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Designing Regional Systems of Biotechnology Regulation

A Transaction Cost Approach to Regulatory Governance

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Abstract

Many developing countries are currently in the process of designing regulatory systems that should make it possible to use the potential of genetically modified organisms (GMOs) for agricultural development, while at the same time managing the risks for food safety and the environment that are potentially associated with these technologies. In view of the considerable costs associated with biotechnology regulation and the scarcity of biosafety specialists, there are processes in various regions of the developing world to establish regional systems of biotechnology regulation. So far, there are major knowledge gaps as to how regional systems of biotechnology regulation can be designed to be effective and efficient and to fulfill principles of good governance, such as transparency, voice and accountability, control of corruption, and avoidance of special interest capture. There is a wide variety of possible regional approaches, which differ with regard to the level of centralization, the scope of a regional system, the types of regional institutions and processes, and the types of financing mechanisms. Based on the literature on environmental and fiscal federalism and transaction costs economics, the paper develops 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 as well as the factors affecting these trade-offs. The paper takes West Africa as an example to illustrate this framework and refers to the European Union for comparison. The paper concludes that involving regional experts, stakeholders and policy-makers into debates on the design of a regional regulatory system is an important strategy to fill knowledge gaps and arrive at conclusions regarding the trade-offs involved in regional biotechnology regulation.

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

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 the functioning of a regulatory system have far-reaching implications for the possibilities to make this technology available to farmers, to ensure environmental and food safety, and to create 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 the functioning of the regulatory system. Therefore, biotechnology regulation is an important element of good governance in the agricultural sector.

More than 120 countries, which are parties to the Cartagena Protocol on Biosafety, currently participate in the "Development of National Biosafety Frameworks" project of the United Nations Environment Program and the Global Environmental Facility (UNEP-GEF). Eight countries have moved to the UNEP-GEF project on the "Implementation of National Biosafety Frameworks". Concerns about the costs associated with biotechnology regulation and potential problems to control transboundary movements of genetically modified organisms (GMOs) across neighboring countries have led to a strong interest in the regional collaboration for biotechnology throughout the developing world (GEF, 2006).

In spite of the increasing interest in regional regulation worldwide, there is almost no literature on the question of which type of regional coordination would be desirable for biotechnology regulation, depending on the context-specific conditions of the region under consideration. Regional coordination can obviously

take different forms, ranging from an informal collaboration of neighboring countries and the harmonization of regulatory standards to the establishment of a regional regulatory system with a central regulatory authority. Which governance structures for a regional biotechnology regulation should countries develop? Which degree of centralization should they aim for? How should the institutions for regional biotechnology regulation look like? How independent from political decision-making bodies should they be? Which forms of public participation should they entail? How should a regional regulatory system be financed? And which factors influence the answers to these questions?

The goal of this paper is to contribute to bridging the knowledge gap on regional biotechnology regulation by developing a conceptual framework that identifies key factors to be considered in 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 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 (WEAMU) also plan to establish a common regional system for biotechnology regulation. These examples are well suited to illustrate the design options and the potentials and challenges of regional biotechnology regulation. Empirical data on biotechnology regulation in West Africa were collected by a multidisciplinary team in the following countries: Burkina Faso, Mali, Benin, Togo and Senegal. The research was conducted between May and August, 2006. Approximately 130 semi-structured interviews were held with stakeholders from ministries, research institutes, producer organizations, non-governmental organizations (NGOs), and the private sector. Documents collected in-country and additional secondary research was used to substantiate the interviews. For purpose of comparison and illustration, the paper also refers to the regional system of biotechnology regulation in the European Union, which is one of the few already existing supranational systems of biotechnology regulation worldwide. Information on biotechnology regulation in the EU is derived from secondary sources.

By developing a conceptual framework based on economic theory, the paper aims at contributing to improved decision-making on the design of regional regulatory systems. The framework does not provide a blueprint for a regional system for biotechnology regulation in West Africa or elsewhere. It rather aims at identifying issues and options on which decisions have to be made when designing a regional regulatory system. The goal is to identify the factors and trade-offs that political decision-makers may wish to consider in the process. The design of a regulatory system, at the national as well as at the regional level, necessarily involves value judgments, since regulation is at the heart of the societal debate on biotechnology. 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 that the countries have signed, and emerging international standards for biotechnology regulation provide important frame conditions for making such decisions. Together with other disciplines, economic theory can provide insights for making decisions on regional regulatory design within these frame conditions, but research can only inform, not replace, the deliberations of policy-makers and society about the reasons they consider legitimate and justifiable in 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.

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 the potential that Bt cotton may have for increasing 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, 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, in Benin for about one third and in Mali for one quarter (USDA, 2006). In view of strong international competition, a long-term decline in world market prices, and agronomic challenges, agricultural research institutions and policy-makers have developed an interest in introducing genetically modified cotton. In collaboration with Monsanto, Burkina Faso started field testing Bt cotton in 2003. Mali has expressed its interest to Monsanto and Syngenta to start field trials, and the Côte d'Ivoire Agricultural Research Institute has suggested that—after restoring peace—the country would become a leader in biotechnology research in the region (USDA, 2006). Among the West African countries, only Burkina Faso has, so far, passed a biosafety law and established a regulatory system that can process applications for field trials and commercial release. 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 is politically contested throughout the region, which has delayed processes of passing biosafety legislation in other countries, especially those where civil society is strong, such as Mali and Senegal (Birner, Resnick, & Linacre, 2007).

As indicated above, three efforts are currently underway to establish regional systems of biotechnology regulation in West Africa, led by CILSS, WEAMU and ECOWAS in collaboration with CORAF. Figure 1 displays shows which countries are members of these regional bodies. Several factors provide a rationale for the interest in regional approaches to biotechnology regulation:

(1) Most of the major cotton-producing countries in West Africa are relatively small in terms of population size, and they belong to the poorest countries in the world. Hence, there is an expectation, especially among donor organizations, that there is a need to exploit economies of scale in a regional approach to biotechnology regulation.

(2) Major agro-ecological zones cut across West Africa, which contributes to economies of scale in risk assessment and risk management.

(3) A regional approach would facilitate the cross-boundary movement of genetically modified crops. This is important for West Africa's landlocked countries, and for the efforts of WEAMU and ECOWAS to establish a common market in West Africa. (4) All countries in the region used the African Model Law as a basis for developing their biosafety frameworks and draft legislation, so that there are no major differences between countries regarding the type of regulatory systems they envisage establishing.

CILSS Framework Convention on Biosafety

Among the three regional biosafety initiatives, the CILSS initiative is currently the most advanced. CILSS was established in 1973 in response to the

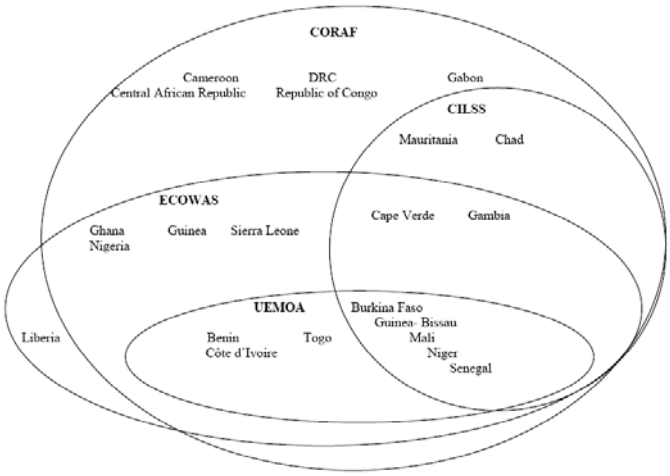

Figure 2: Membership of West and Central African countries in different regional bodies

Source: Resnick (2006)

drought and famine afflicting the region at that time. A Framework Convention Introducing a Common Biosafety Regulation for the Prevention of Biotechnological Risks in the CILSS Countries was

developed in a process of two years and adopted by the CILSS Council of Ministers in 2006. The CILSS countries still have to translate the Convention into national law, which is not expected to be completed before 2008. The Convention aims at harmonizing national biosafety regulation in the member states by specifying procedures, definitions, and responsibilities for the national authorities to be set up by the member states. Under the Convention, a Regional Consultative Committee will be established, which will provide general technical and policy support to the national authorities. The committee will comprise representatives of the member states including the national biosafety agencies and scientific experts as well as non-voting representatives of WAEMU and other relevant regional bodies. The committee can make authorization decisions for countries that have not yet set up a regulatory system and when products will be marketed throughout the region. Otherwise, authorization decisions remain the responsibility of the member states. The CILSS Biosafety Convention has some similarities with the CILSS Common Regulation for the Registration of Pesticides created in 1999, which established a regional process for the registration of pesticides. Under this convention, a company that wants to market a pesticide in any of the nine CILSS member countries needs to submit only one application to a committee of experts who undertake the risk assessment and make a decision for the all nine countries.

Regional biosafety initiatives by ECOWAS and CORAF

The Economic Community of West African States (ECOWAS) encompasses the fifteen countries that comprise the entire West African region (Figure 1). The organization was founded in 1975 with four major objectives: to expand intra-community trade, improve physical infrastructure, reduce excessive external dependence, and creating 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. The plan to elect the members of the Parliament directly is not yet 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 a West Africa conference held in Ouagadougou in June 2004, where it was 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 initiatives in the region in the area of biotechnology. CILSS was designated as the coordinator for the implementation of the region's bio-safety activities in view of CILSS' activities regarding a regional convention, as outlined above. 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 bio-safety.

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 to influence to political debate in favor of biotechnology. Another goal has been to augment the capacity of scientists to use biotechnology for agriculture. With regards to the bio-safety component the program, the main objectives include creating commonalities in bio-safety procedures, strengthening institutional and human capacities in bio-safety implementation, establishing a regional regulatory framework, and sensitizing the public. Donor funding, especially by the United States Agency for International Development (USAID), has played an important role in supporting the CILSS, CORAF and the ECOWAS Initiatives.

The WEAMU Initiative to Establish a Regional Regulatory System

The West African Monetary and Economic Union (WEAMU) emerged in 1994 through a revision of the treaty of the *Communauté Economique de l'Afrique de l'Ouest*, which was launched in 1973. WEAMU is formed by eight francophone West African countries (see Figure 1). The institutional structure of WEAMU comprises a Commission, the Council of Ministers, the Conference of Heads of States, and an Interparliamentary Committee. Unlike in the case of ECOWAS, WEAMU's Council of Ministers has decision-making authority. WEAMU 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. WEAMU is currently in the process of establishing a regional regulatory system for biotechnology. WEAMU expects funding and technical support for establishing this system 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 "(a) produce operational, regionally harmonized methodologies for risk assessment and management of LMOs and LMO products, including a regional manual of procedures; (b) strengthen national biosafety frameworks to enable their implementation; and (c) set up a regional legal framework for biosafety as well as 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." The design of the 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, they expressed concern that project would "promote favorable regulations in a few key countries" and then "use these regulations as a model that can be imposed on neighbouring countries by regional bodies" while side-stepping democratic debates (African Center for Biosafety, ECT Group, GRAIN, & RALLT, 2006).

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. 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, if approved, notifying other member states, 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. This approach comprises four steps (Christoforou, 2004; Wendler, 2005):

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

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. EFSA also requires a method validation from the Community Reference Laboratory to verify whether the methods and samples fulfill the requirements of EU guidelines.

3) When EFSA has completed its Opinion, it is forwarded to the EU Commission, the member state and the applicant. The public has the right to comment within 30 days on the Opinion. 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." 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 consulted on decisions to authorize the release of GMOs. The EU Council has the ultimate authority to approve GM products, but the Council gets involved only if there is disagreement in the Committee. The Council can decide with a qualified majority. If an authorization is granted, it is valid in the EU for ten years an can be renewed after this time.

The Standing Committee on Food Chain and Animal Health appears to be the major forum where negotiations with national administrations and stakeholders take place (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 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, however, have been established at the regional level.

Conceptual Framework

This section presents a conceptual framework that derives insights for the design of a regional regulatory system from different theories of regulation. The section starts with an overview of the institutional design options on which policy-makers in West Africa—and other regions that want to establish a regional regulatory system—have to decide. The second sub-section discusses a set of criteria that policy-makers may wish to consider when comparing different options for regional regulatory system. The third subsection reviews different branches of economic theory to identify factors and trade-offs that influence the comparative advantages and disadvantages of different regulatory design options.

Options for Regional Regulatory Design

Table 1 provides an overview of the institutional design options. An important question is obviously 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 area that may be carried out at the regional level. As the case of the EU shows, a region may decide to regulate approvals for field testing, commercial release, and labeling at the regional level, but leave regulatory decisions on co-existence

regulations and liability at the national level. Likewise, regions may decide to delegate some regulatory activities, such as risk assessment to the regional level, while performing others, such as post-approval monitoring activities at the national level.

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 WEAMU, 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 a regional regulatory agency, a regional regulatory committees, and regional advisory councils. In case of CILSS, a Regional Regulatory Committee was established. In the case of the EU, existing institutions (EFSA, Standing Committee on Food Chain and Animal Health) are used for biotechnology regulation. There is also a need to decide whether regulation should rely on national scientific capacities, as in case of the CILSS common pesticide regulation, or whether regional scientific organizations should be established. The EU relies on a combination of both.

With regard to regulatory decision-making, the question is which level of autonomy from the public administration decision-making bodies should have. This question also arises at the national level. Australia, for example, uses the model of 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, i.e., the Commission, or—in case of disagreement—by a political body, the Council of Ministers.

There is also a need to decide on the decision-mode of a regional body. Decisions could be binding on the member states without being ratified by the member states, as in case of the EU authorization for GMO products. Alternatively, they 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 WEAMU, but not for ECOWAS. The example of the CILSS pesticide regulation shows that even without a regional organization that has the authority to make binding decisions for member states, states can still decide to abide by the decisions of a regional committee they have set up.

A design feature that has potentially far-reaching implications for the time needed to reach a regulatory decision is the nature of the decision-making rules to

be applied. WEAMU requires decision-making by consensus. A legal assessment would be necessary to determine whether WEAMU could use different decision-rules for the case of biotechnology regulation. In ECOWAS, decisions are either made by consensus or with two third majority, depending on the subject. In the EU, the Council can make regulatory decisions with a qualified majority, as indicated above.

A question regarding regulatory decision-making that is controversially discussed at the international level is what is to be considered in regulatory decision-making. While there is an agreement that environmental and health risks should be considered, there is less agreement on the extent to which socio-economic considerations and ethical concerns should be addressed as well in the regulatory process. Since the debate in West Africa focuses on the Cartagena Protocol and on Bt cotton, which is not a food crop, most of the attention has been paid to decision-making with regard to environmental risks, so far. One of the most debated issues in regulatory decision-making on biotechnology is the use of the precautionary principle. In the EU, which adopted the principle for biotechnology regulation, its interpretation 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.

A further 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. The CILSS Pesticide Convention has no provisions for public participation (Jaffe & Meissa Dieng, 2007). Participation has, however, been prominent in the UNEP-GEF assisted development of biosafety frameworks in West Africa. Participation mostly took the form of stakeholder participation in workshops (Resnick, 2006). The national biosafety draft laws in the WEAMU countries differ with regard to the type and degree of public participation in regulatory decision-making they provide for. Some countries plan to set up consultative committees that represent the public or stakeholders as part of their regulatory system (Birner et al., 2007).

The division of responsibilities in risk management and risk 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 have to be conducted by the industry, and are then reviewed by the regulatory agency. There is also a need to decide as to how far the industry is responsible for post-approval monitoring activities.

The way in which a regional regulatory system should be financed is another important design question. A number of different mechanisms for financing regulatory systems exist, which can also be used in combination. They include a market levies; license and applications fees; tax revenues from the respective regional organization; direct contributions from member states (according to some formula); and donor funding.

Criteria for Assessing Regulatory Design Options

The standard literature on environmental policy instruments provides important criteria that can be applied to assess regulatory design options in a comparative perspective. The effectiveness in achieving the societal goals that regulation is supposed to achieve, in particular, ensuring a desired level of environmental and health safety is a crucial criterion, since this is the primary goal of biotechnology regulation. Hence, other criteria only become valid if this criterion is met. This effectiveness criterion is related to the "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 the benefits of regulation as difficult to quantify, cost-effectiveness is a useful criterion: Does the regulatory system achieve the desired levels of environmental and food safety levels at the lowest possible costs? If the benefits can be measured, one can conduct cost-benefit analyses and 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 criteria that can be considered as "good governance" criteria. These criteria can be derived from the literature on good governance. While the concept has remained subject to debate, the dimensions of good governance developed by Kaufmann, Kraay and Mastruzzi (2007) have become widely accepted: 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 other criteria can be applied to biotechnology regulation, as discussed in the following.

The government effectiveness criterion is linked to effectiveness criterion and the economic criteria already discussed, hence it is not listed separately in Table 2. An important aspect of regulatory quality can be seen in minimizing 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. The literature on agricultural biotechnology regulation in developing countries appears to have focused on a different version of the capture theory of regulation, arguing that biotechnology regulation has been captured by environmental groups (Paarlberg, 2001) or by the pesticide industry (Graff & Zilberman, 2004). Good governance in biotechnology regulation would obviously imply to achieve a balance in societal interests and avoid capture by any special interest group. The challenges associated with this criterion are further discussed below.

Avoiding special interest capture is related to another aspect of regulatory quality: the capacity of the process to balance the interests, values and risks attitudes of different groups of society in the regulatory process, so that the outcome of the process is considered to be 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 are accountable to citizens and their political representatives, such as 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.

Little attention has been paid in the literature on agricultural biotechnology regulation to this question, so far. As an indication that this problem is real, in January 2005, Monsanto paid a fine of 1.5 Million US$ for bribing an Indonesian official. The company admitted that one of its employees paid the senior official in a bid to avoid environmental impact studies being conducted on its cotton (BBC News, 2005). Strategies to reduce corruption 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 take into account what can be monitored and enforced, and which capacity needs to be created for this purpose.

A further set of criteria refers to the conformity of a regulatory system with the international obligations that a country has signed, such as the Cartagena Protocol on Biosafety, WTO, with the treaties of the regional communities a country is member of, such as WEAMU or ECOWAS. Moreover, the regulatory system needs to conform with the constitution of the

respective country. Conformity with international good practice in biotechnology regulation may be considered as a criterion, as well.

A final set of criteria, against which regulatory design options can be assessed, is the creation of legitimacy. To a large extent, legitimacy is created by fulfilling the other criteria discussed above. In the case of regional biotechnology regulation in the EU, several authors have distinguished "input legitimacy", which refers to the regulatory process, and "output legitimacy", which refers to the performance and the results of regulation.

Process criteria which can be seen either as goals in their own right, or as instrumental to achieve 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 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 Table 1: What is the appropriate level to which different types of regulatory activities should be assigned? What is the appropriate level of autonomy/independence of regulatory institutions? What level and form of participation is appropriate? And what are the advantages and disadvantages of different ways of 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 literature presented in Subsection 3.3.2 can be applied to all questions.

Environmental and Fiscal Federalism Literature

The literature on environmental federalism highlights the nature of the environmental good and the level at which externalities occur as essential to determine 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 supra-national level. This literature shows that federal and supra-national regulation is justified in 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 case of local public goods without spill-over effects, local regulation will be justified, if one assumes that local governments maximize their constituents' welfare.

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 regulation nor local regulation would be efficient in this case (Oates, 2001). In the absence of transaction costs and distributional concerns, bargaining across local jurisdictions would, according to the so-called Coase Theorem lead to efficient outcomes. However, this is obviously not a practical solution, since transaction costs matter, as Coase (1960) observed. Still, what this theoretical consideration shows is 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). A common concern in case of both local public goods and local spill-over effects is the problem that a "race to the bottom" regarding environmental standards may occur. This argument is debated, however, and there is a large literature that aims at identifying the conditions under which a "race to the bottom" will in fact occur (Wellisch, 2000).

Applying this line of reasoning to the case of biotechnology, one has to distinguish different types of risks associated with the technology. Some risks, such as introducing an allergen into the food chain are potentially externalities at a global level, but they require the transboundary movement of GMOs—in this case GMO food exports—to occur at that level. Hence, they can be managed by controlling transboundary trade. Therefore, they provide only a rationale for supranational regulatory coordination in this regard. The Cartagena Protocol, which six of the eight WEAMU member states ratified, already has provisions for transboundary movements of GMOs. Other potential externalities, such as the creation of an invasive-species-type of problem, are most likely occur at the level of an ecological zone, if they occur If several countries share the same ecological zone and the externality cannot be managed by controlling transboundary trade of seeds, this externality would be a "national spill-over", analogous to the "local spill-over" in Oates' theory referred to above. Applying the Oates (2001) argument, this problem would not necessarily provide an economic rationale for centralized regulation at the regional, but it would make regional coordination necessary. Spill-over effects also occur at the local level in form of gene flow to the fields of farmers who want to produce GM-fee crops. This problem can be managed by co-existence regulations. It has implications for surpra-national regulation only in so far as farmers in border areas may be affected.

The implications for regional regulation change, if one takes into consideration that countries may have limited ability to control transboundary movements of GMOs. This may happen, for example, if farmers exchange seeds across the border. While some respondents interviewed for the study mentioned this possibility, further data collection would be required to establish the relevance of this problem. If the control of transboundary movements of GMOs is a problem, this problem provides a stronger justification for the establishment of regional coordination in biotechnology regulation. The same reasoning applies, if countries want to establish a common market and, therefore, want to reduce controls on transboundary movements of goods. This is actually the case in the WEAMU and in the ECOWAS region. Likewise, the establishment of a common market in the EU has been a strong rationale to delegate 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 USA, Bernauer (2003) analyzed whether political subunits within a federal system can, by unilaterally installing stricter or laxer regulation of agricultural biotechnology, push the stringency of a system-wide regulation up or down. He concluded that in the EU, a process of "ratcheting up" has taken place, whereas such an effect is absent in the USA. 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.

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-overs, is the role of differences in local preferences. Heterogeneity of preferences provides a rationale for decentralization. Applied to the question of regional biotechnology regulation, this argument suggests that the transfer of regulatory authority to a supra-national body is less justified if there are strong national differences in people's preferences regarding biotechnology. To which extent such differences exist is an empirical question. There were differences across the WEAMU countries in the positions of the farmers' organizations and civil society organizations interviewed for this study regarding Bt cotton. This may partly be linked to the fact that the political systems in the WEAMU region differ with regard to the scope they provide for independent civil society organizations to emerge and formulate their positions. Stakeholder information is not necessarily representative for the population as a whole. Including a set of biotechnology questions into representative surveys, such as the Afrobarometer survey, would provide valuable representative information on public opinions and on the opinions of different groups (farmers, consumers) regarding biotechnology.

Table 53 summarizes some major insights derived from the environmental and fiscal federalism literature and the implications derived 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 if national preferences with regard to the environment and the technology differ. This disadvantage has to be weighed against the costs of controlling the cross-border movement of GMOs, which can be reduced through a centralized regulatory system.

New Institutional Economics (NIE) Literature

The NIE perspective helps to 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 are to 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 different options for the institutional design of a regulatory system. To apply this approach to biotechnology regulation, one needs to (1) disaggregate or "unbundle" biotechnology regulation into different regulatory activities or transactions; (2)

identify the types of costs associated with 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 major transactions involved in biotechnology regulation and lists the types of costs and benefits that are associated with each of these transactions. If more areas of regulation are considered, e.g., by including property rights, labeling and seed certification, additional regulatory transactions would need to be included in the table. For reasons of scope, this section discusses only the transaction listed in Table 4. However, the considerations presented in this section can be applied to other regulatory transactions.

For each of the activities, the question arises under which governance structure (level at which regulation takes place; degree of autonomy; role of industry and civil society) it should be organized. To determine the comparative advantage of different governance structures, one needs to identify the factors that affect the costs and benefits that arise under different governance structures. In the case of regulation, it is mainly a matter of definition as to which costs should be considered as "transaction costs" and which types of costs should be considered as other costs. One may consider all costs related to regulation as 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 different costs, not taking into account that—depending on the market structure—the industry may be able to pass on the costs to the farmers, who may be able to pass them on to consumers. In case of the benefits, it is less straightforward to determine how they will be distributed, since this depends not only on the market structure, but also on 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 if this leads to increased trust in the technology.

As indicated above, one can, in principle, determine the "optimal intensity" for each regulatory transaction as the level where the marginal social regulatory costs equal the marginal social benefits. Existing studies have quantified absolute regulatory costs, for example in India (Pray, Bengali and Ramaswami, 2005). However, there is still little empirical information available to date on the marginal costs of regulation and on the absolute and marginal benefits of regulation. The benefits consist to a large extent in the reduction of health, environmental and agronomic risks.

The potential benefits of regulation can be rather high, if one considers the costs that would arise if an allergen is introduced in the food chain or an invasive species-type of environmental problem or an agronomic resistance problem is created. The STARLINK case, even though it did not introduce an allergen into the food chain according to available evidence, is nevertheless an indication of the magnitude of the costs that could arise in such a case. Other benefits of regulation specified in Table 5, such as creation of legitimacy and trust in regulation are rather difficult to quantify as well.

Acknowledging the empirical challenges of collecting empirical information on the marginal costs and benefits of regulation, the following sections apply a cost-effectiveness perspective to compare different governance structures and derive hypotheses regarding the factors that influence the comparative advantages of different governance structures. The approach used is in line with the standard literature of transaction cost economics (Williamson, 1991)

Accordingly, the paper develops hypotheses on the absolute costs incurred for performing a regulatory transaction in a way that ensures a defined outcome. If this outcome is not achieved under a certain governance structure, one could add the benefits forgone as an additional category of costs.

Level of centralization / decentralization

Figure 2 illustrates the application of the transaction cost approach to the question at which level of government 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 (supra-national) governance structure y. The vertical axis indicates the regulatory costs arising for the respective transaction. The horizontal axis displays the attributes, which increase the comparative advantage for centralized regulation.

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, if several countries share an ecosystem with rather similar ecological conditions. In contrast, there 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). Transactions may be intensive in terms of frequency and in terms of spatial dispersion. Enforcing refuge requirements, for example, is far more transaction-intensive in terms of frequency and spatial dispersion than making decisions on the approval of field trial or commercial release applications. The more important these attributes are—indicated by a move to the right on the horizontal axis—the faster is the increase in the hypothetical costs for performing the respective activity under the decentralized (national) governance structure x.

In case of a centralized (supra-national) governance structure y, the regulatory costs increase less rapidly, 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. For $a < a_1$, the decentralized governance structure has a comparative advantage.

Figure 2 also displays the effect 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, for example, 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 from which onwards a centralized organization of the respective transaction has a comparative advantage over a decentralized one 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 already existing supranational governance structure, which reduces the transaction costs required for setting up a new supranational system for all aspects of regulation. In the case of West Africa, countries can partly rely on the already existing governance structures of CILSS, WEAMU and ECOWAS for biotechnology regulation, even though there is a need to build subject-matter specific capacity.

The role of heterogeneous local (national) conditions and preferences, which has been discussed above, can also be considered in Figure 2 as a context-specific factor. In this case, a decentralized agency would be able to perform the respective activity at lower costs. This is indicated by a downward shift of the hypothetical cost curve that indicates decentralized regulation. Accordingly, the point from which decentralized regulation is more efficient moves to a_3. A similar effect occurs, if local knowledge, rather than scientific knowledge, is required to perform a regulatory activity well. For example, local knowledge is important for the monitoring of refuge requirements, while scientific knowledge is important for environmental risk assessment activities.

Table 5 summarizes the attributes of the different transactions derived from this discussion. The table provides a rationale for assigning pre-approval activities (risk assessment) to a supra-national level to make use of economies of scale and scarce scientific knowledge. In case of environmental risk assessment, a rationale for delegation to a supra-national body exists in particular, if countries share the same agro-ecological zones. If the agro-ecology is very diverse,

supra-national bodies may be less suited to be responsible for environmental risk assessment activities. The table suggests that there is also a rationale to assign post-approval (monitoring and evaluation) activities to a national or sub-national level, since such transaction-intensive activities are difficult to control from a supra-national level. In case of decision-making activities—approval of field trials and commercial release—the case is less clear, since these steps in the regulatory process are most contested politically. Therefore, other criteria, such as creating legitimacy need to be considered, as further discussed below.

Level of autonomy

The transaction cost framework can also be applied to the second aspect of a regulatory governance structure mentioned above: the degree of independence or autonomy that the regulatory agency has in performing a regulatory transaction. As in case of the level of regulation discussed above, the transaction cost framework requires the identification of the attributes of regulatory transactions that are relevant in this respect. 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. Creating independent central banks is a well-known example. In Figure 3, the attribute "scope for political interest capture" is displayed at the horizontal axis. From point a_1 onwards, an independent regulatory agency can perform the respective regulatory transaction at lower costs than the public administration, because in this cost-effectiveness consideration, the benefits of reduced political interest capture translate in a less steep increase in 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 that involves less delegation. In the case of biotechnology regulation, the question of legitimacy is rather important, since the technology is politically contested. Delegatee drift occurs if the independent agency pursues goals other than those that the policy-makers had in mind when creating the agency. Delegation may also lead to increased coordination costs and reduced possibilities for monitoring.

With regard to delegatee drift, the question arises as to 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 for 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 the independent agency. It is an empirical question whether improved transparency and accountability can more easily be established in the respective public administration or in an independent regulatory agency. This question may depend on the level—national or regional—at which the regulatory activity is performed.

An important issue related to the independence of the regulatory agency is its influence on the duration of 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. The concepts of legitimacy drift and delegate drift draw attention to the trade-offs involved in using delegation as a strategy to deal with this problem. An alternative strategy is the specification of time periods for each step of the regulatory process, as in case of the EU regulatory system. The EU regulation delegates the authority to approve applications the Commission (i.e., the public administration), if the Council of Ministers (i.e., the political body) fails to come to act on them within three months (Christoforou, 2004).

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 a goal in its own right and as an instrument to reach 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" that a country has developed. 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 time of the participants, and the opportunity costs that are incurred if the time for passing regulatory decisions is increased, so that the technology becomes available later than otherwise. Participation may, however, also speed up 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).

The public choice literature provides additional insights, since identifying appropriate decision-making structures in view of conflicting values and interests has been a central topic in this literature. As shown by Arrow (1950), there is no procedure that makes it possible to aggregate individual interests to a social welfare function, if some basic principles such as the absence of a dictator are met. A classical approach to solve this problem, which is consistent with the framework suggested here, has been developed by Buchanan & Tullock (1962). The authors distinguish costs of decision-making and "external costs", which arise if collective decisions negatively affect the interests of the individual. According to Buchanan & Tullock, these "external costs" can be avoided if the unanimity rule in decision-making is used, which implies that all individuals have to participate in decision-making and to consent. 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.

There is a considerable body of constitutional economics literature dealing 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. If the number of countries is small, as in case of WEAMU, a consensus rule might be most appropriate for important decisions, such as approval of field trials and commercial releases. While consensus rules increase the legitimacy of the decisions made, they entail, however, the problem that one or more countries may block a decision, as discussed above.

If decision-making on biotechnology regulation is transferred to a regional regulatory body, this has important implications for the possibilities of participation. On the one hand, transaction costs arising for participation in decision-making may be reduced if regulatory decisions are made by a supra-national body and participation takes place at that level, resulting in a lower number of participatory processes to be organized. 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 that make them accountable to their membership across national boundaries. In the case of West Africa, the farmers are in fact organized at the WEAMU 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 WEAMU level, but according to the interviews conducted, they also collaborate at the regional level. In spite of the options created by such regional organizations of stakeholders, is unclear to which extent their participation in a regional system may create legitimacy at the national level, if no participatory processes at the national level take place, as well.

If participation is seen as a goal in its own rights rather than just as an instrument to reach other goals, it is useful to combine the efficiency considerations of the NIE and the public choice literature with other approaches. The concept of "volitional pragmatism" developed by Bromley (2006) on the basis of classical institutional economics offers important insights. This approach holds that public policy decisions should be based on 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 needs to 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." 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 which form such participation can be achieved at the regional level as compared to the national level is ultimately an empirical question. One can hypothesize that a minimum level of identification of citizens with a regional community is required to achieve this goal. To which extent people in West Africa consider themselves as members of a West African community, represented by ECOWAS or WEAMU, is an important empirical question. Including this information into a survey conducted in the region may provide important information.

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 accountability vis-à-vis using participatory approaches that may be classified as deliberative or direct democracy. In processes of regional integration, the development of institutions of representative democracy (regional parliaments) often lacks behind the process of economic integration, leaving a "democratic deficit." This problem that has been widely discussed in the EU, as the powers of European Parliament evolved rather slowly. WEAMU and ECOWAS face similar challenges. As indicated above, the European Parliament has the right to be consulted on regulatory decisions regarding biotechnology. Since WEAMU has an Interparliamentary Committee, and ECOWAS has a regional parliament, regional regulatory design needs to take into consideration the role that these institutions could play in the regulatory process.

Financing Regulatory Systems

The literature on regulation is comparatively silent on the question as to how regulatory systems should best be financed. The fiscal federalism literature suggests that, in principle, revenues should be raised at that level of government at which the respective services are provided, but provisions need to be made to avoid regional imbalances (Wellisch, 2000).

The NIE literature suggests that one needs to take into account the transaction costs involved in different types of financing a regulatory system, and the incentives created, e.g., for opportunistic behavior. Table 6 presents some general considerations on that basis, which would need to be substantiated by further research. The different financing mechanisms displayed in the Table separately may in practice be combined to balance potential negative effects. If application fees are used, the costs of regulation are

incurred by the companies or research organizations that develop GMOs. If the regulatory system relies entirely on application fees, the fees might be rather high and create disincentives, especially for small companies and for public sector organizations. Companies may pass on the costs to farmers through seed pricing. This possibility depends on the structure of the seed industry. In the West African cotton case, the seed supply is in the hands of few vertically integrated cotton companies, and the bargaining power of the farmers is limited (USDA, 2006). Hence, the possibilities of passing on the regulatory costs to the farmers are high.

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

For the WEAMU regional biosafety project, a market levy has been discussed as a mechanism to finance a regional regulatory system. If a general market levy is used, all farmers, including those that do not grow GM crops, 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, the transaction costs of administering the levy are increased. The transaction costs of administering a market levy also depend on the market structure. In case of cotton and other export crops, charging a market levy is feasible, but in case of crops that are marketed locally, such as food crops, charging a market levy would involve rather high transaction costs. Linacre (2007) conducted a simulation analysis of financing the proposed WEAMU regional regulatory system through a market levy. The analysis showed that problems of financial

sustainability may 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 release 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 WEAMU 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 uses. A regional system could also be financed by contributions from the member states, in which case the distribution of the costs depends on the ways in which the member states raise their public revenues and on the competing uses of the these revenues. A formula would need to be

developed to decide on the shares that the member states should contribute. The benefits that the member states derive from growing the respective GM crop might be used as 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.

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, respectively, contributions from member states. Donor funding can be considered as another financial mechanism. So far, donors have invested considerably in the establishment of regional regulatory systems in West Africa and they are planning to provide further funding (see above). 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 cover the costs of the system at the time the donor funding ends.

The distribution of the 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 studies on

risk assessment, which are reviewed as part of the regulator process. The interviews held in West Africa suggested that public sector representatives see a comparatively large role for the regulatory agencies with regard to risk assessment and management. This position may well be justified, especially if liability rules or the possibilities to enforce them are weak, thus limiting the incentives for risk assessment and management that the industry faces in countries/regions where liability rules are strong and enforceable.

Rules for the transition to a regional system

As indicated in Table 1, there is a need to establish rules for the transition to a regional system. In particular, the question arises whether or not authorizations for field trials or commercial releases that had been established in a member state before it entered a regional system should remain valid. In case of the EU, prior authorizations become invalid. When joining the EU, Romania, for example, 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. In the case of West Africa, this question is relevant since Burkina Faso has already authorized field trials with Bt cotton.

When deciding on a grand-fathering rule, it is important to consider the incentives that such a rule creates. If the regulatory system at the regional system has stricter standards than a national system, a grandfathering rule may create incentives to push through approvals at the national level before a country enters a regional system. If the regulatory standards at the national and regional level are comparable, this problem is less relevant. However, other factors also need to be considered, too. 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 applying a grandfathering rule.

Regional Biotechnology Regulation– Which Way Forward?

The analysis of regional regulatory design has shown that the comparative advantages and disadvantages of different institutional options depend on an array of economic, ecological and social factors. Regarding some of these factors, the available information is limited in the case of West Africa. For example, in the absence of representative citizen surveys, it is unclear to which extent the preferences with regard to biotechnology differ among the potential member countries of a 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 to a common market that such controls would cause. With regard to environmental effects, it would be useful to take into account that the system to be set up should be able to handle future applications for different types of crops. Hence, the spatial nature of possible environmental risks needs to be considered for the design of a 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 is more pronounced than if this is not the case.

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 of regional parliamentary bodies an appropriate way to increase voice and accountability? Or are other forms of participation more effective? With regard to the financing of a regional system, there are open questions and trade-offs as well. Which distribution of regulatory costs will be considered as fair, while at the same time creating incentives for innovation?

The theoretical considerations presented in this paper can inform the debate on these questions. More empirical research, for example on the spatial dimension of possible risks, and on public perceptions, can also 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 finding answers to 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 find ways of bringing the knowledge of experts, stakeholders and policy-makers in the region to bear—in a structured way—on the specific questions of regional regulatory design identified here. The 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 by reflecting on the appropriate level of organization for each regulatory activity.

Involving stakeholders in such kinds of debate may require forms of interaction other than those typically practiced at stakeholder workshops (such as presentations followed by general discussions). There is a wide range of participatory techniques that have been developed in the context of technology impact assessments, which could be applied in processes of establishing regional regulatory systems. Combining participation with multi-criteria analysis appears to be a particularly promising approach, because regional regulatory systems have to be evaluated against multiple criteria (Table 2), and stakeholders may assign different weights to different criteria. The experience with the use of multi-criteria analysis in participatory processes has shown that this often helps to rationalize emotional debates, and to 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 the way in which they envisage a regional system to work.

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 may be used to "impose" GM crops on countries where resistance against biotechnology is strong. Groups that were in favor of biotechnology were in general also in favor of establishing a regional regulatory system, highlighting potential efficiency gains. Since political disagreement about biotechnology has led to the delay of 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, it will depend on the design of the system and on political economy factors that influence its operation as to 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 such 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 to promote good governance in the regulation of this important and contested technology.

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Table 4: Options for Regional Regulatory Design

Decision points	Options
1) Scope of a regional system	
Substantive areas that can be regulated at regional level	Approvals for field trial applications and contained use commercial releases food and feed use Liability and co-existence regulations Labeling requirements Intellectual property rights
Types of regulatory activities that can be performed 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 a 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
3) Decision-making at the regional level	
Mode of decision-making	Political or administrative decision-making Binding without ratification at country level (=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 a regional system	
Mode of financing the system	Revenues from regional organization or member states Application and license fees Market levies
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) Transition to regional system	
Mode of dealing with existing national regulations	"Grandfathering rules" Discontinuation of existing rules

Source: Adapted from (Birner & Linacre, 2007)

Table 5: Criteria for Assessing Regulatory Design Options

Criterion	Aspects
Effectiveness criteria	Effective in ensuring desired levels of environmental and food safety; Avoidance of 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 equal 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; 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 as fair, transparent, participatory and accountable. *Output legitimacy*: Performance of regulatory process is considered satisfactory; avoidance of regulatory failures; problem-solving capacity.

Table 6: 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 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	Depending on economic interests in GMO-free production	Need for co-existence /distance regulations; including for borders between countries
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

Table 7: 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/P: Costs incurred for participating in decision-making processes F/I: Income forgone in case of delay of approval	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 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: Costs of raising revenues, e.g., administering market levies	Fair / incentive-compatible distribution of regulatory costs

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

Source: authors

Figure 3: Comparative efficiency of different governance structures (1) Level of governance

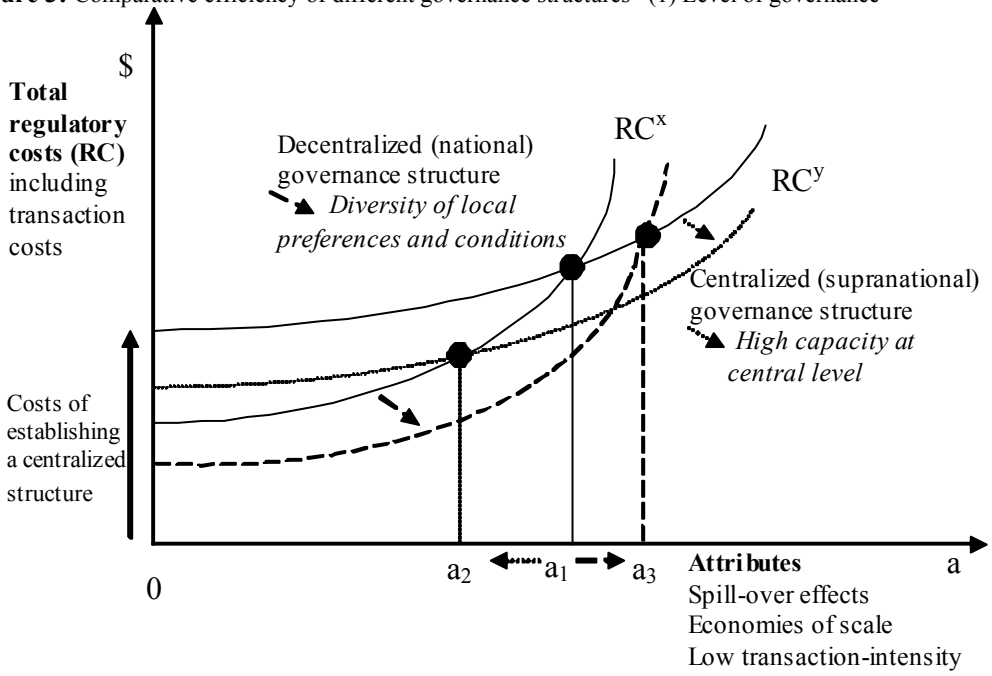

Figure 4: Comparative efficiency of different governance structures (1) Level of governance
Source: Based on Williamson (1991) and Birner & Wittmer (2004)

Table 8: Attributes of Transactions involved in Different Regulatory Transactions

	Transaction intensity: Spatial dispersion	Transaction intensity: frequency	Type of knowledge needed
Food safety risk assessment	low	low	scientific
Environmental risk assessment	depending on ecology	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	medium	local
Enforcement of transboundary transport regulation	high	high	local

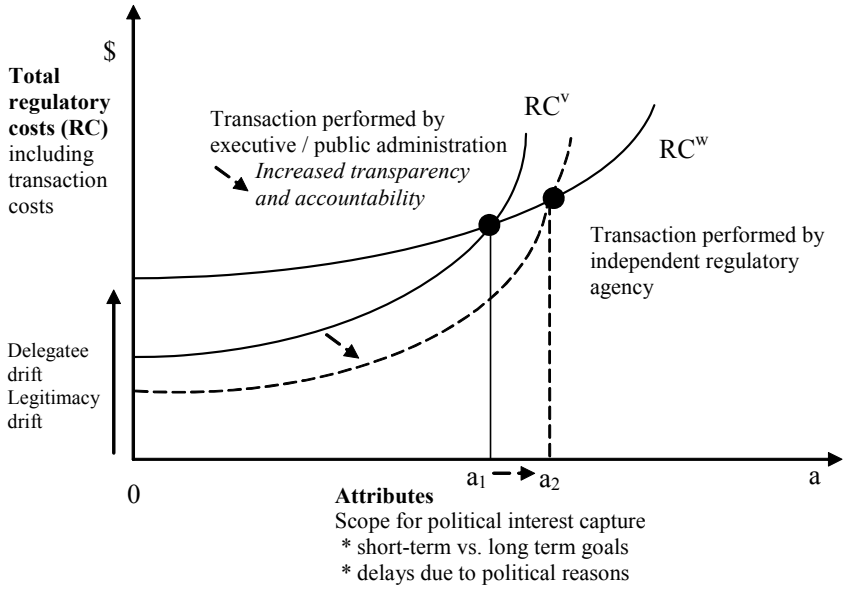

Figure 5: Comparative efficiency of different governance structures (2) Degree of autonomy

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

Table 9: Implications of Different Ways to Finance a Regional Regulatory Syste

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; potentially high, if marketing system is diverse/ fragmented and if 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	Depending on the extent to which donors set up own financial procedures

* Different financial mechanisms may be combined