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IFPRI Discussion Paper 00753

February 2008

Regional Biotechnology Regulations

Design Options and Implications for Good Governance

Regina Birner, International Food Policy Research Institute
and
Nicholas Linacre, The University of Melbourne

Development Strategy and Governance Division
and
Environment and Production Technology Division

INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE

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INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE

2033 K Street, NW
Washington, DC 20006-1002 USA
Tel.: +1-202-862-5600
Fax: +1-202-467-4439
Email: ifpri@cgiar.org

www.ifpri.org

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ABSTRACT

Many developing countries are currently in the process of designing regulatory systems that should allow them to use genetically modified organisms (GMOs) for agricultural development, while also managing the food safety and environmental risks potentially associated with these technologies. Various regions of the developing world are seeking to establish regional systems of biotechnology regulation. However, considerable costs are associated with biotechnology regulation, and biosafety specialists are scarce. In addition, there is no consistent understanding of how regional systems of biotechnology regulation can be designed to be effective and efficient, while also fulfilling the principles of good governance, such as transparency, voice and accountability, control of corruption, and avoidance of special interest capture. There are a wide variety of possible regional approaches, differing with regard to the level of centralization, the scope of the regional system, the types of regional institutions and processes, and the types of financing mechanisms. Here, based on findings in the fields of environmental and fiscal federalism and transaction costs economics, we develop a conceptual framework for the assessment of regional systems of biotechnology regulation. The framework specifies design options and assessment criteria, and identifies major trade-offs and their mediating factors. We use the case of West Africa to illustrate this framework, and refer to the European Union for comparison. Our analysis indicates that involving regional experts, stakeholders and policy-makers in the design of a regional regulatory system will help fill knowledge gaps and generate conclusions regarding the trade-offs involved in regional biotechnology regulation.

Keywords: regional biotechnology regulation; regulatory federalism; transaction cost economics; West Africa; European Union

1. INTRODUCTION

Genetically modified (GM) crops offer a considerable potential for contributing to agricultural development. While the perceptions regarding the risks associated with this technology differ widely, there is agreement that the introduction of GM crops requires regulation. In fact, regulation is the primary policy instrument that societies use to manage the risks associated with this technology. The institutional design and function of a regulatory system have far-reaching implications in terms of making this technology available to farmers, ensuring environmental and food safety, and creating incentives for innovation. Whether or not the public will develop or maintain trust in biotechnology also depends to a large extent on the design and functionality of the regulatory system. Therefore, biotechnology regulation is an important element of good governance in the agricultural sector.

Agricultural biotechnology regulation seeks to manage the different types of potential risks associated with GM technology. The environmental risks include gene flow to non-cultivated plants, which may have negative effects for biodiversity. The agronomic risks can include resistance problems in the GM crops themselves, and (as a consequence of gene flow) in weeds related to the cultivated crops (Ellstrand, Prentice, & Hancock, 1999). Another issue that regulation can address is the potential of gene flow to the fields of farmers who prefer growing non-GM crops, and who may lose a price premium as a consequence (co-existence regulations). The food and feed safety regulations seek to prevent the inclusion of allergens and toxins in GM crop-derived food or feed. Another area of biotechnology regulation deals with the import and export of GM crops and their derived products. The labeling of food and feed derived from GM crops, as well as the socio-economic risks associated with the introduction of GM crops, can all be subject to regulation.

Considerable disagreement exists within and across countries regarding the importance of these risks and the scientific possibilities for adequately assessing them. There is also disagreement regarding the need for labeling and regulation of socio-economic risks. This disagreement has led to the development of a wide range of regulatory systems around the world, varying from stringent to permissive. The regulatory system of the EU is widely considered to be on the stringent end of this spectrum, while that of the US is on the permissive end (Paarlberg, 2001; Bernauer, 2003). Obviously, regulatory decision-making is only partly determined by the institutional features of a given regulatory system. The global "regulatory divide" in biotechnology regulation is also due to differences in political and economic factors, as well as in societal values (Bernauer, (2003). Contrasting regulatory philosophies play a role, too, as pointed out by Arcuri (2000). In this respect, a "technocratic" philosophy, which assumes that the risks involved in biotechnology can be fully understood by science and managed in a rational fashion, may be distinguished from a "deliberative" philosophy, which holds that scientific

knowledge can inform, but not replace, policy-maker and societal debates regarding public decisions on biotechnology (Bromley, 2006).

Against the background of this global regulatory divide, many developing countries are currently in the process of developing regulatory systems for biotechnology. More than 120 countries party to the Cartagena Protocol on Biosafety are currently participating 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 next stage, namely the UNEP-GEF project on the "Implementation of National Biosafety Frameworks".[1] Concerns about the costs associated with biotechnology regulation, and potential problems with controlling trans-boundary movements of genetically modified organisms (GMOs) across neighboring countries have sparked a strong interest in regional collaborations for biotechnology regulation throughout the developing world (GEF, 2006).

Despite this increasing interest in regional regulation worldwide, however, there is almost no literature examining which type of regional coordination for biotechnology regulation would be preferred, based on the context- and region-specific conditions. Regional coordination can obviously take different forms, ranging from informal collaborations, mutual recognition systems and voluntary guidelines on the harmonization of regulatory standards, all the way to the establishment of a regional regulatory system overseen by a central regulatory authority. Countries that are interested in regional regulation need to answer a range of questions regarding the governance structure of that system. Which degree of centralization should they aim for? How should the institutions for regional biotechnology regulation be structured? How independent from political decision-making bodies should they be? Which forms of public participation should they entail? How should the regional regulatory system be financed? To design a regional regulatory system, the countries need to assess which factors influence the answers to these questions.

The goal of this paper is to help bridge the knowledge gap on regional biotechnology regulation by developing a conceptual framework that identifies key factors for consideration when designing a regional system. This framework is mainly based on two branches of literature: the theory of environmental and fiscal federalism (Oates, 2001; Oates, 2004), and the New Institutional Economics literature, especially the transaction cost approach developed by Williamson (1991). The paper also takes the classical institutional economics literature into account (Bromley, 2006).

The region of West Africa is taken as an example to illustrate this framework. West Africa is an interesting case, as several initiatives are currently underway in this region 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

[1] See http://www.unep.ch/biosafety/parcountrieslist.htm.

for a Common Biosafety Regulation. 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 (WAEMU) also plan to establish a common regional system for biotechnology regulation. These examples allow us to illustrate the design options, potentials and challenges of regional biotechnology regulation.

Empirical data on biotechnology regulation in West Africa were collected by a multidisciplinary team in Burkina Faso, Mali, Benin, Togo and Senegal, between May and August of 2006. Approximately 130 semi-structured interviews were held with stakeholders from ministries, research institutes, producer organizations, non-governmental organizations (NGOs), and the private sector.[2] In-country document collection and additional secondary research were used to substantiate the interviews. For the purpose of comparison and illustration, the paper also refers to the regional system of biotechnology regulation in the European Union (EU), using secondary sources on biotechnology regulation in the EU.

By developing a conceptual framework based on economic theory, the paper seeks to improve decision-making during the design of regional regulatory systems. The framework does not provide a blueprint for a regional system for biotechnology risk regulation in West Africa or elsewhere. Likewise, the regulatory system in the EU is used only to illustrate the discussion, not as a "model" for other countries to follow. The EU system was chosen because it is de facto the only fully integrated regional system implemented worldwide.[3] As indicated above, this system is located on the stringent end of the regulatory spectrum, and is therefore not representative of the existing regulatory systems. Rather than providing blueprints or models, we herein attempt to identify issues and options relevant to the design of a regional regulatory system.

Our goal is to identify the factors and trade-offs that political decision-makers may wish to consider during the design process. The development of a regulatory system, at both the national and regional levels, necessarily involves societal value judgments, for example, about the level of acceptable risk (Fischhoff, Lichtenstein, Slovic, Derby, & Keeney, 1981). Hence, it is important that countries and regional communities make their own decisions, in line with the preferences of their societies, on the way in which they wish to regulate biotechnology. International agreements such as the Cartagena Protocol on Biosafety, regional treaties, and emerging international standards for biotechnology regulation provide important conditions for framing such decisions. Together with other disciplines, economic theory can provide insights for making decisions on regional regulatory design within these conditions. However,

[2] A list of the organizations visited for this study is presented in the Annex.
[3] One may argue that the regulatory system established under NAFTA also fulfills this criterion.

research can only inform, not replace, the deliberations of policy-makers and society regarding what they consider to be legitimate and justifiable reasons for various public policy decisions (Bromley, 2006).

This paper is structured as follows. Section 2 briefly describes major initiatives for regional biotechnology regulation in West Africa and outlines the system in place in the European Union for the purpose of comparison. Section 3 presents the conceptual framework and Section 4 derives conclusions for the West African case.

2. THE QUEST FOR REGIONAL BIOTECHNOLOGY REGULATION IN WEST AFRICA

Background

The initiatives to establish regional systems for biotechnology regulation in West Africa are largely motivated by hopes that Bt cotton (insect-resistant cotton, which is genetically engineered using the soil bacterium Bacillus thuringiensis) may be able to increase the competitiveness of cotton production in the region. West Africa is one of the major cotton producing regions in the world. In Benin, Burkina Faso, Mali and Côte D'Ivoire, which account for 80% of cotton production in West Africa (USDA, 2006), cotton is a major revenue source for a large part of the rural population, and a major source of export earnings. In Burkina Faso, cotton exports account for more than half of all export earnings, while those in Benin and Mali account for about one third and one quarter of export earnings, respectively (USDA, 2006). In the face of strong international competition, a long-term decline in world market prices, and various agronomic challenges, agricultural research institutions and policy-makers have developed an interest in introducing GM cotton. In collaboration with Monsanto, Burkina Faso started field testing Bt cotton in 2003. Mali has contacted Monsanto and Syngenta to express interest in starting field trials, and the Côte d'Ivoire Agricultural Research Institute has suggested that once Côte d'Ivoire restores peace, it could become a regional leader in biotechnology research (USDA, 2006).

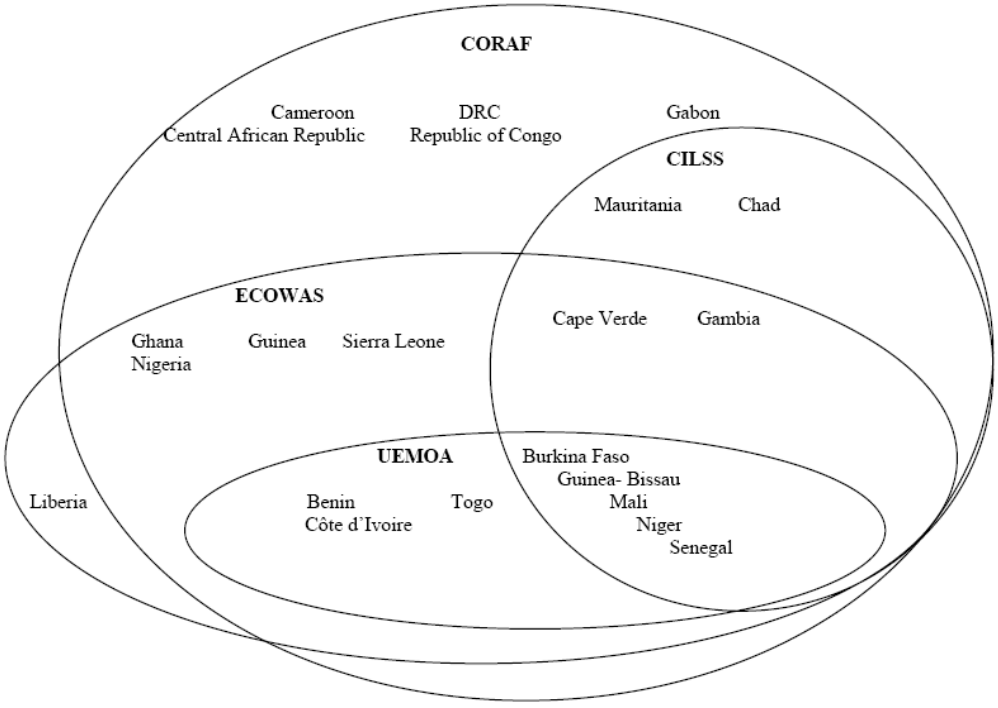
Among the West African countries, to date only Burkina Faso has passed a biosafety law and established a regulatory system capable of processing applications for field trials and commercial releases. Most of the other countries have completed a Biosafety Framework with the assistance of UNEP-GEF, and they are in the process of developing biosafety laws (Jaffe & Meissa Dieng, 2007). The introduction of biotechnology has been politically contested throughout the region; these debates have delayed the passage of biosafety legislation in various countries, especially those having strong civil societies, such as Mali and Senegal (Birner, Resnick, & Linacre, 2007). As of 2002, Benin had declared a five-year moratorium on GMO use (Jaffe et al., 2007).[4]

As indicated above, three efforts are currently underway to establish regional systems of biotechnology regulation in West Africa, led by CILSS, WAEMU and ECOWAS in collaboration with CORAF. Figure 1 shows the countries that are currently members of these regional bodies. A number of factors provide a rationale for this interest in regional approaches to biotechnology regulation, as follows: (1) Most of the major cotton-producing countries in West Africa are relatively small in terms of population size, and they are among the poorest countries in the world. Hence, there is an expectation, especially among donor organizations, that these countries should exploit economies of scale in a regional

[4] However, the officials interviewed by the study team in Benin were unable to provide a government document establishing or describing this moratorium (Jaffe et al., 2007).

approach to biotechnology regulation. (2) Major agro-ecological zones cut across West Africa, contributing to economies of scale at the levels of risk assessment and risk management. This is especially the case for the cotton cultivation area, which covers a wide band of dry land located in central West Africa at the southern border of the Sahara. (3) A regional approach would facilitate the cross-boundary movement of GM crops. This is important for West Africa's landlocked countries, and for the efforts of WAEMU and ECOWAS to establish a common market in West Africa. (4) All countries in the region have used the African Model Law as a basis for developing their biosafety frameworks and draft legislation, meaning that there are no major between-country differences regarding the type of envisioned regulatory systems.

Figure 1. Membership of West and Central African countries in different regional bodies



Source: Resnick (2006)

CILSS Framework Convention on Biosafety[5]

Among the three regional biosafety initiatives, the CILSS initiative is currently the most advanced. CILSS was established in 1973 in response to the drought and famine conditions afflicting the region at that time. The Framework Convention Introducing a Common Biosafety Regulation for the Prevention of Biotechnological Risks in the CILSS Countries was developed over the course of two years and adopted by the CILSS Council of Ministers in 2006. The CILSS countries still have to translate the convention

[5] This section is based on Jaffe and Meissa Dieng (2007).

into national law; this is not expected to be completed before 2008. The convention seeks to harmonize national biosafety regulation in the member states by specifying the procedures, definitions, and responsibilities for the national authorities that will be set up by the member states. Under the convention, authorization is required for any activity involving GMOs, including their use in contained laboratories, confined field trials, and commercial releases, as well as for import and export. The convention addresses GMOs as well as products derived from GMOs, but the regulations apply only to derived products that are used as food or feed. Under the convention, a Regional Consultative Committee will be established to provide general technical and policy support to the national authorities. This committee, which will comprise representatives of the member states, will include individuals from the national biosafety agencies, as well as scientific experts and non-voting representatives of WAEMU and other relevant regional bodies. The committee will be able to make authorization decisions for countries that have not yet set up their regulatory systems, and decide when products will be marketed throughout the region. Otherwise, the authorization decisions will remain the responsibility of the member states.

The CILSS Biosafety Convention has some similarities with the CILSS Common Regulation for the Registration of Pesticides. The latter body, created in 1999, established a regional process for the registration of pesticides. Under this convention, a company seeking to market a pesticide in any of the nine CILSS member countries must submit a single application to a committee of experts, who then assess the risks and make a decision for all nine countries.

Regional Biosafety Initiatives by ECOWAS and CORAF[6]

The Economic Community of West African States (ECOWAS) encompasses the 15 countries that comprise the entire West African region (Figure 1). The organization, which was founded in 1975, has four major objectives: to expand intra-community trade, improve physical infrastructure, reduce excessive external dependence, and create a single ECOWAS currency. The institutional structure of ECOWAS includes a secretariat, the Council of Ministers, the Authority of Heads of State and Government, and a parliament. Direct election of parliament members is planned by has not yet been implemented. Decisions made by ECOWAS need to be translated into national law to become effective.

An important step for regional cooperation with regard to biosafety regulation at the ECOWAS level was the organization of a West Africa conference, which was held in Ouagadougou in June 2004. At this conference, the delegates decided to create: (1) a public information system on biotechnology for the region; (2) a partnership between West African and North American research institutes; and (3) a West African Biotechnology Center. At a conference held in Abuja in November 2004, attended by the West African Ministers of Science and Technology, it was decided that ECOWAS would take ownership of all

[6] This section and Section 2.4 are based on Resnick (2006) and Birner, Linacre & Resnick (2007).

biotechnological initiatives in the region. Based on discussions from the abovementioned regional convention, CILSS was designated as the coordinator for the implementation of the region's biosafety activities. Since CORAF is considered to be a technical arm of ECOWAS, CORAF's Biotechnology and Bio-safety Program was adopted at the Abuja meeting as the ECOWAS agenda for agricultural research and development activities concerning biotechnology and biosafety.

CORAF is a network of the National Agricultural Research Systems (NARS) of 21 countries within the West and Central African regions. One of the main objectives of CORAF's Biotechnology and Biosafety Program has been to demonstrate the potentials of biotechnology and influence political debates in favor of biotechnology. Another goal has been to augment the capacity of scientists to use biotechnology for agriculture. With regards to the biosafety component the program, the main objectives include creating commonalities in biosafety procedures, strengthening institutional and human capacities in biosafety implementation, establishing a regional regulatory framework, and sensitizing the public. Donor funding, especially that from the United States Agency for International Development (USAID), has played an important role in supporting the CILSS, CORAF and ECOWAS initiatives.

The WAEMU Initiative to Establish a Regional Regulatory System

The West African Monetary and Economic Union (WAEMU), which includes eight francophone West African countries (see Figure 1), emerged in 1994 through a revision of the treaty of the Communauté Economique de l'Afrique de l'Ouest that was launched in 1973. The institutional structure of WAEMU comprises a Commission, the Council of Ministers, the Conference of Heads of States, and an Interparliamentary Committee. WAEMU's Council of Ministers, unlike the corresponding body within ECOWAS, has decision-making authority; WAEMU can pass legislation that becomes immediately effective in the member states without having to be translated into national law. WAEMU's trade liberalization scheme became effective in January 2000, resulting in the abolition of all tariffs on goods produced within the member states, the adoption of a common external tariff, and the standardization of business laws.

WAEMU is currently in the process of establishing a regional regulatory system for biotechnology. WAEMU expects funding and technical support for establishing this system will come from the proposed GEF West Africa Regional Biosafety Project, which will be co-funded by the World Bank and the International Development Association (IDA). The project aims to: (1) produce operational, regionally-harmonized methodologies for risk assessment and management of Living Modified Organisms (LMOs) and LMO products, including a regional manual of procedures; (2) strengthen national biosafety frameworks to enable their implementation; and (3) set up a regional legal framework for biosafety, strengthen policies on intellectual property rights pertaining to transgenic plants, and

establish a regional observatory to monitor possible environmental and health impacts and socioeconomic issues.[7] The design of this regional regulatory system is still under discussion.

The initiative to establish a regional regulatory system with support from the World Bank has been criticized by African and international civil society organizations that oppose the introduction of Bt cotton in the region. In a news release from 2006, members of these groups expressed concern that the project would "promote favorable regulations in a few key countries" and then "use these regulations as a model that can be imposed on neighboring countries by regional bodies" while side-stepping democratic debates (African Center for Biosafety, ETC Group, GRAIN, & RALLT, 2006).[8]

A Snapshot of the Regulatory Procedure for Biotechnology in the EU

For the purpose of comparison, the regional regulatory system for biotechnology in the European Union is briefly sketched here.[9] Prior to 2003, the competent authority in the EU member state where the product was to be released was responsible for assessing its safety and notifying other member states of its approval, thus opening the way for marketing throughout the EU. EU-level intervention took place, however, if one member state disagreed with another's decision. In 2003, Regulation 1829/2003 EC established a "one-door-one-key" approach to biotechnology regulation. This approach comprises four steps (Christoforou, 2004; Wendler, 2005):

1) A company submits an application to a national authority, which passes the application along to the European Food Safety Authority (EFSA). EFSA is responsible for assessing the use of GMOs for food and feed, and the deliberate release of GMOs into the environment, which is necessary for GM crop production (prior iterations required two separate approval processes).[10]

2) EFSA informs all EU member states and the public, and establishes an Opinion within six months. EFSA may ask a national food safety authority to carry out a food safety or environmental risk assessment, and requires a method validation from the Community Reference Laboratory to verify that the methods and samples fulfill the requirements of EU guidelines.

3) When completed, the EFSA Opinion is forwarded to the EU Commission, the member state and the applicant. Members of the public have the right to comment on the Opinion within 30 days.

[7] See http://go.worldbank.org/MARGRHEKU0. This is a proposed four-year project, estimated to cost US$24.3 million, including US$5.4 million in GEF funding and US$5.3 million in IDA funding.

[8] While the introduction of Bt cotton is generally contested in the region, the WAEMU initiative has attracted particular attention from international environmental NGOs, because it is one of the first projects in the area of agricultural biotechnology that the World Bank decided to undertake after having refrained from a high-profile engagement in this area for many years.

[9] See http://www.gmo-compass.org/ for an overview.

[10] The delegation of environmental risk assessment to EFSA was not without criticism. Denmark, for example, questioned whether EFSA would have sufficient competence to address the various natural and environmental differences in the EU regions (Levidow, Carr, & Wield, 2007).

The Commission may consult with the European Group on Ethics in Science and New Technologies in developing a draft decision.

4) The Commission's draft decision is submitted to the Standing Committee on Food Chain and Animal Health, in which the member states are represented. A decision is made there according to a regulatory committee procedure known as "comitology."[11] If the measures envisaged by the Commission are not in accordance with the committee's opinion, the Commission must refer them to the Council. The European Parliament must be informed about decisions to authorize the release of GMOs.[12] The EU Council has the ultimate authority to approve GM products, but the Council gets involved only if there is disagreement within the committee. The Council can decide with a qualified majority.[13] If an authorization is granted, it is valid in the EU for ten years an can be renewed after this time. If the EU Council does not reach a qualified majority, the decision is referred back to the Commission, which can then adopt its draft resolution.[14]

The Standing Committee on Food Chain and Animal Health appears to be the major forum for negotiations with national administrations and stakeholders (Wendler, 2005). EFSA is also engaging with stakeholders. Its management board represents bodies across the agro-food chain, including consumer organizations, and its advisory forum includes representatives of the expert advisory or regulatory bodies of member states. The Commission engages with stakeholders through the Advisory Group on Food Chain and Animal Health. While authorization of GM products has been delegated to the EU level, the EU has left the specification of the regulations concerning the co-existence between GM and non-GM crops, including liability, to the member states, based on the assumption that cost-efficient solutions may differ between countries (Fischler, 2003). Labeling requirements for GM food, however, have been established at the regional level.

[11] See http://europa.eu/scadplus/glossary/comitology_en.htm.

[12] The parliament does not vote on the authorization decisions.

[13] In the EU Council, votes are assigned to member states according to population size. For a qualified majority, 255 votes out of a total of 345 are required. Moreover, a member state may request verification that the QM represents at least 62% of the total population of the European Union. See http://europa.eu/scadplus/glossary/qualified_majority_en.htm.

[14] Virtually none of the applications processed since the end of the de facto moratorium in 2004 reached a qualified majority in the Council due to systematic voting abstention by certain countries, meaning that the applications have been sent back to the Commission. The abstention partly reflects internal disagreements within member states. For example, the coalition government that ruled Germany between 1998 and 2005, consisting of the Social Democrat and the Green Party, abstained from Council votes dealing with issues on which the two parties disagreed. This was frequently the case for GM approvals.

3. CONCEPTUAL FRAMEWORK

This section presents a conceptual framework that uses different theories of regulation to examine the design of a regional regulatory system. The section starts with an overview of the institutional design options currently available to policy-makers in West Africa and other regions looking to establish a regional regulatory system. The second sub-section discusses a set of criteria that policy-makers may wish to consider when comparing different regional regulatory system options. The third subsection reviews different branches of economic theory to identify factors and trade-offs that influence the comparative advantages and disadvantages of the different regulatory design options.

Options for Regional Regulatory Design

Table 1 provides an overview of the institutional design options.

1) Scope of the regional system: Obviously, it is important to determine the scope that a regional system should have, both in terms of substantive areas that may be regulated at the regional level, and in terms of the regulatory activities associated with each of these areas. As seen in the EU, a region may decide to regulate approvals for field testing, commercial release, and labeling[15] at the regional level, while leaving regulatory decisions on co-existence regulations and liability at the national level. Likewise, regions may decide to delegate some regulatory activities (e.g. risk assessment) to the regional level, while performing others (e.g. post-approval monitoring) at the national level. Apart from the EU, Australia's federal system provides another example in which regulatory authority is assigned to different levels. The Australian Gene Technology Regulator controls centralized safety decisions, while the individual states act as autonomous units regarding the implementation of decisions (in this case for trade reasons). This strategy allows states to implement and maintain moratoria on the release of GMOs.[16]

2) Institutional structure of a regional system: A second design feature of a regional regulatory system is the institutional structure to be established. If a regulatory system is established within the framework of an existing regional organization, such as in the case of WAEMU, ECOWAS and the EU, the institutional structure of the regional organization provides important frame conditions for the institutional design of the regional regulatory system. Regulatory institutions that may be set up at the regional level include regional regulatory agencies, regional regulatory committees, and regional advisory councils. In case of CILSS, a regional regulatory committee was established. In the case of the EU, EFSA

[15] As indicated in the introduction, the need for labeling is debated. There is no international consensus, rule or guideline on the use of mandatory labeling for GM food, so a regional system may or may not include labeling requirements. If one or more member states of a regional system have already established mandatory labeling, decisions on the regional system need to deal with this question. In the case of WAEMU, most member states have foreseen labeling in their draft biosafety laws (Jaffe and Meissa Dieng, 2007).

[16] Currently GM canola may not be planted in Tasmania and Western Australia. It may now be planted in Victoria and is being considered in New South Wales. Queensland never had a moratorium on its planting.

was created in part because of the need to implement the EU regulation on GMOs. However, EFSA is also responsible for other types of environmental and food safety regulations. To some extent, the regulatory process in the EU also used pre-existing institutions, such as the Standing Committee on Food Chain and Animal Health. System designers should also decide whether regulation should rely on national scientific capacities, as in the case of the CILSS common pesticide regulation, or whether regional scientific organizations should be established. The EU relies on a combination of both.

3) Decision-making at the regional level: With regard to regulatory decision-making, it is necessary to determine how much autonomy the decision-making body will have from the public administration. This question also arises at the national level. Australia, for example, uses an independent regulator who is accountable to the parliament. In the EU, by contrast, regulatory decisions are made by the public administration of the EU (the Commission), or in case of disagreement by a political body (the Council of Ministers).

Table 1. Options for regional regulatory resign

Decision points	Options
1) Scope of the regional system	
Substantive areas that can be regulated at regional level	➢ Approvals for a) field trial applications and contained use b) commercial releases c) food and feed use ➢ Liability and co-existence regulations ➢ Labeling options ➢ Intellectual property rights
Types of regulatory activities that can be performed at the regional level	➢ Standard-setting for and review of national pre- and post-approval activities ➢ Pre-approval risk assessments ➢ Approval decisions (see above) ➢ Post-approval monitoring, compliance and enforcement activities ➢ Enforcement of transboundary transport regulations
2) Institutional structure of the regional system	
Type of institutions to be established	➢ Regional authority with our without abolishment of national authorities ➢ Regional advisory bodies, committees ➢ Use of existing institutions or creation of specific institutions ➢ Level of independence/autonomy
Scientific capacity	➢ Regional scientific institutions established or denominated versus reliance on national institutions

Table 1. Continued

Decision points	Options
3) Decision-making at the regional level	
Mode of decision-making	➢ Political or administrative decision-making ➢ Binding without ratification at country level (i.e. self-executing) vs. binding after ratification vs. advisory ➢ Consensus versus majority rules
Degree and form of public participation in decision-making at different levels	➢ Compulsory versus voluntary ➢ Advisory councils, written comments, stakeholder meetings, public hearings, surveys
Issues considered in decision-making	➢ Environmental and health risks; level of precaution ➢ Socio-economic considerations ➢ Ethical issues
4) Financing of the regional system	
Mode of financing the system	➢ Revenues from regional organization or member states ➢ Application and license fees ➢ Market levies ➢ Donor funding
5) Distribution of responsibilities between regulatory agency and industry	
Distribution of responsibilities	➢ Different degree of responsibility of the industry for risk assessment and management
6) Enforcement of the regional system	
Institutions and procedures used for enforcing regional decisions at the country level	➢ Use of existing legal mechanisms (e.g. regional courts) ➢ Creation of specific institutions for enforcement ➢ Types of sanctions to be used
7) Transition to regional system	
Mode of dealing with existing national regulations	➢ "Grandfathering rules" ➢ Discontinuation of existing rules

Source: Adapted from (Birner & Linacre, 2007)

There is also a need to decide on the decision mode of the regional body. Decisions could be binding on the member states without their ratification, as in the case of the EU authorization for GMO products. Alternatively, decisions may require ratification at the national level, or they may have only advisory character. Making decisions binding without ratification at the country level may be more feasible in regional organizations that can make binding decisions in other areas. This is the case for WAEMU, but not for ECOWAS. Alternatively, even in the absence of regional organization that has the authority to make binding decisions for member states, the states can still decide to abide by the decisions of a regional committee, as in the case of CILSS pesticide regulation. In this example, the system facilitates access to pesticides and reduces regulatory costs, apparently providing sufficient incentives for the states to abide by its recommendations.

A design feature that has potentially far-reaching implications on the speed of regulatory decision-making is the nature of the rules that will be applied to this process. WAEMU requires decision-making by consensus. A legal assessment would be necessary to determine whether WAEMU could use

different decision-making rules for the case of biotechnology regulation. In ECOWAS, decisions are made either by consensus or with a two-thirds majority, depending on the subject. In the EU, the Council can make regulatory decisions with a qualified majority, as indicated above.

One issue that has proven rather controversial at the international level is the determination of factors that should be considered during regulatory decision-making. While it is generally agreed that environmental and health risks should be considered, there is some debate regarding the extent to which socio-economic considerations and ethical concerns should be addressed during the regulatory process. Since the debate in West Africa focuses on the Cartagena Protocol and Bt cotton (which is not a food crop), most of the attention to date has focused on addressing environmental risks within the decision-making process. One of the most debated issues in regulatory decision-making on biotechnology is the use of the precautionary principle.[17] Even in the EU, which adopted the principle for biotechnology regulation, the interpretation of the precautionary principle in the regulatory process for biotechnology has remained debated (Levidow et al., 2007). Since the Cartagena Protocol and the African Model Law on Biosafety embrace the precautionary principle, it is an important issue in the debate on regional biotechnology regulation in West Africa.

Another aspect of regulatory decision-making is the role of public participation, which may take different forms. The public can be granted the right to be informed and to submit opinions at various stages of the regulatory process. An early example of this approach is the US Administrative Procedure Act of 1946, which requires that federal regulatory agencies provide for public participation by inviting written comments. Stakeholders may also be involved in a more institutionalized form, such as in advisory bodies. The EU uses both approaches. In contrast, the CILSS Pesticide Convention has no provisions for public participation (Jaffe et al., 2007). Participation has, however, been prominent in the UNEP-GEF-assisted development of biosafety frameworks in West Africa; in this context, public involvement has mostly taken the form of stakeholder participation in workshops (Resnick, 2006). The national biosafety draft laws in the WAEMU countries differ with regard to the type and degree of public participation that will be provided for in regulatory decision-making. Some countries plan to set up consultative committees that represent the public or stakeholders as part of their regulatory systems (Birner et al., 2007).

4) Financing of the regional system: The way in which the regional regulatory system should be financed is another important design question. A number of different mechanisms for financing regulatory systems exist, and these may be used alone or in combination. They include market levies, license and

[17] The "precautionary principle" justifies actions to avoid potential harm to health or the environment, despite lack of scientific certainty as to the likelihood, magnitude, or causation of that harm (see http://www.pprinciple.net/the_precautionary_principle.html).

applications fees, tax revenues from the respective regional organizations, direct contributions from member states (according to some formula), and donor funding.

5) Distribution of responsibilities between the regulatory agency and industry: The division of responsibilities in risk management/assessment between the regulatory agency and the biotechnology industry is another question of institutional design. In most existing regulatory system for biotechnology, risk assessment studies are conducted by the industry and are then reviewed by the regulatory agency. It is further necessary to decide how much (or how little) post-approval monitoring will be handled by the industry.

6) Enforcement of the regional system: A functional regional system, unless completely voluntary, will also need a system of enforcement to ensure that member countries comply with centralized decisions. The case of the EU illustrates this point. In May 2004, the EU resumed GMO approvals, thus ending its de facto general moratorium. However, five EU member states maintained approval bans under their national safeguard measures. The EU Commission had strong incentives to induce these member states to lift their bans, as this had been required by the ruling of the World Trade Organization (WTO) on the biotechnology dispute.[18] The EU Council rejected a Commission-submitted proposal requiring that member states lift their bans, leaving the Commission with the option to bring an infringement action before the European Court of Justice (ECJ). However, in view of the politically charged atmosphere surrounding GMOs in the EU, it was considered to be highly inappropriate for the Commission to initiate litigation at the ECJ (Arcuri, 2007). The question of enforcement is also relevant for the West African case, as countries in the region have typically differed in their approaches for dealing with GMOs. At present, their strategies range from the approval of field trials in Burkina Faso to a moratorium in Benin.

7) Transition to a regional system: Rules must be established for the transition to a regional system. In particular, it should be decided whether to uphold authorizations for field trials or commercial releases that had been established in a member state prior to its entry into the regional system. This question is relevant for the case of WEAMU, since Burkina Faso has already authorized field trials.

Criteria for Assessing Regulatory Design Options

The literature on environmental policy instruments provides important criteria that can be used to compare the various regulatory design options. Effectiveness in achieving the desired level of environmental and health safety is crucial, since this is the primary goal of biotechnology regulation. Hence, other criteria only become valid if this criterion is met. The effectiveness criterion is related to the

[18] In 2003, the United States, Canada, and Argentina used the WTO dispute settlement mechanism to challenge the European Union's (EU's) de facto moratorium on biotechnology product approvals, which had been in place since 1998 (Hanrahan, 2006).

"Public Interest Theory" of regulation (Viscusi, Harrington, & Vernon, 2007), which assumes that the primary goal of regulation is to correct market failures and address externalities.

Economic theory adds a range of economic criteria. If one considers that the benefits of regulation are difficult to quantify, cost-effectiveness becomes a useful criterion, assessing whether the regulatory system achieves the desired levels of environmental and food safety at the lowest possible costs. In contrast, if the benefits can be measured, cost-benefit analyses can be used to consider the "optimal intensity" of regulatory activity as a criterion. This intensity would be reached at the point where the marginal costs of regulation equal the marginal benefits. Another economic criterion highlighted in the environmental policy literature is dynamic efficiency, which is related to the effects of the regulatory system on the long-term effects, such as the creation of incentives for innovation.

Next to effectiveness and economic criteria, there is a range of "good governance" criteria that can be derived from the literature on good governance. While this concept has remained subject to debate, the dimensions of good governance developed by Kaufmann, Kraay, and Mastruzzi (2007) have become widely accepted; these include voice and accountability, regulatory quality, government effectiveness, control of corruption, rule of law, and political stability. Except for the last criterion, which applies to the country level as a whole, all of the other criteria can be applied to biotechnology regulation (see below).

The government effectiveness criterion is linked to the abovementioned effectiveness and economic criteria, and is thus not listed separately in Table 2. An important aspect of regulatory quality is the minimization of special interest capture in regulation. This problem was highlighted in a seminal paper by Stigler (1971), which laid the foundation for the "capture theory of regulation." The main argument of this theory is that firms have a strong interest in extracting rents from regulation, especially since regulation can restrict the entry of new firms, while voters do not have sufficient political incentives to prevent this type of rent-seeking. In the literature on agricultural biotechnology regulation, the question of capture is contested. Graff and Zilberman (2004) suggest that biotechnology regulation in Europe has been captured by the pesticide industry, which has an economic interest in restricting the introduction of GM crops, whereas Paarlberg (2001) argues that biotechnology regulation in developing countries has been captured by environmental groups rather than by biotechnology firms. Using the case of India, Newell (2007a) shows that the biotechnology industry has played a major role in the country's evolving regulatory regime. He finds that biotechnology entrepreneurs from larger multinationals and successful start-up firms with good national and global connections were particularly influential. Based on his research, he argues against Paarlberg's view (Newell, 2007b). Good governance in biotechnology regulation would obviously imply the need to balance societal interests while avoiding capture by any special interest group. The challenges associated with this criterion are further discussed below.

Table 2. Criteria for assessing regulatory design options

Criterion	Aspects
Effectiveness criteria	• Effectively ensuring desired levels of environmental and food safety • Effectively avoiding regulatory failures
Economic criteria	• *Cost-effectiveness*: Achieving desired levels of environmental and food safety at lowest possible costs • *Optimal "intensity" of regulation*: Expected marginal benefits from regulation equaling expected marginal costs • *Dynamic efficiency*: Creating/protecting incentives for innovation
Good governance criteria	• *Control of special interest capture*: Regulation is not captured by special interest groups (biotechnology industry, environmental groups) • *Fairness*: Acceptable balance of different societal interests, and acceptable distribution of costs and benefits • *Voice and accountability*: Processes are transparent and provide scope for citizen participation; regulatory agencies are accountable to citizens and their political representatives • *Control of corruption*: Regulation does not create incentives for corruption/has safeguards against corruption • *Rule of law*: Regulations can be enforced
Conformity criteria	• Regulation conforms with international agreements (Cartagena Protocol, WTO) • Regulation conforms with regional treaties and national constitutions • Regulation conforms with international good practice standards
Legitimacy criteria	• *Input legitimacy*: Regulatory process is considered fair, transparent, participatory, and accountable • *Output legitimacy*: Performance of regulatory process is considered satisfactory, regulatory failures are avoided, and problem-solving capacity is in place

Source: Authors

Avoiding special interest capture is related to another aspect of regulatory quality: the capacity of the regulatory process to balance the interests, values and risk attitudes of different society groups in such a way that the outcome of the process is considered fair. This criterion is linked to the voice and accountability criterion. Applying this criterion to the regulation of biotechnology implies that regulatory processes should be transparent and provide scope for citizen participation, and that regulatory agencies should be accountable to citizens and their political representatives (e.g. parliaments).

Another good governance criterion is control of corruption in biotechnology regulation. This includes avoiding the creation of incentives for corruption and introducing safeguards against corruption. Unlike special interest capture, corruption refers to illegal activities. Although little attention has been paid to this point thus far in the literature on agricultural biotechnology regulation, it is a real problem. For example, in 2005, Monsanto paid a fine of 1.5 Million US$ when it was revealed that one of the company's former senior managers directed an Indonesian consulting firm to give a $50,000 bribe to a high-level official in Indonesia's environment ministry, in an effort to avoid environmental impact studies being conducted for Monsanto's GM cotton (BBC News, 2005). Strategies to reduce corruption in

biotechnology regulation may include increased transparency and public participation, as well as improved audits and administrative or political oversight.

Applying the rule of law criterion to biotechnology regulation implies that regulatory decisions should be monitored and enforced. Hence, it is important in regulatory decision-making and in the design of regulatory systems to determine what aspects can be monitored and enforced, and what capacities should be created for this purpose.

A further set of criteria refers to the conformity of the regulatory system with the international obligations that a country has signed, such as the Cartagena Protocol on Biosafety, as well as with regional treaties, such as WAEMU or ECOWAS. Moreover, the regulatory system needs to conform to the constitution of each member country. Conformity with international good practice in biotechnology regulation may be considered a criterion, as well.

A final set of criteria for assessing regulatory design options are those dealing with the creation of legitimacy. To a large extent, legitimacy is created by fulfilling the above-described criteria. In the case of regional biotechnology regulation in the EU, several authors have distinguished between "input legitimacy," which refers to the regulatory process, and "output legitimacy," which refers to the performance and results of the regulation. The related process criteria, which can be seen as either goals in their own right or as pieces instrumental to achieving other goals, include transparency, participation, fairness and accountability. Performance criteria, which constitute output legitimacy, include the problem-solving capacity of the regulatory system and the avoidance of regulatory failures (Skogstad, 2002; Wendler, 2005).

Insights from the Literature

This section reviews different branches of the economic literature on regulation in order to identify factors and trade-offs that policy-makers in West Africa and elsewhere may wish to consider when making decisions on the design options outlined in Table 1. The review concentrates on four major questions that can be derived from the table: (1) What level should different types of regulatory activities be assigned? (2) What level of autonomy/independence should be borne by regulatory institutions? (3) What level and form of participation is appropriate? (4) What are the advantages and disadvantages of the different options for financing a regional regulatory system? The environmental and fiscal federalism literature discussed in Subsection 3.3.1 concentrates on the first question, while the New Institutional Economics (NIE) literature presented in Subsection 3.3.2 can be applied to all of these questions.

Environmental and Fiscal Federalism Literature

The literature on environmental federalism highlights the nature of the environmental good and the degree to which externalities are essential to determining the optimal level of government at which environmental regulation should take place (Oates, 2001; 2004). While developed with a focus on local versus national governments, the theory can be applied to the national versus supranational level. This literature shows that federal and supranational regulation is justified in the case of pure public goods, such as greenhouse gas emissions, because the environmental quality in one location is a function of the emissions in all other locations. In the case of local public goods without spill-over effects, in contrast, local regulation will be justified if one assumes that local governments maximize the welfare of their constituents.

In the case of local public goods with spill-over effects, it is more challenging to identify the appropriate level of regulation, since neither national nor local regulation would be efficient (Oates, 2001). In the absence of transaction costs and distributional concerns, bargaining across local jurisdictions would lead to efficient outcomes, according to the so-called Coase Theorem. However, this is obviously not a practical solution since transaction costs do matter, as noted by Coase (1960). Still, this theoretical consideration shows that in case of spill-over effects, "the efficient outcome will *not* in general take the form of uniform national standards for environmental quality. The efficient pattern of pollution control will generally imply different levels of environmental quality across jurisdictions" (Oates, 2001:5). In the case of local public goods and local spill-over effects, a common concern is the potential for a "race to the bottom" regarding environmental standards. This argument is debated, however, and numerous studies have sought to identify the conditions under which a race to the bottom would actually occur (Wellisch, 2000).

Applying this line of reasoning to the case of biotechnology, it becomes necessary to distinguish different types of technology-associated risks. Some risks, such as escape of unapproved GMOs through international trade, are potentially externalities at a global level. However, international escape would require the transboundary movement of GMOs, meaning that this risk can be managed by control of transboundary trade. The Cartagena Protocol, which six of the eight WAEMU member states have ratified, already contains provisions for transboundary movements of GMOs. In case of GM food exports, the risk of introducing allergens into the food chain constitutes a potential externality at the global level. However, the first-best solution to this problem is to prevent it at the source, before the products reach any border.[19] Other potential externalities, such as the creation of an invasive species-type problem,

[19] There is also the issue of the potential allergenicity of a product for a small segment of the population. Even groups that are critical of labeling requirements for GM food in general agree on the need of labeling requirements for non-substantially equivalent GM food products with the potential to provoke allergies. Hence, this case can be considered an international externality that requires coordination to ensure that all parties make this information available. It is, however, contested whether

would most likely occur at the level of a specific ecological zone, if such an event were to occur.[20] If several countries share the same ecological zone and the externality cannot be managed by controlling transboundary seed trade, this externality would be a "national spill-over" analogous to the "local spill-over" in Oates' theory (see above). Applying the Oates (2001) argument, this problem would not necessarily provide an economic rationale for centralized regulation at the regional level, but it would suggest the need for regional coordination. Spill-over effects may also occur at the local level in the form of gene flow to the fields of farmers who want GM-free crops. This problem can be managed by co-existence regulations, and has implications for supranational regulation only insofar as may affect farmers in border areas.

The implications for regional regulation change, however, when one considers that countries may have only a limited ability to control transboundary movement of GMOs. This may happen, for example, if farmers exchange seeds across the border. While some respondents interviewed for the present study mentioned this possibility, further data collection would be required to establish the relevance and degree of this problem. If the control of transboundary movements of GMOs proves to be problematic, then there is stronger justification for the establishment of regional coordination in biotechnology regulation. The same reasoning applies if countries want to establish a common market, and thus wish to reduce controls on transboundary movements of goods. This is actually the case in the WAEMU and in the ECOWAS region. Likewise, the establishment of a common market in the EU has been a strong rationale for the delegation of environmental regulation, including biotechnology regulation, to the EU level.

There is limited evidence available regarding the question of whether a race to the bottom (see above) regarding biotechnology regulation may occur across countries within the same region. Comparing biotechnology regulation in the EU and the US, Bernauer (2003) analyzes whether political subunits within a federal system could push the stringency of system-wide regulation up or down by unilaterally installing stricter or laxer regulation of agricultural biotechnology. He concludes that a process of "ratcheting up" has taken place in the EU but not in the US. His analysis shows that this outcome depends on the degree of centralization and autonomy of the federal regulatory system, and the political economy of interest group politics within the system. Oates (2001) finds that federal (centralized) environmental regulation in the United States for local public goods with spill-over effects has resulted in stronger environmental regulation than would be justified on efficiency grounds.

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labeling is sufficient for such products, or whether they should be avoided altogether.

[20] While such problems may not be likely in the case of Bt cotton, a regional regulatory system should be designed to process applications for other crops, as well, including food crops. In a literature review of the world's 13 most important food crops, Ellstrand, Prentice & Hancock (1999) show that 12 of these crops hybridize with wild relatives in some part of their agricultural distribution. The authors use population genetic theory to predict the evolutionary consequences of gene flow from crops to wild plants and discuss two applied consequences of crop-to-wild gene flow: the evolution of aggressive weeds and the extinction of rare species.

The fiscal federalism literature, which precedes the environmental federalism literature, provides additional insights (see Weingast, 2007 for a review). One factor highlighted in this literature, in addition to economies of scale and spill-over, is the role of differences in local preferences, which may provide a rationale for decentralization. When applied to the question of regional biotechnology regulation, this argument suggests that the transfer of regulatory authority to a supranational body is less justified if there are strong national differences in people's preferences regarding biotechnology. The extent of such differences, however, is an empirical question. The farmers' organizations and civil society organizations interviewed for this study revealed differences across the WAEMU countries in terms of positions regarding Bt cotton. This may partly be linked to the fact that the political systems in the WAEMU region differ in the scope they provide for independent civil society organizations to emerge and formulate their positions. Stakeholder information is not necessarily representative of the population as a whole. In the future, the inclusion of biotechnology questions into representative surveys, such as the Afrobarometer surveys,[21] might provide valuable representative information on public opinions and on the opinions of different groups (farmers, consumers) regarding biotechnology.[22] This will only hold true if the respondents already have knowledge of biotechnology, so the future inclusion of questions on biotechnology might help establish the extent to which people are informed about biotechnology, and which sources of information they have used. Both proponents and opponents of biotechnology in West Africa have engaged in media campaigns, but it is unclear to what extent information from both sides has reached consumers and farmers on a broad scale.[23]

Table 3 summarizes some major insights derived from the environmental and fiscal federalism literature, and their implications for biotechnology regulation. The major conclusion is that this literature suggests a need for regional coordination, but it does not in itself provide a rationale for centralized decision-making on biotechnology regulation. The literature draws attention to the fact that centralized decision-making may lead to regulatory standards that are, from an efficiency perspective, either too high or too low, especially in the face of national preference differences with regard to the environment and technology. This disadvantage must be weighed against the cost of controlling cross-border movement of GMOs, which can be reduced through a centralized regulatory system.

[21] The Afrobaromenter project conducts comparative series of national public attitude surveys on democracy, markets and civil society in Africa. See http://www.afrobarometer.org/.

[22] The Eurobarometer survey may serve as an example. An expert group of researchers from different European countries formulates a set of questions on biotechnology that is regularly included into the Eurobarometer survey, thus making it possible to track cross-country differences in public perceptions on biotechnology and their changes over time. This survey shows considerable cross-country differences in public opinion (Gaskell et al., 2006). The latest round of the Afrobarometer survey covered 18 countries, including Benin, Ghana Mali, Nigeria and Senegal in West Africa (Afrobarometer Network, 2006).

[23] If the level of information is low, an opinion survey obviously has little value because the answers may only reflect the type of information provided to the respondent.

Table 3. Types of risks and implications for regulatory design

Type of risk	Level at which externality/spill-over occurs	Heterogeneity of preferences	Implications for regulatory design
Food safety risks (e.g. allergens, toxins)	National and all countries to which GM food products are exported	Risk attitudes of consumers may vary across countries	Need for regulation of transboundary movements Economies of scale in risk assessment for all countries where respective food is consumed
Gene flow to other farmers' fields	Local; may affect border areas of neighboring countries	Depend on economic interests in GMO-free production	Need for co-existence/distance regulations, including border controls between countries (segregation and identity-preservation production and processing methods)
Gene flow to wild species leading to agronomic problems and/or loss of biodiversity	Ecosystem; may affect neighboring countries if they share the same ecosystems; may occur with or without cross-border trade	Risk attitudes of farmers and general population and preferences for biodiversity may vary across countries	Need for regulation of transboundary movement Need for cross-country coordination at ecosystem level Economies of scale in risk assessment at cross-country-level, if countries share the same agro-ecological zones
Escape of non-approved GMOs via international trade	International (all countries through which GMOs are transported)	Risk attitudes of consumers may vary across countries	Need for regulation of transboundary movements

Source: Authors

New Institutional Economics (NIE) Literature

The NIE perspective helps identify additional factors that influence the comparative advantage of different regulatory design options. According to Williamson's (1991) "discriminating alignment hypothesis," transactions that differ in their attributes should be aligned with governance structures that differ in their costs and competence, so as to effect an economizing result. The term "governance structures" refers to the different options for institutional design of a regulatory system. To apply this approach to biotechnology regulation, it is necessary to: (1) disaggregate or "unbundle" biotechnology regulation into its different regulatory activities or transactions; (2) identify the types of costs associated with the different transactions; and (3) identify the attributes and context-specific factors that influence the costs arising under different governance structures. These steps are outlined in the following sections.

Types of Costs and Benefits of Different Regulatory Transactions

Table 4 specifies the major transactions involved in biotechnology regulation, and lists the types of costs and benefits associated with each. When considering more areas of regulation (e.g. property rights, labeling and seed certification), additional regulatory transactions should be included in the table. For

reasons of scope, this section discusses only the transactions listed. However, the considerations presented in this section can be applied to other regulatory transactions.

We first look at the choice of governance structure (i.e. the level at which regulation takes place, degree of autonomy, role of industry and civil society, etc.). To determine the comparative advantage of different governance structures, it is necessary to identify the factors affecting the costs and benefits that arise under each one. In the case of regulation, this is mainly a matter of defining which costs should be considered "transaction costs" and which should be considered "other" costs. One may consider all regulation-related costs to be transaction costs. In the following, we use the term "regulatory costs" for the sum of all costs that arise for carrying out a specific regulatory transaction.

Table 4 also specifies who will incur the different costs; however this does not account for the possibility that, depending on the market structure, the industry may be able to pass the costs on to farmers, who may be able to pass them on to consumers. In the case of benefits, it is less straightforward to determine how they will be distributed, since this depends on both market structure and indirect effects. For example, if the regulatory system performs well in terms of risk management, the general public benefits directly, but the industry may also benefit indirectly from increased public trust in the technology.

As indicated above, the "optimal intensity" for each regulatory transaction can ideally be determined as the level where the marginal social regulatory costs equal the marginal social benefits. Prior studies have quantified absolute regulatory costs, for example in India (Pray, Bengali, & Ramaswami, 2005). However, little empirical information is available regarding the marginal costs of regulation and the absolute and marginal benefits of regulation, which consist of reductions in health, environmental and agronomic risks.

The potential benefits of regulation can be rather high, if one considers the costs that would arise following the introduction of an allergen into the food chain, or the creation of an invasive species-type of environmental problem or an agronomic resistance problem. One example would be the StarLink™ case in the US, in which GM maize that was only approved for animal feed was found in the human food supply. Even though the allergenicity of StarLink™ was contested, this situation is nevertheless an indication of the magnitude of costs that could arise (Talyor & Tick, 2001). Other benefits of regulation specified in Table 4, such as creation of legitimacy and trust in regulation, are also rather difficult to quantify.

Acknowledging the challenges of collecting empirical information on the marginal costs and benefits of regulation, the following sections use a cost-effectiveness perspective to compare different governance structures and derive hypotheses regarding the factors that influence the comparative advantages of the various governance structures. The utilized approach, which is in line with the standard

literature of transaction cost economics (Williamson, 1991), develops hypotheses on the absolute costs incurred for performing a regulatory transaction that ensures a defined outcome. If this outcome is not achieved under a certain governance structure, the forgone benefits may be considered to comprise an additional cost category.

Table 4. Types of costs and benefits of different regulatory transactions

Regulatory transaction	Types of costs*	Types of benefits
Risk assessment for food and environmental safety	I: Costs incurred for conducting trials/studies A: Costs of assessing dossiers and conducting additional tests; costs incurred for ensuring compliance with field test regulations	Avoiding health problems and environmental/ agronomic problems Building public trust in GM technology
Agronomic/socioeconomic assessment	As above	Reducing economic risks for farmers
Decision-making on approval for contained and confined trials and for commercial release	A: Costs incurred for negotiations; coordination among committees; organization of participatory processes I: Application fees I/C/F: Costs incurred for participating in decision-making processes F/I: Income forgone in case of approval delay	Avoiding health problems and environmental/ agronomic problems Building public trust in GM technology Creating legitimacy for biotechnology regulation
Post-approval monitoring and enforcement, e.g. of distance (co-existence) regulations and refuge guidelines	F: Costs incurred for compliance I: Costs incurred for monitoring[24] A: Costs incurred for monitoring and enforcement	Avoiding environmental problems Avoiding agronomic/ resistance problems
Control of transboundary movements of GMOs	A: Costs incurred for border control I: Costs incurred for documentation	Avoiding environmental/ agronomic problems
Raising revenues for regulation	A/F/I: Costs of raising revenues, e.g. administering market levies	Fair/incentive-compatible distribution of regulatory costs

Source: Authors
* Costs incurred by A: regulatory agency; I: biotechnology industry and public sector organizations developing GM crops; C: civil society organizations/stakeholders; F: farmers.

Level of Centralization/Decentralization

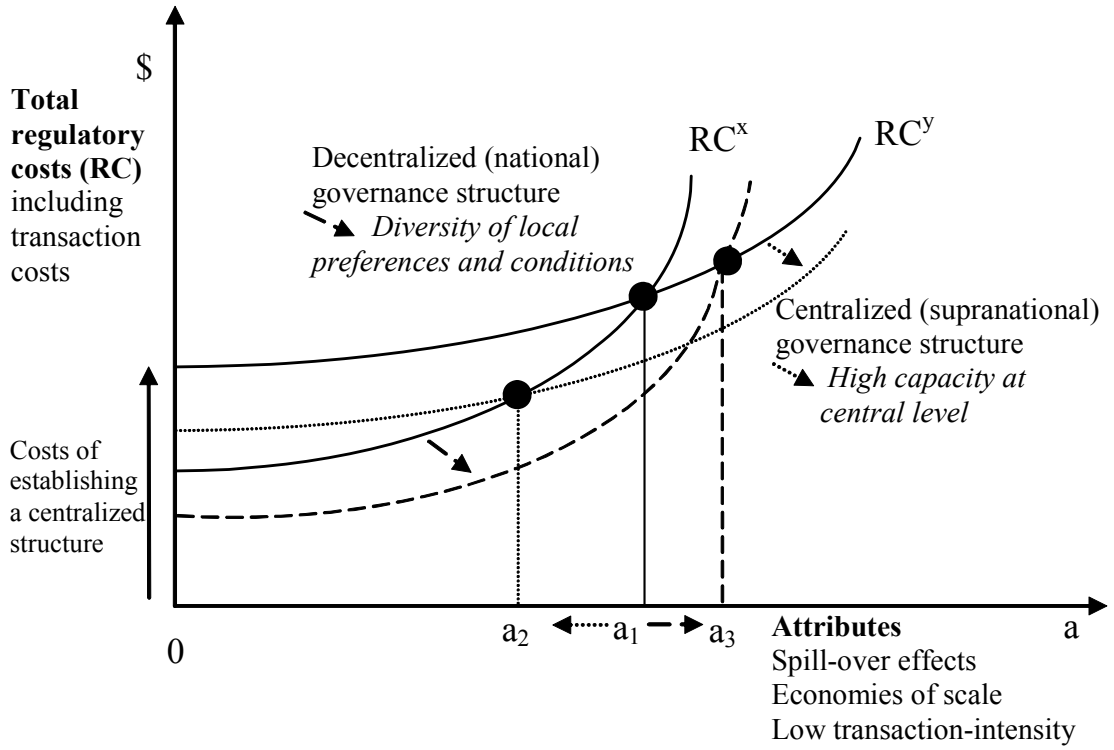
Figure 2 illustrates use of the transaction cost approach to determine the optimal level of government at which various regulatory transactions should be carried out. The figure shows hypothetical cost curves for the regulatory activity under a more decentralized (national) governance structure, x, and a more centralized (supranational) governance structure, y. The vertical axis indicates the regulatory costs arising

[24] These costs are not necessarily incurred by the biotechnology industry, as they may also be incurred by various actors in the market chains (i.e. exporters and importers).

for the respective transaction, while the horizontal axis displays the attributes, which increase the comparative advantage for centralized regulation.[25]

As can be derived from the regulatory federalism literature discussed above, spill-over effects and global public good characteristics are important attributes. Economies of scale in performing the respective activity are obviously another important attribute. For example, there are potentially large economies of scale in centralizing risk assessment for environmental safety in cases where several countries share an ecosystem with rather similar ecological conditions. In contrast, there are fewer economies of scale in post-approval monitoring activities. The economies of scale in regulatory activities are linked to their "transaction intensity" (Pritchett & Woolcock, 2004), which reflects the frequency and spatial dispersion of transactions. Enforcing refuge requirements, for example, is far more transaction-intensive compared to decision-making on the approval of field trial or commercial release applications. The more important these attributes are—as indicated by a move to the right on the horizontal axis—the faster the increase in the hypothetical costs for performing the respective activity under the decentralized (national) governance structure, x.

Figure 2. Comparative efficiency of different governance structures: Level of governance



Source: Based on Williamson (1991) and Birner & Wittmer (2004)

[25] Note that it is not necessary to quantitatively measure the attributes. The approach displayed in Figure 2 is typically used to derive hypotheses on the comparative advantage of different governance structures, which can then be tested empirically. See Shelanski & Klein (1995) for a review of the empirical transaction cost economics literature.

In the case of the centralized (supranational) governance structure, y, the regulatory costs increase at a slower pace, which is indicated by a smaller slope of the respective hypothetical cost curve. If the respective attributes are not relevant (moving to the left-hand side on the horizontal axis), a decentralized (national) governance structure has a comparative advantage over the centralized governance structure. From point a_1 onwards, a centralized governance structure has a comparative advantage over a decentralized governance structure for performing the respective regulatory transaction. In contrast, for a $< a_1$, the decentralized governance structure has a comparative advantage.

Figure 2 also displays the effects of context-specific factors. For example, if the capacity of a supranational regulatory agency is increased, it will, ceteris paribus, be able to perform the same regulatory activity at lower costs (e.g. because the opportunity costs caused by delays in decision-making are reduced). This is indicated by a downward shift of the respective hypothetical cost curve in Figure 2. Accordingly, the point at which a centralized organization of the respective transaction begins to have a comparative advantage over a decentralized organization moves from a_1 to a_2. The same effect may occur if the respective regulatory activity can be carried out at least partly through an existing supranational governance structure, as this reduces the transaction costs required to set up a new supranational system for all aspects of regulation. In the case of West Africa, countries can partly rely on the existing governance structures of CILSS, WAEMU and ECOWAS for biotechnology regulation, although it will be necessary to build subject matter-specific capacity.

The role of heterogeneous local (or national) conditions and preferences (see above) can also be considered as a context-specific factor in Figure 2. In this case, a centralized agency would incur higher costs than a decentralized agency, yielding an upward shift of the hypothetical cost curve that indicates centralized regulation. Alternatively, a downward shift of the curve may be seen as indicating decentralized regulation, relative to the curve indicating centralized regulation. If this representation is chosen, the point from which decentralized regulation is more efficient moves to a_3. A similar effect occurs if knowledge and information on local conditions, rather than scientific knowledge, is required to perform a regulatory activity efficiently. For example, local information is important for monitoring whether farmers comply with refuge requirements, whereas scientific knowledge is important for environmental risk assessment activities. The development of a system for enforcing transboundary regulation requires technical and scientific knowledge, but local information is required for actual monitoring of transboundary movements (e.g. movement of trucks across borders, etc.).

Table 5 summarizes the attributes of the different transactions derived from this discussion. The table provides a rationale for assigning pre-approval activities (e.g. risk assessment) to a supranational level, in order to utilize economies of scale and scarce scientific knowledge. In the case of environmental risk assessment, the rationale for delegation to a supranational body is strong if countries share the same

agro-ecological zones. If the agro-ecology is very diverse, however, supranational bodies may be less suited for environmental risk assessment responsibilities. The table suggests that there is also a rationale for assigning post-approval monitoring and evaluation activities to a national or sub-national level, since such transaction-intensive activities are difficult to control from a supranational level. This is less clear-cut in the case of decision-making activities, such as approval of field trials and commercial release, since these steps in the regulatory process tend to be the most politically contested. Therefore, other criteria should be considered, such as the creation of legitimacy (see below).

Table 5. Attributes involved in different regulatory transactions

	Transaction intensity: spatial dispersion	**Transaction intensity: frequency**	**Type of knowledge/ information needed[a]**
Food safety risk assessment	low	low	scientific
Environmental risk assessment	dependant on ecology[b]	low	scientific
Decision on field trial approval	low	low	scientific
Decision on commercial release	low	low	scientific
Monitoring of refuge and co-existence regulations	high	high	local
Post-approval monitoring (e.g. for gene flow and resistance)	dependant on ecology and goals of monitoring[c]	dependant on ecology and goals of monitoring[c]	scientific
Enforcement of transboundary transport regulation	high	high	local

Source: Authors
a "Scientific knowledge" implies that scientists with special knowledge on biotechnology need to be involved. "Local knowledge" implies that staff without scientific qualifications in biotechnology can carry out the respective activities, which depend more heavily on knowledge of the local conditions.
b The transaction intensity in terms of spatial dispersion depends on the diversity of the area. It increases with the number of agro-ecological zones to be covered.
c The spatial dispersion and frequency of post-approval monitoring activities depend on the agro-ecology and the goals of the monitoring program. For example, the transaction intensity of monitoring for gene flow is higher in areas with frequent cyclones.

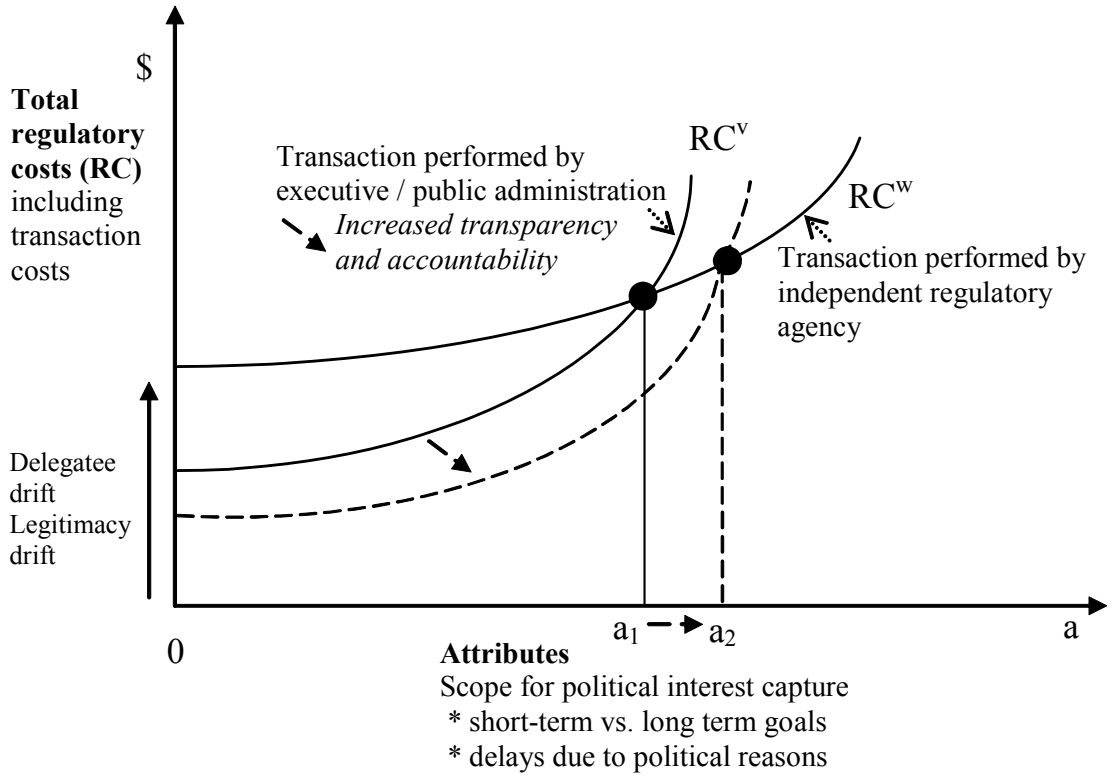
Level of Autonomy

The transaction cost framework can also be applied to the second aspect of regulatory governance structure mentioned above: the degree of independence or autonomy that the regulatory agency has in performing a regulatory transaction. As in the case of the level of regulation discussed above, the transaction cost framework requires identification of the relevant regulatory transaction attributes.

The literature on political transaction costs and delegation (Dixit, 1996; Calvert, McCubbins, & Weingast, 1989) provides important insights in this regard. This literature suggests that delegation of authority from the political realm to an independent agency can reduce problems of "political interest

capture," which arise, for example, if there is a strong trade-off between short-term and long-term interests. The creation of independent central banks is a well-known example. In Figure 3, the attribute "scope for political interest capture" is displayed on the horizontal axis. From point a_1 onwards, an independent regulatory agency can perform the respective regulatory transaction at a lower cost than the public administration, because in this cost-effectiveness consideration, the benefits of reduced political interest capture translate into a lower slope of the respective hypothetical cost curve. For $a < a_1$, however, an independent regulatory agency does not have a comparative advantage, because delegation also involves costs. These costs have been attributed to "legitimacy drift" and "delegatee drift" (Voigt & Salzberger, 2002). Legitimacy drift occurs if the public does not attribute the same legitimacy to the independent agency that they would attribute to a governance structure with less delegation. In the case of biotechnology regulation, which is politically contested, the question of legitimacy is rather important. Delegatee drift occurs if the independent agency pursues goals other than those that the policy-makers had in mind when they created the agency. Delegation may also lead to increased coordination costs and reduced possibilities for monitoring.

Figure 3. Comparative efficiency of different governance structures: Degree of autonomy



Source: Based on Williamson (1991) and Birner & Wittmer (2006)

With regard to delegatee drift, it is necessary to consider whether an independent agency or the executive/public administration is likely to be subject to interest group capture, either by the industry or by environmental groups. In both cases, increased transparency and accountability can reduce the scope of this problem, resulting in a downward shift of the respective cost curve. In Figure 3, this option is indicated for the case of the public administration, but it would apply equally for an independent agency. It is an empirical question as to whether improved transparency and accountability can be established more easily in the respective public administration versus an independent regulatory agency, and the answer to this question may depend on the level at which the regulatory activity is performed (i.e. national or regional).

An important issue related to the independence of the regulatory agency is its influence on the duration of the regulatory decision-making processes. Delegating decision-making authority to the public administration or to an independent regulatory agency may have the advantage of reducing the time required for decision-making by reducing the scope for politically motivated "blockages," which may occur especially if a consensus rule is applied. However, the concepts of legitimacy drift and delegatee drift draw attention to the trade-offs involved in using delegation to deal with this problem. An alternative strategy is the specification of time periods for each step of the regulatory process, as seen in the EU regulatory system. The EU regulation delegates the authority to approve applications to the Commission (i.e. the public administration) if the Council of Ministers (i.e. the political body) fails to act on them within three months (Christoforou, 2004). In practice, virtually all approval decisions since the end of the de facto moratorium in 2004 have been made by the Commission, since no qualified majority has been reached in the Council.

Role of Participation in Decision-Making

In addition to the questions of centralization and autonomy, the role that the private sector and civil society should play in biotechnology regulation is an important dimension of regional regulatory design (Table 1). The question of stakeholder and public participation is particularly relevant for decision-making, but the public may also be involved in other regulatory activities, such as post-approval monitoring.

Participation in regulatory decision-making can be considered as both a goal in its own right and an instrument for reaching other goals, such as reducing conflicts by creating legitimacy. Regulatory systems differ considerably with regard to the role of participation, as this question is linked to the wider "regulatory culture" developed within a given country. If participation is seen from an instrumental perspective, transaction cost economics can be used to analyze the trade-off between increased transaction costs of decision-making caused by participation, and the benefits achieved by participation. The

transaction costs of participation include the resources needed to organize participatory processes, the opportunity costs of the participants' time, and the opportunity costs that are incurred if the time required to pass regulatory decisions is increased through participation, meaning that the technology becomes available later than it would have otherwise. However, participation may also speed decision-making by creating legitimacy and providing a formal forum for interaction. Other benefits of participation may include reduced enforcement costs due to the creation of legitimacy (cf. Birner & Wittmer, 2004; Mburu & Birner, 2002).

Identifying appropriate decision-making structures in view of conflicting values and interests has been a central topic in the public choice literature. As shown by Arrow (1950), there is no procedure that makes it possible to aggregate individual interests into a social welfare function (assuming some basic principles are met, such as the absence of a dictator). Buchanan & Tullock (1962) developed a classical approach for solving this problem that is consistent with the framework suggested here. The authors distinguish between the costs of decision-making and "external costs," the latter of which arise if collective decisions negatively affect the interests of the individual. According to Buchanan & Tullock, these external costs can be avoided by use of the unanimity rule in decision-making, which implies that all individuals must participate in decision-making and consent to the decision. However, as this rule increases the costs of decision-making, the decision rule that is optimal from the individual's point of view depends on the trade-off between the costs of decision-making and the external costs for the decision under consideration.

A considerable body of constitutional economics literature deals with the efficiency of different collective choice rules based on this approach (Mueller, 2003). This literature could inform the design of decision rules to be adopted in regional biotechnology regulation. For example, if the number of countries is small, as in case of WAEMU, a consensus rule might be most appropriate for important decisions, such as approval of field trials and commercial releases. However, while consensus rule increases the legitimacy of decisions, it does entail the problem that one or more member countries may block a given decision.

The transfer of decision-making on biotechnology regulation to a regional regulatory body has important implications for the possibilities of participation. On one hand, transaction costs arising from participation in decision-making may be reduced if regulatory decisions are made by a supranational body and participation takes place at that level, resulting in the need to organize a lower number of participatory processes. On the other hand, the possibilities to create legitimacy by participation at that level are more limited. Stakeholder organizations would need to be organized at the level where decision-making takes place, and they would need to have mechanisms making them accountable to their membership across national boundaries. In the case of West Africa, the farmers are organized at the

WAEMU level through the umbrella organization, ROPPA (Réseau des Organisations Paysannes et de Producteurs Agricoles de l'Afrique de l'Ouest, Network of Peasant Organizations and Agricultural Producers of West Africa). Consumer and industry organizations do not have a formal umbrella organization at the WAEMU level, but the interviews conducted in this study revealed that the organizations do collaborate at the regional level. Despite the options created by such regional organizations of stakeholders, however, it is unclear to which extent their participation in a regional system may create legitimacy at the national level in the absence of national-level participatory processes.

If participation is seen as a goal in its own right rather than just as an instrument for use in reaching other goals, it is useful to combine the efficiency considerations of the NIE and public choice literatures with other approaches. The concept of "volitional pragmatism" developed by Bromley (2006) on the basis of classical institutional economics offers important insights. This concept, which corresponds to the "deliberative" approach to regulatory philosophy, holds that public policy decisions should be based on the reasons that citizens can accept as a basis for political action. Scientific findings provide an important basis for making such decisions, but according to the volitional pragmatism perspective, the public must have the opportunity to judge scientific assertions in terms of reasons that matter to them. As Bromley (2006: 165) puts it, "in democratic market economies, citizens retain the authority to decide if and when scientific assertions constitute valuable belief."[26] Along similar lines, the concept of deliberative democracy suggests that the deliberations that take place in participatory processes can play an important role in creating agreement on the reasons that people can accept for public decisions (Fung & Wright, 2001).

According to these perspectives, it is important to establish forms of public participation that allow for meaningful deliberation. Whether and in what form such participation can be achieved at the regional versus national level is ultimately an empirical question. A minimum level of citizen identification with a regional community would likely be required to achieve this goal. This makes it important to determine the extent to which people in West Africa consider themselves to be members of a West African community, represented by ECOWAS or WAEMU. Most likely, countries that share the same official language and have experienced similar recent histories will have a stronger sense of regional identity. Future inclusion of questions on regional identification into a survey conducted in the region may provide important information on this matter.

This question of participation is also linked to the need to identify a desirable balance between using the institutions of representative democracy, especially parliaments, to provide voice and

[26] This perspective may be criticized by those who argue that regulation should be based on strictly scientific principles. This argument ignores the fact that it is a societal decision to transfer decision-making authorities to bodies that are supposed to consider strictly scientific principles. Obviously, the degree to which societies are willing to make this decision depends on the trust that the public has in scientific regulation. Opinion polls show that this trust differs considerably across countries. It is, for example, considerably lower in the EU than in the US (Bernauer, 2003: 78).

accountability versus using participatory approaches that may be classified as deliberative or direct democracy. In processes of regional integration, the development of a representative democratic institution (i.e. regional parliament) often lags behind the process of economic integration, leaving a "democratic deficit." This problem has been widely discussed with regard to the EU, where the powers of European Parliament evolved rather slowly. WAEMU and ECOWAS face similar challenges. As indicated above, the European Parliament has the right to be informed on regulatory decisions regarding biotechnology. Since WAEMU has an Interparliamentary Committee and ECOWAS has a regional parliament, regional regulatory designs should consider the role that these institutions could play in the regulatory process.

Financing Regulatory Systems

The literature on regulation provides some guidance on the question of how regulatory systems should best be financed. Crespi and Marette (2001) and Marette and Crespi (2005) compare the economic benefits of different mechanisms for financing regulatory authorities, including public revenue, industry fees, and penalties. They show that the level of competition in the respective industry, the expected compliance of firms with quality standards, and the monitoring costs all have important effects on the comparative advantage of different financing mechanisms. The fiscal federalism literature suggests that, in principle, revenues should be raised at the level of government where the respective services are provided, but provisions should be made to avoid regional imbalances (Wellisch, 2000). The NIE literature suggests that it is necessary to account for the transaction costs involved in different types of regulatory system financing, as well as the created incentives (e.g. for opportunistic behavior). Table 6 presents some general relevant considerations; future work is warranted to substantiate these considerations. The different financing mechanisms are displayed separately in the table, but may in practice be combined to balance potential negative effects.

If application fees are used as a financing method, the regulation costs are thereby incurred by the companies or research organizations developing the GMOs. If the regulatory system relies entirely on application fees, the fees might become high and create disincentives, especially for small companies and for public sector organizations. Companies may pass these costs on to farmers through seed pricing, though this possibility depends on the structure of the seed industry. In the West African cotton case, the seed supply is in the hands of a few vertically integrated cotton companies. Thus, even though the farmers are comparatively well organized and play a role in the political process (USDA, 2006), their bargaining power is limited and it would be fairly easy for the companies to pass on the regulatory costs to the farmers.

The extent to which farmers can pass on additional costs to consumers also depends on the market structure. Farmers are typically price takers, and small countries are price takers in international markets, such as cotton. Hence, there are only limited opportunities for farmers to pass the costs on to consumers. Accordingly, the benefits that farmers receive from growing GM crops would need to be sufficient to cover the incurred costs of their regulation. One advantage of using application fees, however, is that the transaction costs of administering application fees are low compared to other options.

For the WAEMU regional biosafety project, a market levy has been discussed as a mechanism for financing the regional regulatory system. If a general market levy is used, all farmers, including those not growing GM crops, will incur the costs of regulation. Farmers who do not want to grow GM crops may not consider this to be a fair distribution of regulatory costs. If the levy is charged only for GM crops, however, the transaction costs of administering the levy are increased. The transaction costs of administering a market levy also depend on the market structure. In the case of cotton and other export crops it is feasible to charge a market levy, whereas in the case of crops that are marketed locally, such as food crops, a market levy would involve rather high transaction costs. Linacre (2007) conducted a simulation analysis of financing the proposed WAEMU regional regulatory system through a market levy. The analysis showed that problems of financial sustainability could arise if adoption rates are low and the system relies only on a market levy collected for Bt cotton. If the collection of revenues through the levy is not sufficient to finance the system after the expected donor support ends, this financing mechanism may create incentives to approve commercial releases without due process, in order to bridge the financial gap.

A regional regulatory system may also be financed or co-financed from the revenues of the regional economic organization under which it is established. Both WAEMU and ECOWAS raise regional revenues by taxing imports from non-member states. If these revenues are used to finance the regulatory systems, the costs are incurred by the producers and consumers of the imported goods, which may not be considered optimal. Moreover, the use of these funds for regulation competes with other fund uses. A regional system could also be financed by contributions from the member states; in this case the cost distribution depends on the ways in which the member states raise their public revenues, and on competing uses for the these revenues. A formula would need to be developed to decide on the shares that the member states should contribute. The benefit derived by a member state from growing a given GM crop might be used as the basis for such a formula. Financing a regional regulatory system through regional revenues or contributions from member states does not create any obvious disincentives for innovation, and the transaction costs of using these two mechanisms will be comparatively low if regional organizations already have systems in place to collect regional revenues and contributions from member states.

Table 6. Implications of different ways to finance a regional regulatory system

Financial mechanism*	Distributional implications	Implications for incentives	Transaction costs of administering the financing mechanism
Application fees	Costs initially incurred by applicant; in case of industry applicants, costs maybe passed on to farmers and then to consumers, depending on market structure	Disincentives for innovation, especially for small enterprises and public sector research organizations	Comparatively low
Market levy	Costs incurred by all farmers or farmers growing GM crops, depending on the system used; costs maybe passed on to consumers, depending on market structure	If levy applies only to GM crops, problems of financial sustainability may arise, depending on adoption rates; system may create incentives to approve commercial release without due process to bridge financial gaps	Need for administration of the market levy; costs depend on market structure and are potentially high, if marketing system is diverse/fragmented and levy is only charged for GM crops
Revenues of regional organization	Depends on the way in which regional revenues are raised (e.g. imports); competition with other uses of regional funds	No obvious disincentives	Comparatively low, if regional system of revenue collection is already in place
Contributions from member states	Costs incurred by tax payers of member countries; cross-country distribution depends on formula used; competition with other uses	No obvious disincentives	Comparatively low, if system of national contributions to regional organization is already in place
Donor funding	Costs incurred by tax payers in donor countries; competition with other uses	Problems of financial sustainability may arise if funding is not guaranteed	Depends on the extent to which donors set up own financial procedures

Source: Authors
* Different financial mechanisms may be combined.

Donor funding can be considered another financial mechanism. To date, donors have invested considerably in the establishment of regional regulatory systems in West Africa, and further funding is expected. With respect to financial sustainability, donor funds might best be used to cover the fixed costs of establishing a regulatory system. If they are used to cover running costs, it is important to establish mechanisms that will cover these costs once the donor funding ends.

The distribution of regulatory costs is also influenced by the distribution of responsibilities for risk assessment and risk management between the biotechnology industry and the regulatory agencies. If the biotechnology industry takes a major responsibility for risk assessment and risk management, the costs incurred by the regulatory agency will be reduced. In most existing regulatory systems, it is the responsibility of the applicant to conduct risk assessments, which are then reviewed as part of the regulatory process. However, the interviews held in West Africa indicated that public sector representatives see the regulatory agencies as having a comparatively large role in risk assessment and

management. This position may be justified, especially if liability rules or their enforcement possibilities are weak, thus limiting industry incentives for risk assessment and management in countries/regions where liability rules are strong and enforceable.

Rules for the Transition to a Regional System

As noted in Table 1, it is necessary to establish rules for the transition to a regional system. Of particular interest is whether or not authorizations for field trials or commercial releases established in a member state before it entered a regional system should remain valid after entry. In the case of the EU, prior authorizations become invalid. For example, when Romania joined the EU, it had to withdraw the approval for Round-up Ready Soy, which was already in cultivation (Gullickson, 2006). A "grandfathering rule" can be used to avoid such situations. This is a relevant issue in West Africa, since Burkina Faso has already authorized field trials with Bt cotton.

When deciding on a grandfathering rule, it is important to consider the incentives created by such a rule. If the regulatory system at the regional level has stricter standards than the national system, a grandfathering rule may create incentives for a country to push through approvals at the national level before entering the regional system. If the regulatory standards at the national and regional level are comparable, this problem is less relevant. However, other factors should also be considered. If joining a regional system is associated with the free movement of GMOs in the respective region, an environmental risk assessment at the regional level may be necessary before a grandfathering rule is applied.

4. REGIONAL BIOTECHNOLOGY REGULATION– WHICH WAY IS FORWARD?

This paper has shown that countries interested in a regional approach to biotechnology regulation must make decisions on a range of institutional design options (Table 1). The analysis shows that the comparative advantages and disadvantages of different institutional options depend on an array of economic, ecological and social factors. Table 7 summarizes the issues that should be considered in each area.

Table 7. Factors to be considered in decisions on regulatory design options

Decision points	Factors to be Considered
1) Scope of the regional system	
Substantive areas and types of regulatory activities to be regulated at regional versus national level	*Attributes of regulatory transactions* (1) Economies of scale in regulation, e.g. those arising because countries share the same agro-ecological zones (2) Transaction intensity (frequency, spatial distribution) (3) Type of information/knowledge needed (scientific, local) (4) Level at which externalities and spill-overs occur (international, national, local) *Contextual factors* (5) Heterogeneity of preferences regarding GMOs and risks (6) Existing capacity of regulatory agencies at national and regional levels and prospects to build this capacity at different levels (7) Homogeneity of existing national regulatory systems (8) Existence of or prospects for a common economic space with easy transboundary movements of goods
2) Institutional structure of the regional system	
Type of institutions to be established	(9) Possibilities to use existing regional institutions for regulation (10) Point (6) above; see also points (11) to (15)
3) Decision-making at the regional level	
Mode of decision-making; degree and form of public participation in decision-making at different levels; issues considered in decision-making	(11) Existing decision rules and procedures in regional organization; role of regional parliament (12) Scope for political interest capture and corruption (13) Potential for "delegatee drift" and "legitimacy drift" arising in case of delegation (autonomy of regulatory agency) (14) Degree of organization of stakeholders (15) Existing forms and traditions of public participation
4) Financing of a regional system	
Mode of financing the system	(16) Existing financing mechanisms of regional organization (17) Structure (incl. level of competition) of the biotechnology industry and the seed industry (18) Expected compliance of firms with quality standards and monitoring costs (19) Transaction costs involved in different finance mechanisms (e.g. costs of administering a levy) (20) Role of financing gaps that may cause safety hazards

Table 7. Continued

Decision points	Factors to be Considered
5) Distribution of responsibilities between regulatory agency and industry	
Distribution of responsibilities	(21) Comparative capacity of state agency versus industry in generating data needed for regulation (22) Incentives of state agency versus industry to provide appropriate data
Decision points	**Factors to be Considered**
6) Enforcement of a regional system	
Institutions and procedures used for enforcing regional decisions at the country level	(23) Legal and political possibilities to use existing regional institutions of enforcement (24) Points (5) and (7) above
7) Transition to regional system	
Mode of dealing with existing national regulations	(25) Differences in standards between national and regional systems, and resulting incentives created by different transition rules (26) Degree to which member countries have already authorized GMOs (27) Point (7) above

Source: Authors

Regarding some of these factors, the available information for West Africa is limited. For example, in the absence of representative citizen surveys,[27] it is unclear what level of information producers and consumers have about agricultural biotechnology, and to what extent biotechnology preferences differ among the potential member countries of the regional regulatory system. Likewise, there is limited information on the extent to which cross-border movements of GMOs can be controlled (and at what costs), and on the nature of possible disruptions such controls could have on a common market. With regard to environmental effects, it would be useful if the regional system had the ability to handle future applications for different types of crops. Hence, the spatial nature of possible environmental risks should be considered during the design of the regional regulatory system, even if such risks are not relevant for Bt cotton, which dominates the current debate on regional regulation. If agronomic or environmental risks lead to spill-over effects across country borders, the rationale for a regional approach to regulation becomes more pronounced than otherwise.

With regard to the good governance criteria for assessing regulatory systems, there is also a range of open questions. Will it be easier to guarantee transparency, to avoid special interest capture, and to control for corruption at the national or at the regional level? Can meaningful public participation and deliberation be achieved at the regional level? Under what conditions will regulatory decisions at the regional level be considered legitimate? How much trust does the public have in regional organizations? Will a consensus rule for decision-making at the regional level, which may enhance legitimacy, lead to a blockage of regulatory decisions? Is involving regional parliamentary bodies an appropriate way to increase voice and accountability, or are other forms of participation more effective? With regard to the

[27] See footnote 23.

financing of a regional system, there are open questions and trade-offs as well, such as determining which distribution of regulatory costs will be considered fair, while at the same time creating incentives for innovation.

The theoretical considerations presented in this paper can inform the debate on these questions. Additional empirical research, for example on the spatial dimension of possible risks, and on public perceptions, will further improve the basis for decision-making on regional regulatory design. To a large extent, however, the knowledge of local experts, stakeholders and policy-makers will be key to answering these questions. The organizations that have promoted the establishment of a regional regulatory system in West Africa have all placed strong emphasis on participation, mostly by organizing workshops with stakeholders. The analysis presented in this paper suggests that it would be useful to bring the knowledge of regional experts, stakeholders and policy-makers to bear—in a structured way—on the specific questions of regional regulatory design identified herein. Our analysis also shows that there is merit in paying attention to the details of a regional regulatory system by unbundling regulation into different activities and reflecting on the appropriate level of organization for each regulatory activity.

Involving stakeholders in these debates may require forms of interaction other than those typically practiced at stakeholder workshops (presentations followed by general discussions). A wide range of participatory techniques have been developed in the context of technology impact assessments, and these could be applied during the establishment of regional regulatory systems. Combining participation with multi-criteria analysis appears to be a particularly promising approach, because regional regulatory systems should be evaluated against multiple criteria (Table 2), and stakeholders may assign different weights to different criteria. Prior use of multi-criteria analysis in participatory processes has shown that this strategy often helps rationalize emotional debates, and may narrow down the number of options on which different groups disagree (Rauschmayer & Wittmer, 2006).

Ultimately, the process of establishing a regional regulatory system is a political process. The way in which decision-making will be organized at the regional level, and the way in which the expected costs and benefits of a regional system are distributed, have important implications for the political economy of establishing such a system. Different interest groups may promote or oppose the process, depending on how they envision the regional system working. In the West African case, the interviewed groups that were critical of biotechnology were also critical of the establishment of a regional regulatory system, as they were concerned that such a regional system could be used to "impose" GM crops on countries where resistance against biotechnology is strong. Groups that were in favor of biotechnology were generally also in favor of establishing a regional regulatory system, highlighting potential efficiency gains. Since political disagreement about biotechnology has led to delays in establishing national systems for biotechnology regulation in several countries of the region, it is unclear whether the goal of

establishing a regional regulatory system will speed up or further slow down the creation of a legal basis for the introduction of biotechnology in the region. Likewise, the design of the system and the political economy factors influencing its operation will help determine whether regional regulation will ultimately lead to a more or a less precautionary approach towards biotechnology in the region. An analysis of the political economy of biotechnology regulation in West Africa was beyond the scope of this paper, but this is certainly an important field of research relevant to the establishment of regional regulatory systems.

While West Africa and the EU have been used as empirical cases in this paper, the analytical framework presented in Section 3 is equally relevant for other regions of the world that are engaged in establishing a regional regulatory system for biotechnology. A dialogue and the sharing of experience among experts and stakeholders from different regions might provide further fruitful insights on regional regulatory design. Hopefully, this paper can contribute to such dialogues and thus help citizens in different regions of the world promote good governance in the regulation of this important and contested technology.

APPENDIX: INTERVIEWEE AFFILIATION

Individuals from the following organizations were interviewed during the course of this research:

Benin
- National Biosafety Committee
- Ministry of Science and Research
- Ministry of Agriculture
- Ministry of Environment
- University d'Abomey-Calavi
- National Agricultural Research Institute
- JINUKUN/COPAGEN (NGO)
- Institute for Tropical Agriculture (IITA)
- C/SFEND
- ENAM
- National Center for Intellectual Property

Burkina Faso
- National Biosafety Agency
- Ministry of Environment
- Ministry of Science and Research
- Ministry of Agriculture
- Confederation of Burkinabe
- National Union of Cotton Producers of Burkina Faso
- Network of Peasant Organizations and Agricultural Producers of West Africa
- CVeille OGM
- National Agricultural Research Institute
- DTA (Food Safety)
- Lawyers
- WAEMU

Mali
- USAID
- West and Central Africa World Agroforestry Centre
- National Biosafety Committee
- Ministry of Science and Research
- Ministry of Agriculture
- Ministry of Environment
- ANSSA (Food Safety)
- National Assembly
- Journalists
- CNOP
- Campaign for the Development of Textiles.
- Consumers Association
- Journalists
- Lawyers

Senegal
- ENDA-SYPRO (NGO)
- University of Gaston Berger
- National Biosafety Committee
- Ministry of Science and Research
- Ministry of Agriculture
- Ministry of Environment
- Plant and Pesticides (PCP)
- University of Cheikh Anta Diop (UCAD)
- National Farmers Organization
- National Science academy
- CONGAD (NGO)
- Journalists
- Lawyers

Togo
- University of Lome
- National Biosafety Committee
- Ministry of Science and Research
- Ministry of Agriculture
- Ministry of Environment
- Friends of the Earth Togo
- COPAGEN/INADES (NGO)
- INADES (NGO)
- Journalists
- Lawyers

Guinea Bissau
- National Agricultural Research Institute INPA

Niger
- Ministry of Water and Environment

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2033 K Street, NW
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Tel.: +1-202-862-5600
Fax: +1-202-467-4439
Email: ifpri@cgiar.org

IFPRI ADDIS ABABA

P. O. Box 5689
Addis Ababa, Ethiopia
Tel.: +251 11 6463215
Fax: +251 11 6462927
Email: ifpri-addisababa@cgiar.org

IFPRI NEW DELHI

CG Block, NASC Complex, PUSA
New Delhi 110-012 India
Tel.: 91 11 2584-6565
Fax: 91 11 2584-8008 / 2584-6572
Email: ifpri-newdelhi@cgiar.org