for biotechnology regulation. The countries that are members of West Africa's Permanent Inter-State Committee for the Fight Against Drought in the Sahel (CILSS) have developed a Framework Convention for a Common Biosafety Regulation (Institut du Sahel [INSAH], 2006). The Economic Community of West African States (ECOWAS) has been collaborating with CILSS and with the West and Central African Council for Agricultural Research and Development (CORAF) to establish a regional system of biotechnology regulation in the wider ECOWAS region. The francophone countries that form the West African Economic and Monetary Union (WEAMU) also plan to establish a common regional system for biotechnology regulation.

The introduction of biotechnology is politically contested throughout the region, which has delayed processes of passing biosafety legislation in other countries, especially those where civil society is strong, such as Mali and Senegal (Biner, Resnick, & Linacre, 2007). Due to the contested nature of biotechnology and its regulation in West Africa, the importance of societal sources of risk are relatively more significant than traditional sources of investment risk such as war and appropriation of assets (Howell, 2002; O'Connell, 1997; Slovic, 1993). Risk perceptions, the distribution of risks and benefits, and levels of public trust play an important role in the civil society debate over biotechnology and its regulation. Any perceived failures arsing from bad regulatory design of regional frameworks may lead to a loss of public trust, which may negatively impact development institutions supporting regionalization. This may consequently impact development institutions' ability to deliver on their Millennium Development Goal (MDG) commitments.[4] In this context, design risk refers to the intrinsic characteristics of the sustainable financing structure that may lead to negative perceptions impacting MDG commitments and/or investment losses by donor agencies. The regionalization of biotechnology regulation poses unique risks for institutional investors and donors, and any assessment of investment risk needs to be carried against the organizational goals used to rationalize the investment of time and money into the development of regional biotechnology regulatory frameworks.

A common strategy to fund regional regulatory initiatives in West Africa is the use of a market levy[5] collected as a percentage of the value of production or sales. Such models of funding create a dependence of the regulator on the market, and since a market does not currently exist for Bt cotton in Africa, a potential moral hazard exists for any regional regulatory agency. There may be financial incentives for the regulatory agencies for approval and promotion of the adoption of the technology without appropriate risk analysis processes being followed due to short falls in funding before adequate revenues are available from the market levy. However, this risk may be mitigated to some extent by providing financing during the early years of the system.[6] Detailed analysis is presented on this approach and practical recommendations are developed to mitigate the risks arising from the market levy.

The research presented in this article was conducted by a multi-disciplinary team that collected empirical data on biotechnology regulation in Benin, Burkina Faso, Mali, Niger, Senegal, and Togo between May and August 2006 and involved approximately 130 semi-structured interviews with stakeholders from environment and agriculture ministries, research institutes, producer organizations, non-governmental organizations (NGOs), and the private sector. Documents collected in-country, additional secondary research, and model development were used to substantiate the interviews. In this article, we develop three theoretical frameworks of potential regional approaches to biosafety and develop a Monte-Carlo simulation model, which is used to evalu-

4. *See http://www.un.org/millenniumgoals/.*
5. *In 1993, ECOWAS revised its treaty to apply a 0.5% levy on all products imported from non-ECOWAS countries so as to finance integration projects (Asante, 2004). WAEMU uses a market levy to fund its regulation of veterinary medicines.*
6. *This assumes that the regional regulator will eventually approve safe products from which it will derive income. This assumption is debatable in the case of biotechnology due to potential difficulties that might be encountered during the approvals process.*

ate the implications (for different regional frameworks) of the market-levy funding mechanism currently used in the region. Then we provide the results of the simulation and discuss the implication of the results and identify important lessons for regional regulatory development from the perspective of international development institutions and those countries considering regional approaches.

Regional Model Development

The development of regional environmental regulatory frameworks, consistent with the convention, requires countries to make a number of decisions covering the appropriate balance between regional and sovereign control over decisions, the scope of the regulation, the approach to regulation, and financing. In order to examine the types of risks associated with developing sustainable financing, three conceptual approaches to regionalization are presented. The approaches represent different levels of regional integration and may be described as (a) complete, (b) cooperative, and (c) conforming.[7] Under complete models of regional integration countries give sovereignty of biotechnology regulatory decisions to a central decision-making authority that makes binding decisions on all aspects of the regulation and approval of biotechnology products. Under cooperative arrangements, some substantial sovereign aspects of regulation are ceded to a regional authority and for conforming systems a form of harmonization occurs with no substantial aspects of the sovereign decision being ceded to a regional body.

For the purposes of this analysis, three theoretical models are compared that represent different levels of regional integration. The models are a system that regulates pre-market, post-market, and commercial release decisions at the regional level (Option 1); regulates only commercial releases (Option 2); and facilitates harmonization between the countries (Option 3). The models outlined are illustrative and do not represent any specific model implemented in the region. The analysis provides an indication of the types of costs and trade-offs that might be encountered. Costs are based on data supplied by the National Biosafety Agency of Burkina Faso. However, analysis of these models cannot replace analysis of real and specific models being considered for implementation.

7. *An alternative characterization is offered by Paarlberg (2001).*

Option 1: Regional Regulation of Commercial Releases and Pre- and Post-Market Issues

Under this model, a regional regulatory agency or committee is established and would be responsible for all aspects of regulation, including pre-market, commercial release, and post-market decisions. The regional regulatory body would assess registration dossiers for field trials and commercial releases submitted by the developers and grant field-trial permits and commercial-use permits as well as establish the conditions or use or restrictions under which the GMO can be grown. The decisions of the regional body would be binding on all member states and valid throughout the region (except where a permit geographically limits the use of the GMO). This regional regulatory system provides the greatest level of integration and centralization of decision-making but comes at the cost of reduced independence of national-level decision-making. A single regional biosafety body is established under this model and any national biosafety agencies only play an advisory or public awareness function. Table 1 summarizes positive and negative aspects of this model.

Option 2: Regional Regulation of Commercial Releases; National Regulation of Field Trials

Under this model, a regional regulatory agency or committee is established to assess registration dossiers submitted by developers for the commercial release of a GMO and to grant sales permits valid for all its member states. The agency or committee would be responsible for commercial release decisions that would be binding on countries and would identify any needed use restrictions or other risk management measures. Under this regional system, countries would remain responsible for pre-registration issues, including the regulation and permit issuance for contained-use experiments and field trials (both confined and unconfined). The national regulatory agency would also be responsible for post-registration issues, including monitoring ecological impacts, ensuring compliance with any use restrictions, and enforcing any violations of the commercial release permit. Thus, both national and regional biosafety agencies would be established under this model, with national agencies regulating field trials and ensuring compliance of commercial-use permits; the regional body would be responsible for commercial release decisions applicable throughout the region. Therefore, this split of legal responsibilities between the national and regional authorities is very similar to what is currently done with pesticide regulation by INSAH and veterinary

Table 1. The positives and negatives of a centralized model.

+	• Covers all aspects of the regulatory decision and ensures the greatest level of integration and decision-making centralization • Risk-assessment data should be obtainable across all agro-ecological zones • Allowed under the CBP • Consistency across jurisdictions is guaranteed on data collection and compliance requirements • Potential cost savings • Potential efficiency and safety gains from better use of scientific capital both human resources and infrastructure investments • More likely avoid trade impediments • Countries with limited technical capacity benefit • Ensure access to GM food aid by land-locked countries through regional approvals • Provides for a uniform safety decision about a GMO that is applicable in all the countries, addressing the problem of obtaining different decisions by national agencies on the same GMO
−	• Does not account for the different stages of development of West African Economic and Monetary Union (WAEMU; in native language, Union Economique et Monetaire Ouest Africaine [UEMOA]) countries with respect to the approval of confined field trials* • Reduced independence of national-level decision-making depending on opt-out clauses • Need to develop regional mechanisms to get public participation in the decision-making process • Decision making of the committee and composition may be complicated

** Although, conditions of release by the regional body can restrict the areas where pre-market activities can take place. For example, in the US system, states are consulted and can refuse a field trial that is proposed to APHIS or can append state-specific conditions.*

Table 2. The positives and negatives of a moderately centralized model.

+	• Similar to veterinary medicines and chemical pesticides regional regulatory systems currently in operation in West Africa • Allows countries with the technical capacity and political will to conduct field trials to move forward; gives other countries the ability to limit such activities in the immediate future • Allowed under the CBP • Countries with limited technical capacity benefit • Some efficiency and safety gains are possible • Ensure access to GM food aid by land-locked countries through regional approvals • Provides for an open market throughout WAEMU for a commercial GMO once the regional authority has determined it is safe • Allows for a regional risk assessment to be considered in the decision-making process
−	• Risk-assessment data may not be obtained across all agro-ecological zones as this may depend on the countries that choose to participate in field trials • Consistency is not guaranteed on data collection and compliance requirements • Need to develop methods to obtain public participation in the decision-making process for commercial release decisions by the regional regulatory body • Requires each WAEMU country to have an operational national biosafety regulatory body with the legal authority to issues permits for pre-market activities • Not all WAEMU countries may have the technical capacity and financial resources to establish functional national biosafety regulatory systems

drug regulation by WAEMU (INSAH, 1999). Table 2 summarizes positive and negative aspects of this model.

Option 3: Regional Harmonization of Regulations and Procedures with all Decisions Conducted at the National Level

In this case, the development of a regional framework could focus on the standardization of regulations governing pre-market, commercial release, and post-market activities in member countries, such as standardized approaches for the classification, licensing, and management of contained facilities; the licensing, data requirements, and management of confined field experiments; and development of human and infrastructure capacity in the region, commercial environmental risk assessments, and insect resistance management. In effect, the regional body would act as a standards-setting body and represent the region in international and inter-regional negotiations. No regional agency is established and only national biosafety agencies exist.

Under this model, there is no regional regulatory body and all decisions about GMOs (i.e., approving applications for field trials and commercial products) are made by national biosafety regulatory agencies. An advisory regional body is established to develop a regional framework to help the national bodies in their regulatory process and decision-making. That regional advisory body could focus on standardizing regulations and procedures governing pre-market, commercial release, and post-market activities in member countries, applications, and data

Table 3. The positives and negatives of a harmonized model.

+	• Greater flexibility for individual national level decision-making that takes into account specific national issues • Accounts for the different stages of development of countries in WAEMU with respect to the approval of confined field trials. • Allowed under the CBP. • Countries with limited technical capacity benefit. • Some efficiency and safety gains are possible. • Standard procedures and data requirements will allow developers to test and market GMOs in more than one country without too much additional expense.
−	• Consistency on decisions is not guaranteed across countries • Likely to be the least cost effective model • Potential trade problems for land-locked countries • Does not ensure access to GM food aid by land-locked countries through regional approvals • No regional environmental or food-safety assessment • Does not address limited biosafety technical capacity in the region • Products approved in one country may move to neighboring countries where that product has not been approved

Table 4. The Excel spreadsheet projection used to generate the deterministic model.

	A	B	C	D	E	F	G	H	I	J	K
Year	Production value	Adoption	Production value (Bt)	Revenue	Initial	Cost esc	Renewal	Net	Field trial#	Field trial fees	Net
1	$219,450,500	3.0%	$6,583,515	$16,459	$572,215	1.00	$248,329	($804,085.4)	10	$100,000	($704,085)
2	$219,450,500	12.0%	$26,334,060	$65,835	$0	1.01	$250,812	($184,977.0)	10	$100,000	($84,977)
3	$219,450,500	18.0%	$39,501,090	$98,753	$0	1.01	$253,320	($154,567.5)	10	$100,000	($54,568)
4	$219,450,500	27.6%	$60,568,338	$151,421	$0	1.01	$255,853	($104,432.6)	10	$100,000	($4,433)
5	$219,450,500	38.0%	$83,391,190	$208,478	$0	1.01	$258,412	($49,934.0)	10	$100,000	$50,066
6	$219,450,500	48.0%	$105,336,240	$263,341	$0	1.01	$260,996	$2,344.5	10	$100,000	$102,344
7	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$263,606	$10,707.1	10	$100,000	$110,707
8	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$266,242	$8,071.0	10	$100,000	$108,071
9	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$268,905	$5,408.6	10	$100,000	$105,409
10	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$271,594	$2,719.5	10	$100,000	$102,720
11	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$274,310	$3.6	10	$100,000	$100,004
12	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$277,053	($2,739.5)	10	$100,000	$97,260
13	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$279,823	($5,510.0)	10	$100,000	$94,490
14	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$282,621	($8,308.3)	10	$100,000	$91,692
15	$219,450,500	50.0%	$109,725,250	$274,313	$0	1.01	$285,448	($11,134.5)	10	$100,000	$88,866

requirements, and the conduct and review of risk assessments. The regional advisory body could also develop human and infrastructure capacity in the region, educate the public and build public awareness, and even conduct a review of risk assessments for national regulatory agencies with limited technical capacity. Thus, under this model, the regional body would act as a standards-setting body ensuring that the regulatory procedures and processes in each of its member countries is nearly identical. The legal authority about whether to approve a GMO application, however, would remain with each national government. The advisory regional body might also represent the region in international and inter-regional negotiations. Table 3 summarizes positive and negative aspects of this model.

Risk/Sustainability Model Development

A basic revenue and expenditure cash-flow projection was developed with costs apportioned between initial and renewal costs. The approach is based on the standard business model for estimating net present values (Hare & McCutcheon, 1991) and is shown in Equation 1.

$$CashFlow_t = a_t \cdot v_t \cdot f + l_t - c_t \,, \tag{1}$$

where a_t is the adoption rate, v_t is the market value of cotton, f is the levy percentage, l_t represents the license fees collected, and c_t is the cost in year t. For broad comparison purposes between different scenarios, net present values (NPVs) are used. Typically investment decisions are based on a combination of the NPV of

Table 5. Production values (ICAC, 2006). An inverse Gauss distribution function was fitted to the total production data, shown as 594,000 metric tons in the bottom right-hand corner of the table.

	Benin			Burkina Faso			Mali			Senegal			Togo			Total
	Area (000 ha)	Yield (kgs/ha)	Prod (000 MT)	Area (000 ha)	Yield (kgs/ ha)	Prod (000 MT)	Area (000 ha)	Yield (kgs/ ha)	Prod (000 MT)	Area (000 ha)	Yield (kgs/ ha)	Prod (000 MT)	Area (000 ha)	Yield (kgs/ha)	Prod (000 MT)	Prod (000 MT)
1996/97	292	492	143	196	461	90	420	451	190	50	322	16	108	561	61	500
1997/98	386	388	150	295	476	140	498	437	218	54	317	17	135	542	73	598
1998/99	394	311	123	355	335	119	504	430	217	48	99	5	159	491	78	541
1999/00	372	408	152	245	445	109	482	408	197	18	360	6	154	362	56	520
2000/01	337	418	141	260	447	116	228	447	102	22	404	9	135	362	49	417
2001/02	357	482	172	359	440	158	532	451	240	32	486	15	173	404	70	655
2002/03	313	455	143	405	419	170	468	389	182	35	464	16	194	399	77	588
2003/04	323	440	142	459	443	204	540	482	260	45	491	22	187	365	68	696
2004/05	325	526	171	566	466	264	565	431	244	50	350	18	202	366	74	770
2005/06 est.	200	408	82	650	455	296	551	406	223	48	393	19	105	276	29	649
Risk model	**336**	**437.9288**	**147**	**423**	**446.008**	**189**	**496**	**433.3**	**215**	**42**	**380.731**	**16**	**154**	**413.6576**	**63**	**594**

profits, the payback period t, and the probability of success p. The NPV is the sum of the discounted stream of net cash flows. NPV requires subtracting all the costs necessary to bring the project into existence and an estimate of future revenues. The NPV is discounted at the hurdle rate of return, which is simply the rate of interest applied to discount the stream of net benefits. The hurdle rate represents an existing benchmark rate of interest, usually the rate of return demanded for projects calculated on the proportion of debt and equity used to finance the project.

Column A in Table 4 shows the value of production, which is based on 10 years worth of production and price data shown in Tables 5 and 6, obtained from the International Cotton Advisory Committee (ICAC, 2006). A Monte Carlo[8] simulation was run to obtain the mean of the distribution—$219,450,500 USD[9]—which appears in Column A. This assumes that the market levy will be applied to the value of production.[10] An inverse Gauss distribution function was fitted to the total production data (Table 5) and an exponential distribution function was fitted to the average producer prices (Table 6). The price data was combined with the production data to produce a distribution of production values. Column B shows the adoption rates assumed in the projection; these were obtained from James (2002). Column C combines Columns A and B to show the estimated value of Bt cotton production. Column D combines Column C and the market levy to estimate the revenue generated for the regulator. Columns E, F, and G present the esti-

Table 6. Producer prices (ICAC, 2006). An exponential distribution function was fitted to the average producer prices across five countries, shown as 184.61 in the table. The price data was combined with the production data to produce a distribution of production values in USD, shown as $219,316,680. This is one instance of the Monte Carlo simulation and is not equal to the mean used in the deterministic projection.

	Producer prices (CFA/kgs)				
Season	**Benin**	**Mali**	**Senegal**	**Togo**	**Avg.**
96/97	200	155	170	180	177
97/98	200	170	185	210	189
98/99	225	185	185	200	196
99/00	185	150	185	190	179
00/01	200	170	185	200	185
01/02	200	200	185	200	197
02/03	185	180	185	175	180
03/04	190	200	185	175	185
04/05	190	210	195	185	198
05/06	170	165	195	160	173
Risk model	184.61				
Production value	594,000,000 kgs $219,316,680				

8. *Monte Carlo analysis uses probability theory and numerical analysis to combine uncertainty in a way that reveals how probable each of the possible outcomes is (Ferson, Root, & Kuhn, 1998; Morgan & Granger 1990; Nelson, 1995; Vose, 1996).*
9. *Unless noted, all amounts in this article are in US dollars.*
10. *This is different to the value of exports.*

Table 7. Base cost assumptions used in the model to generate intial & renewal costs used in the financial projection.

Assumptions			Source
Exchange rate	500	CFA/USD	
	Fixed		
Computers	1500000	CFA/person	ANB
Software	$1,500	USD/person	Est
Vehicle	27000000	CFA/vehicle	ANB
Photocopier	2500000	CFA/copier	ANB
Fax	$500		Est
Phone equipment	$100	Per person	ANB
Computer network	$10,000	Per person	Est
Office furniture	$3,000	Per person	ANB
	Variable		
Phone/office	$50	Per office/ mth	Est
Electricity	113	CFA/KWh	World Bank
Electricity/office	$208	KWh/mth	DOE
Rent	50,000	CFA/month/ room	ANB
Average office size	20	m2	ANB
Water	10	Per office/ mth	Est
Office cost	$10.00	Per office/ mth	Est

mated initial and renewal cost associated with establishing a single regional regulator and allow for cost escalation in the renewal costs. Column H presents the net cash flow, which is revenues less costs or Column D less Columns E and G. Columns I and J estimate potential revenue from field trails, and Column K represents the net cash flow taking into account revenue generated from field trials. Important assumptions include: 1) adoption rates, 2) the stability of the market price for cotton, and 3) the stability of the exchange rate.

A number of cost assumptions, including salaries, travel and training costs, and so on, were made during the development of the deterministic model and were used to generate intial and renewal costs. These assumptions affect the intial and recurrent expenditure by the agency and may be partially variable in nature (Tables 7, 8, and 9). The analysis is predicated on a regulatory approval process that does not require extensive equipping of a regional biosafety laboratory. The development of such a laboratory could add substantially to the initial investment required on the part of donors. Estimates provided by the Institut des Science de l'Environment suggest equipment costs in the order of $500,000, but this is likely to substantially underestimate the

Table 8. Initial cost assumptions associated with establishing the regional biosafety agency.

Initial costs		Optional studies	
# offices	14	**Situation analysis**	$ -
# people	16	**Economic benefit**	$ -
Computers	$42,000	**Stakeholder mapping**	$ -
Software	$21,000	**Risk communication**	$100,000
Vehicle	$54,000	**Strategic environmental assessment**	$150,000
Photocopier	$5,000		
Fax	$500		
Phone	$1,600		$250,000
Network	$10,000		
Furniture	$48,000		
Subtotal	$182,100		
	Initial training		
	# people	**Cost/person**	**Source**
Number of cty	8		WAMEU
Inspectors/cty	2		Est
Field trial inspectors	16	$32,000	PBS
CFT applications	10	$32,000	PBS
Regional workshop	30	$80,000	PBS
Subtotal		$144,000	

amount of money required to be invested to develop a state-of-the-art regional laboratory. Additional projection assumptions are shown in Table 10. Adoption rates were taken from James (2002) and were estimated in the later years, with an assumed maximum of adoption of 50% (Table 11). Different adoption patterns are discernable between China, Mexico, and South Africa; however, all provide relatively rapid, if different, adoption scenarios. In contrast, Argentina provides a low adoption rate scenario.

A stochastic version of the model was developed to explore the impact of variability on the time taken to reach sustainable financing using a combination of market-levy and field-trial revenues. The model uses an inverse Gauss distribution function fitted to the total production data (Table 5) and an exponential distribution function fitted to the average producer prices (Table 6). The price data was combined with the production data to produce a distribution of production values, from which random values were drawn using Latin Hyper-

Table 9. Renewal costs generated from the cost assumptions for the regional biosafety agency.

		Cost/mo				
Variable	**Grade**	**(CFA)**	**(USD)**	**Annual cost**	**# people**	**Total per year**
			Salary			
WAEMU	A	400,000	800	$9,600	1	$9,600
	B	300,000	600	$7,200	11	$79,200
	C	200,000	400	$4,800	2	$9,600
	D	100,000	200	$2,400	2	$4,800
Subtotal salary					16	$103,200

Variable costs	**Grade**	**# offices**	**Office space (m^2)**		**Rent**	**Electricity**	**Water**	**Phone**	**Office**	**Total**
	A	1	25	25	$125	47	10	50	$10	
	B	11	20	220	$1,100	518	110	550	$110	
	C	1	20	20	$100	47	10	50	$10	
	D	1	20	20	$100	47	10	50	$10	
Subtotal monthly		14			$1,425	$659	$140	$700	$140	
Subtotal annual					$17,100	$7,910	$1,680	$8,400	$1,920	$37,010

Vehicle travel	
Car maintenance (CFA/yr)	2,000,000
Travel (km)	40,000
Gas (CFA/l)	700
Efficiency (l/100 km)	10
Total per year	**$5,600**

			Air travel		
# persons	**# trips**	**Avg stay**	**Per diem**	**Avg air**	**Total cost**
5	5	7	$250	$1,500	$81,250
2	2	7	$300	$3,000	$20,400
1	1	14	$350	$6,500	$11,400
Total					$113,050

Table 10. Projection assumptions.

Field trial revenue	$1,000 per trial
Adoption rates	Optional
Number of trials	10
Levy	0.10% of export value Bt cotton
Cost inflation	1.00%

cube sampling of the distribution to obtain variation is market values.

Results

The type of regulatory system adopted may affect the cost structure of the regulator and therefore impact on the potential for moral hazard arising from shortfalls in financing. Regulatory cost results are presented in terms of assumed differences in the costs of regulation and indicate the anticipated relative ordering of the three models outlined above. The results do not reflect any actual system in place within the region, but reflect pos-

Table 11. Adoption rates.

Year	China	Mexico	Argentina	S. Africa
1	1.0%	1.0%	0.7%	3.0%
2	2.0%	7.0%	3.6%	12.0%
3	11.0%	15.0%	5.4%	18.0%
4	22.0%	20.0%	5.3%	28.0%
5	31.0%	33.0%	6.0%	38.0%
6	40.0%	35.0%	7.0%	48.0%
7	50.0%	40.0%	8.0%	50.0%
8	50.0%	45.0%	9.0%	50.0%
9	50.0%	50.0%	10.0%	50.0%
10	50.0%	50.0%	10.0%	50.0%
11	50.0%	50.0%	10.0%	50.0%
12	50.0%	50.0%	10.0%	50.0%
13	50.0%	50.0%	10.0%	50.0%
14	50.0%	50.0%	10.0%	50.0%
15	50.0%	50.0%	10.0%	50.0%

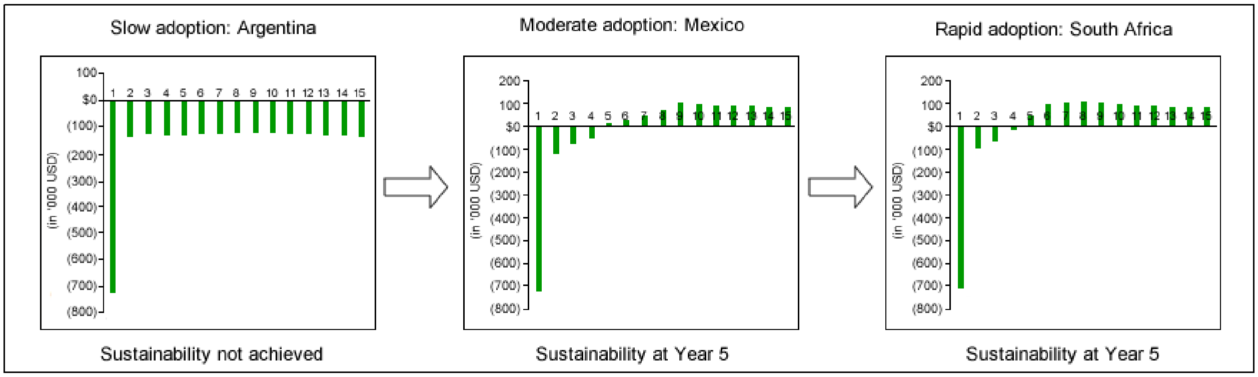

Figure 1. Option 1: Cash-flow signature using various adoption rates and showing the number of years to sustainable financing for a market levy of 0.25% on the value of production and assuming $100,000 in field-trial revenue.

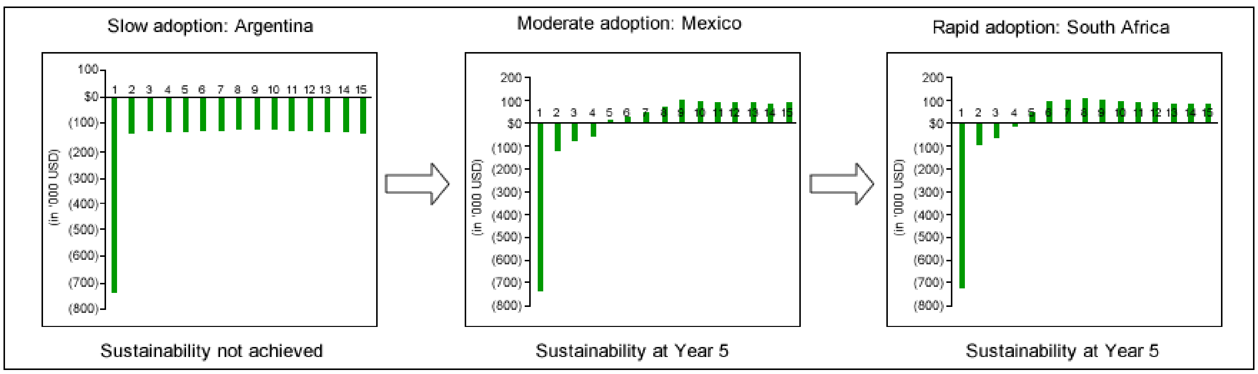

Figure 2. Option 2: Cash-flow signature using various adoption rates and showing the number of years to sustainable financing for a market levy of 0.25% on the value of production and assuming $100,000 in field-trial revenue.

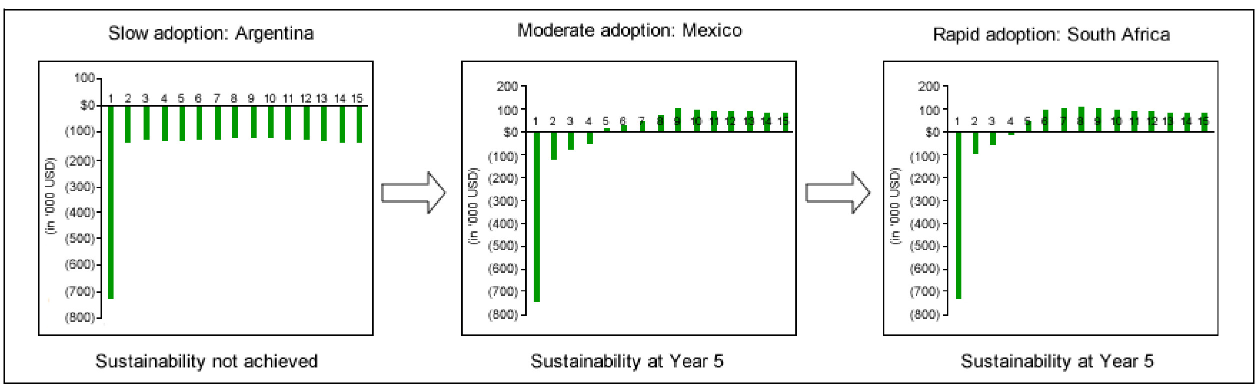

Figure 3. Option 3: Cash-flow signature using various adoption rates and showing the number of years to sustainable financing for a market levy of 0.25% on the value of production and assuming $100,000 in field-trial revenue.

sible ways in which regional regulation may be organized. Costs are based on data supplied by the National Biosafety Agency of Burkina Faso and various assumptions that will vary from the costs incurred in practice. The cost of the different options impacts the regulators costs and, when combined with the amount and timing of revenue streams, provides estimates of the amount of initial and recurrent expenditure required to support the regulator. This in turn provides an estimate for the amount of financing and the timing of financing requirements.

Regulatory Costs

Option 1. A single regional biosafety agency is established and the national biosafety agencies are abolished. The financial analysis suggests that initial funding in the vicinity of $600,000[11] is required to establish the regional agency and provide for critical training that the initial capacity-building needs. Further recurrent funding of approximately $250,000 is required per annum.[12]

Option 2. A regional biosafety agency is established and the national biosafety agencies are retained, but with reduced responsibilities. The financial analysis suggests initial funding in the vicinity of $600,000 is required to establish the regional agency and provide for critical initial capacity-building needs. Further recurrent funding is required of approximately $125,000 per annum for the regional agency and $1.0 million per annum for maintaining the eight national biosafety agencies. Similar training costs are anticipated for both Option 1 and Option 2 because of similar training needs. The costs for Option 2 were generated by making the assumption that smaller recurrent staff training and operating budgets occur at both the regional and national levels, equivalent to 50% of the costs associated with the renewal costs of Option 1 (the single regional regulator). Some cost reductions at the regional level arise because pre-market (confined field trials) and post-maket (enforcement and compliance) occur at the national level.

Option 3. National biosafety agencies are retained. The financial analysis suggests initial funding in the vicinity of $420,000 is required to establish the regional harmonization efforts and provide for critical training and initial capacity-building needs. Further recurrent funding of approximately $1.5 million is required per annum to support the eight national biosafety agencies. Initial costs are reduced, as no initial investment is required in establishing the regional office. It is likely that a number of studies will need to be done and training provided to establish regional harmonization, accounting for the initial costs. It is also assumed that smaller staff, training budget,s and operating costs equivalent to 75% of those in Option 1 are incurred by the countries.

Risk/Sustainability Analysis

Using the adoption patterns for Argentina, Mexico, and South Africa to illustrate the range of adoption patterns from slow to rapid, the cash-flow signatures show that sustainable financing is achieved under scenarios of moderate to rapid adoption of Bt cotton (Figure 1). In the case of slow adoption, sustainable financing is not achieved.

For regional Options 1, 2, and 3, the impact of varying adoption rates with the market levy of 0.25% are shown in Figures 1, 2, and 3, respectively. The effect of increasing the market levy for Options 1, 2, and 3 from 0.25% to 0.50% and 0.75% are shown in Figures 4, 5, and 6, respectively. The results suggest that a higher market levy combined with rapid adoption could result in sustainable financing within three years of the first regional regulatory approval of Bt cotton. However, a market does not currently exist for Bt cotton in West Africa, and gap financing may be required from institutional investors in order to avoid any potential safeguard risks that may be associated with the financial incentives for the regulatory agencies for approval and promotion of the adoption of Bt technology without appropriate processes being followed due to shortfalls in financial provisioning after the end of the project (3 years) and when adequate revenue is available from the market levy.

Some evidence exists that adoption could be rapid for some countries (2 to 3 years). In situations where farmers obtain seed from the national cotton company, adoption may partly be limited by the ability of the national research system and cotton company to bulk up seed for distribution. It is expected that this could take 2 to 3 years. If Bt cotton seed production occurs during the project implementation period, it is possible that farmer adoption could lead to a sustainable financial situation for the regulator within 3 to 5 years after first approval, reducing the need for gap financing.

The results from the stochastic simulation are presented in Figures 7, 8, and 9 and suggest that sustainable financing may be achieved within 3 years using a 0.75% market levy on production values with a probability of 99% after approval of Bt cotton assuming that the adoption rates follow the assumed rates for South Africa and $100,000 in field trial revenue is generated. However, if adoption rates are slower than those assumed then this would reduce the probability of achieving sustainable financing 3 years after regulatory approval.

Discussion

The results of our analysis should be used to inform thinking on the execution of financial instruments that support the development of regional environmental reg-

11. *This includes $250,000 for regional studies.*
12. *A caveat applies to these numbers. The initial cost is sensitive to the amount of capacity-building needed and to the number and types of foundation studies required by the agency. The initial cost could be as high as $1.0 to $1.5 million if several regional studies are required on different aspects of the regulatory system, such as human capacity, training needs, risk perceptions, and so on.*

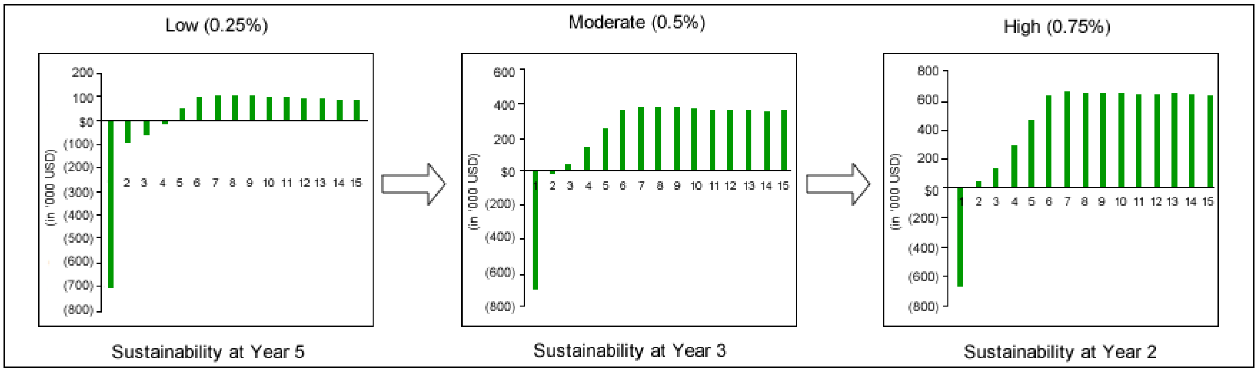

Figure 4. Option 1: Cash-flow signature using various market levies and showing the number of years to sustainable financing. The analysis assumes the rapid adoption scenario for Bt cotton, i.e., using assumed South African adoption rates and $100,000 in field-trial revenue.

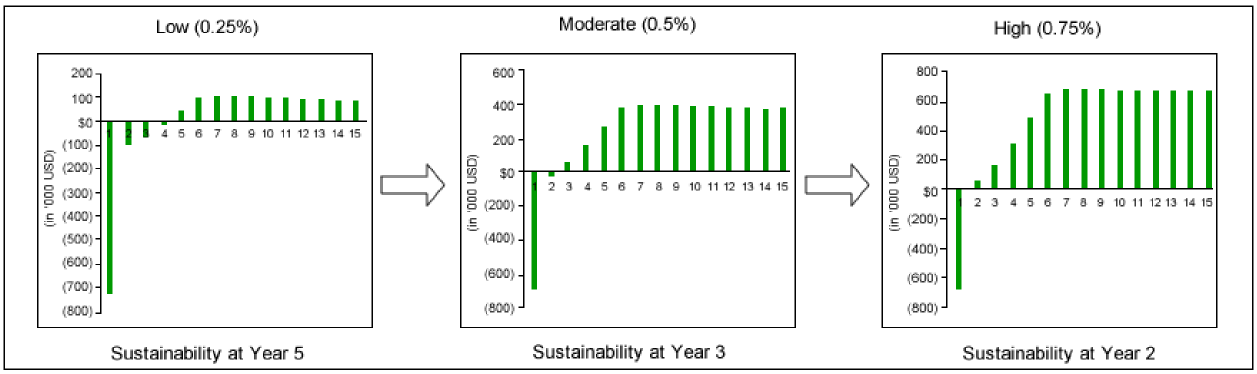

Figure 5. Option 2: Cash-flow signature using various market levies and showing the number of years to sustainable financing. The analysis assumes the rapid adoption scenario for Bt cotton, i.e., using assumed South African adoption rates and $100,000 in field-trial revenue.

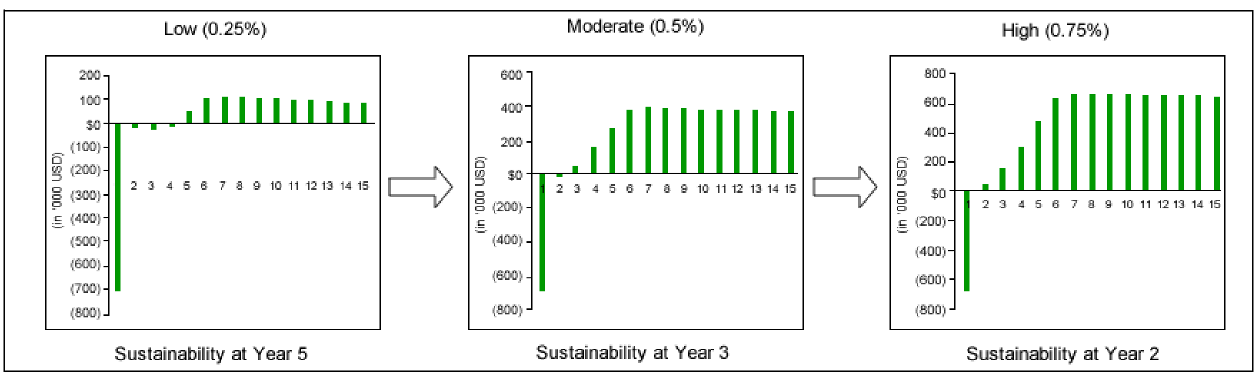

Figure 6. Option 3: Cash-flow signature using various market levies and showing the number of years to sustainable financing. The analysis assumes the rapid adoption scenario for Bt cotton, i.e., using assumed South African adoption rates and $100,000 in field-trial revenue.

ulation. This is a familiar problem for the insurance and reinsurance industries (or risk industries), which conceptually analyze this type of problem using a value creation chain, composed of risk discovery, risk quantification, risk mitigation, and risk transfer (Hutchin, 2002). Much of the preceeding analysis deals with the identification of the moral hazard and risk associated with using market levies when no market currently exists for Bt cotton and on the quantification of this risk. Therefore, the predominant focus of this section is on exploring mechanisms and options for the mitigation and transfer of this risk and the potential implication for donors.

However, there are a number of limitations and caveats with the risk quantification analysis presented in the results section. While some indication of the relative cost ranking of the different models is provided, the ranking is based on assumptions about relative cost sav-

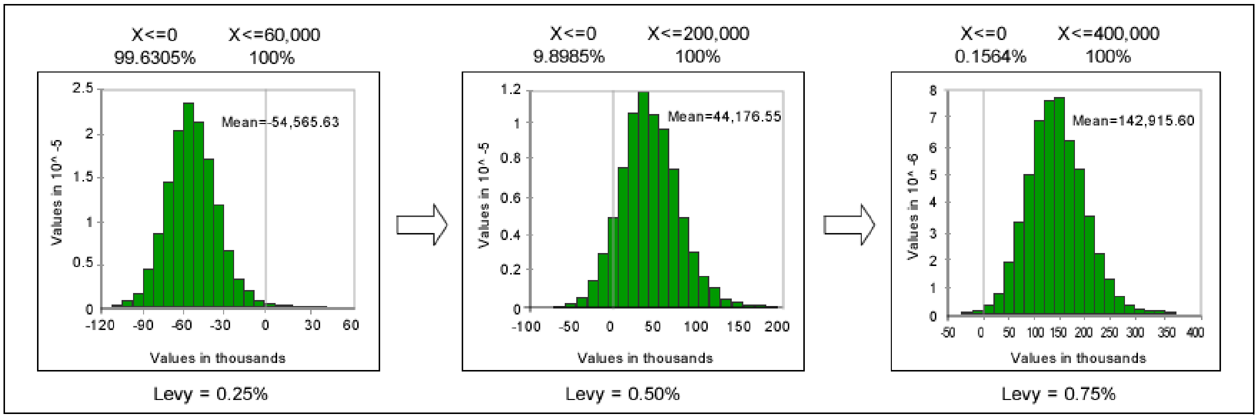

Figure 7. Option 1: Shows the change in probability of achieving sustainable financing 3 years after approval of Bt cotton assuming that the adoption rates follow the assumed rates for South Africa; $100,000 in field-trial revenue is assumed. For a 0.25% levy there is less than a 1% chance of sustainable financing; this increases to a 90% chance if 0.5% levy is used or 99% is a 0.75% levy is used.

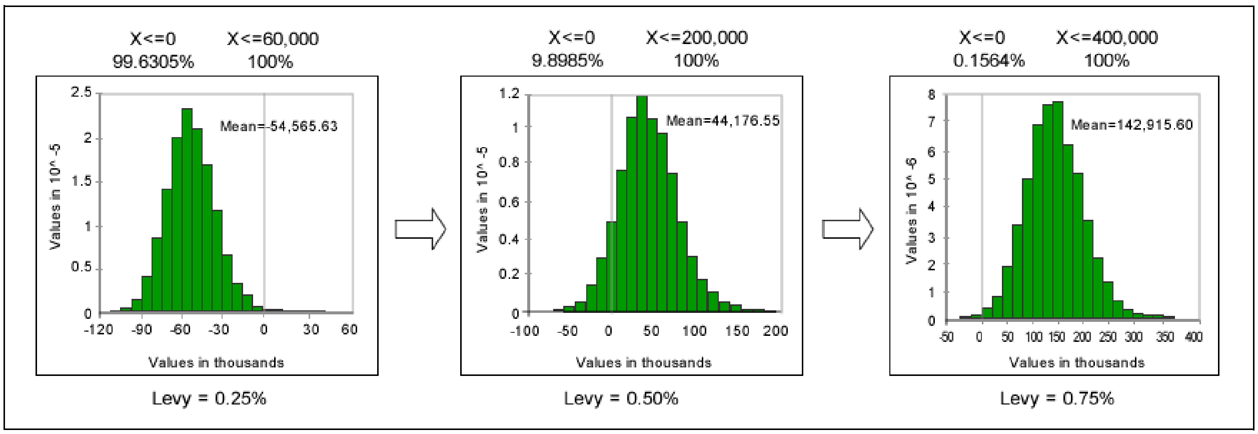

Figure 8. Option 2: Shows the change in probability of achieving sustainable financing 3 years after approval of Bt cotton assuming that the adoption rates follow the assumed rates for South Africa; $100,000 in field-trial revenue is assumed. For a 0.25% levy there is less than a 1% chance of sustainable financing; this increases to a 90% chance if 0.5% levy is used or 99% is a 0.75% levy is used.

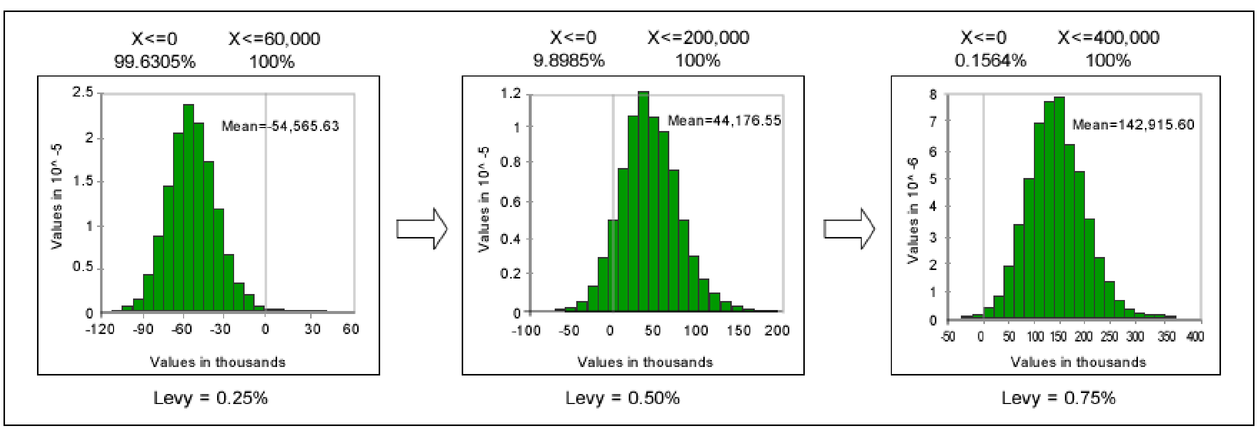

Figure 9. Option 3: Shows the change in probability of achieving sustainable financing 3 years after approval of Bt cotton assuming that the adoption rates follow the assumed rates for South Africa; $100,000 in field-trial revenue is assumed. For a 0.25% levy there is less than a 1% chance of sustainable financing; this increases to a 90% chance if 0.5% levy is used or 99% is a 0.75% levy is used.

ings between the different models and provides illustrative value. Further analysis of existing regional systems may provide actual data to provide a more reliable indication of the types of efficiencies that might be expected from different types of regional integration. It is also possible that rank order of these models could change depending on the actual implementation details of the specific proposals. Important assumptions are made about the nature of the uncertainty—the distribution, mean, and variance. These patterns may change, as the model simulations rely solely on statistical fits of past data. Exact numerical results will depend on the actual distributions and parameter estimates experienced in the future. However, the key issue is the impact that variation has on the extent and likelihood of an environmental safeguard risk arsing from the moral hazard associated with financing gaps.

Generally options for financing the system can be classified as (i) supported from general revenue (examples include countries in the European Union); (ii) short-term governmental grants such as the World Bank and GEF funding for biosafety; and (iii) assorted private-sector imposts such as market levies, license fees, and applications fees. Due to the limited financial resources of many developing countries and the need to spend limited conservation resources on urgent conservation needs, reliance is generally placed on short-term grants and private-sector imposts. Apart from the market levy, a number of different financing mechanisms—or a combination of these—potentially exist for financing biotechnology regulatory systems that aim to protect biodiversity and include using license and applications fees, bonds, and direct contributions from donors and countries (from general revenue).

License and Applications Fees

Public-sector institutions account for approximately 94% of the $12.1 billion spent annually on agricultural research in developing countries during the mid-1990s (Pardey & Beintema, 2001). As more research is done, biotechnology license and application fees could be charged on institutions conducting biotechnology research with funds used to support the regulatory system. However, cost may be prohibitive for many but the wealthiest public-sector institutions. Regulatory approval cost estimates vary widely but may be in the order of $500,000 per approval.

Bonds

Bonds[13] could be sold to global debt markets with a World Bank/Multilateral Investment Guarantee Agency (MIGA) guarantee. Such an approach may offer one potential avenue for a public-private partnership to support the cost of regulating biotechnology. The bond portfolio would be backed by returns generated from a market levy on the production value of Bt cotton in the region. Funds would be used to pay the coupon plus face value of the bond upon expiration.

The main risks with this approach to funding would be potential default risks and mismatch risks arising from mismatching of cash inflows and outflows from the revenue generated from the levy and repayments on the debt. Risk-management options include the establishment of financial reserves to cover mismatching risks associated with revenue volatility and expenditure stability. Some proportion of the risk may be addressed by expressing more of the regulatory cost as variable costs, which can be reduced during times of revenue decreases. However, this alone is unlikely to address the revenue impact of price shocks. Generally, the establishment of reserves will increase the financial strain in the early years of the project and provide earnings from the investment of these funds (Jorion, 2005).

Direct Contributions

Direct investments from donors and contributions from member countries could be used to support the system. However, this creates the potential problem of unpaid contributions; this has hampered ECOWAS, which has been unable thus far to design an adequate funding structure to replace its current reliance on member-state contributions. The existing funding structure has proved inadequate, leading to an accumulation of $38.1 million in unpaid member-state dues as of 2000 (Adedeji, 2004).

Implications for Donors—Reputational Risk

The market levy places a charge on the value of production or seed sales or exports to provide financing for a regional regulatory system. It is also likely that a market-levy system would be based on the value of production due to the structure of commercial operations within the region, which is based on parastatals[14] that

13. *A bond is a security that is issued in connection with a borrowing arrangement. In exchange for receiving cash, the borrower is obligated to make a series of payments to the bond holder (Jorion, 2005).*

provide a reliable source of seeds, fertilizers, and pesticides to farmers and also provide a fixed price. All farm production is sold to the parastatals, who deduct the cost of farm inputs (i.e., providing farm financing) and, under the current system, farmers receive free seed. With the introduction of Bt cotton, it is anticipated that farmers will pay the parastatals for the seed and this increase in costs will be offset by reduced demand for pesticides.[15] The market levy would be an additional cost taken by the parastatals and paid to the regional body regulating biotechnology. Interviews conducted by the authors with farmers' organizations[16] within the region suggest that it may be unpopular to charge farmers for the cost of seeds and biosafety regulation.

The critical point is that farmers do not have a choice of seed that they use. The implications of this are that adoption rates may be faster than anticipated and limited by the ability to bulk up seed suitable for the different microclimates encountered in West Africa. This tends to support the argument of rapid adoption and therefore lowers risks associated with potential shortfalls in financing the regulatory system. However, it does not remove the moral hazard and potential incentives to approve Bt cotton without appropriate testing; importantly, it may add to potential reputational risk for donors supporting regional frameworks. Farmers have no choice and will be required to plant the seeds given to them irrespective of their preferences or market opportunities. Based on interviews conducted in the region with farmer organizations, it is reasonable to expect that a lack of choice is likely to be a potential source of reputational risk to donors. It is also anticipated that local NGOs would reasonably object to any system of compulsion. Therefore pressure for market segregation and choice may delay the introduction of Bt cotton in the region, increasing the need for sustainable financing options. An alternative view is that some farmers will be persuaded—based on the field trials in Burkina Faso—to plant Bt cotton and competition will ensue for farmers to have access to the technology. This would tend to support the argument that West Africa will follow the pattern of adoption in India. However, the reported recent travel ban to observe field trials in Burkina Faso should raise concerns over transparency and may add to regional insecurities about the technology, again increasing the need for sustainable financing options.

Conclusions

Each mechanism of financing creates different challenges for obtaining a political agreement over the mechanism and level of funding to be provided. It appears likely that a regional system for biosafety regulation would be financed using a combination of revenue sources, including a market levy and field-trial revenues. This approach is consistent with the approaches currently used in the region.[17,18] It may also be possible for bonds to be sold into global debt markets, with the World Bank underwriting the default risk and proceeds used to provide initial funding of regional regulatory systems. However, the key limiting factor for sustainable financing using the market-levy approach will be the adoption rates for Bt cotton within the region. Accelerating adoption, increasing the market levy and reducing the recurrent expenditures will reduce the number of years taken to produce a self-sustained financial situation. Alternative funding mechanisms such as license fees and application fees could be used but may necessitate additional financial imposts on public-sector development institutions and universities. Public-private partnership could also provide some financing, but it was practically difficult to obtain any clear commitments from potential investors for support of a system that is still in the early stages of development. Farmers groups interviewed expressed concern over the market-levy approach.

Given all the complications associated with the market levy, it would appear to be prudent for donors to investigate insurance-based solutions, such as those offered by MIGA. However, any product offering would still have to deal with the problem of moral hazard. If this problem cannot be addressed, then the most effective way to remove this risk is by a (potentially unpopular) levy on current cotton production. Alternatively, greater commitment is needed from donors such as the Global Environment Facility. Given the many other important conservation needs in Africa, it is important

14. *A company or agency owned or controlled wholly or partly by the government.*
15. *This is based on interviews with Campagnie Malienne pour le Developpement des Textiles (CMDT) and the Société Burkinabè des Fibres Textiles (SOFITEX), which is the main cotton parastatal in Mali and Burkina Faso (June-July 2006).*
16. *Nationale des Organisation Paysannes du Mali (CNOP)*
17. *In 1993, ECOWAS revised its treaty to apply a 0.5% levy on all products imported from non-ECOWAS countries so as to finance integration projects (Asante, 2004). WAEMU uses a market levy to fund its regulation of veterinary medicines.*
18. *Agreement on veterinary medicines.*

that a more transparent debate occurs over the use of GEF funds to support market-development activities for national agricultural research centers and multinational seed companies.

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