# Seife Ayele

Governance arrangements for genetically modified organisms (GMOs) are widely acknowledged as important, but often inadequately implemented. This paper examines legitimation and harmonisation issues around evolving GMO governance in Africa. It draws on empirical research from Ethiopia, South Africa and pan-African biosafety system harmonisation initiatives. Analysis shows that the process of institutionalising biosafety systems has become a major source of contention, and dominant protagonists have emerged on both sides of the debate. The legitimacy of the emerging systems is, however, at stake, since those making and implementing the rules are perceived as having failed to find a way through the competing views and concerns over GMOs. The paper highlights the need for a competence-based and more inclusive approach to governing GMOs.

NUMBER OF FACTORS have gradually brought the genetically modified organisms (GMOs) debate into the public domain in Africa. These include research and development, the prospect of widespread commercialisation of genetically modified (GM) crops, and trade and food aid in GM products. The controversy in 2002 over USA GM maize food aid to some African countries was notable (Zondi, 2003; Newell, 2003).

As signatories of the Cartagena Protocol on Biosafety (the Protocol hereafter), many African countries are currently engaged in the implementation of the Protocol's biosafety framework. Moreover, there is now a widely perceived need to harmonise biosafety systems across the continent. This paper discusses the emerging regulatory systems in Ethiopia, South Africa and at pan-African level.

While institutionalisation of biosafety systems progresses, across the region opinions about GMOs

remain as polarised as ever. Proponents see GMOs as potential sources of increased food supply and environmental sustainability resulting from, for example, reduced application of chemicals (Wambugu, 2003; Keese *et al*, 2002). Opponents not only contest such claims but also emphasise the potential risks — that GMO might deplete biodiversity and increase the vulnerability of smallholder farmers (Egziabher, 2003; Mayet, 2003).

Conflicting views on GMOs are not unique to Africa but global in scope (FAO, 2004). In recent years a significant global diffusion of GM crops has been recorded, some economic benefits realised, and food derived from such crops has also been regarded as 'safe to eat' (FAO, 2004; James, 2006). Despite such developments, many people remain sceptical of the benefits, and concerned about the potential risks and the ethical and moral implications.

Research has reported on the mechanisms by which government policy-makers and technology developers engage with the public and respond to concerns, and thereby become accountable for their decisions (Purdue 1999; Rowe and Frewer, 2000). Similarly some research on Africa has analysed actors, including GMO developers and suppliers, government and non-governmental agencies, and their involvement in GMO decision-making and implementation processes (Freidberg and Horowitz, 2004; Harsh, 2005).

However, while widely reporting on the disagreements over the inherent attributes of GM technology, the literature overlooks the process by which

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GMO rules and institutions are constituted and legitimised in Africa. The central aim of this paper is therefore to fill this gap and contribute to the literature on science and technology regulation and governance. It examines the extent to which the emerging GMO governing bodies accommodate contested views and produce integrated solutions in Africa.

Ethiopia and South Africa offer contrasting examples, evolving under different historical and socio-economic conditions. South Africa has been approving GMOs since 1990, and passed a GMO act in 1997. However, its decisions have been contested, and sometimes criticised for being controlled by technology developers and suppliers.

Ethiopia, with no research and development (R&D) or GMO field-trial programmes, started implementing the Protocol in 2004. The focus of the emerging system has been to address the potentially adverse effects of GMOs on smallholder farmers and the country's biodiversity. Some actors see the emerging system as prohibitive to the development and use of the technology as it sets high standards, for example, by endorsing socio-economic conditions as evaluation criteria. What explains the contrasting features of the two national regulatory systems, and what does it mean for Africa-wide biosafety system harmonisation?

Analysis of empirical evidence reported here shows that, besides the disagreements on the inherent attributes of the technology, the process of rulemaking and institutionalising GMO administration has become a major source of disagreement, as it tends to be dominated by one of the main protagonists, leaving little confidence in the minds of those marginalised that the governance system would be free of bias. At the pan-African level, biosafety systems harmonisation is pursued to minimise differences in the outcome of decisions on GMOs. Yet harmonisation efforts are complicated, first, by the differences in the independently emerging national systems and, second, by the multiplicity of initiatives and methods of convergence being considered.

In the light of its findings, this paper argues that a GMO governing body, at national and sub-regional or continental levels, must ensure its acceptability to the major actors by accommodating divergent views over decisions, and assigning competent implementing

agencies free from perceived bias. It underlines that flaws at crucial steps in the institutionalisation process must be avoided as these may become potent sources of scepticism and/or opposition to pending decisions over GMOs.

The evidence used in this paper was drawn primarily from 26 detailed interviews with key actors involved in the development and regulation of GMOs in Ethiopia, South Africa, and at pan-African level in 2005. It also draws from legal and technical documents related to GMO governance.

The rest of the paper is structured into five sections. The next section discusses the concepts and theory related to legitimacy of governance of new technologies, particularly GMOs. Sections three and four discuss evolving GMO governance in Ethiopia and South Africa respectively. Section five relates findings, and discusses pan-Africa biosafety harmonisation initiatives. Section six concludes the paper.

# Role and legitimation of GMO governance

Research has increasingly looked at actors' participation in the politics and decision-making process of GMOs (Purdue, 1999; Harrison and Mort, 1998; Black, 1998; Haas, 2004; Freidberg and Horowitz, 2004). It has focused on the modalities of participation, such as citizens' juries, deliberative polls and public consultations. Actors' standing in relation to the technology and communication between actors are considered.

Participation strategies are meant to bring in new perspectives to understand better the problem at hand, enlist support for implementation of policy and increase trust in governance (Haas, 2004). Black (1998: 622) articulates that opening up the decisionmaking process means to "deny any one voice authority in that process, and through the integration of views and perspectives to arrive at accepted solutions to intractable problems".

Purdue (1999: 80) summarises the models that governments use to legitimise their decisions on science and technology as: expert; democratic; and model. The expert model often consists of a committee of "recognised experts" who claim to be "independent of commercial and sectoral interests". The democratic model allows, or claims legitimacy for, public debate of different or sometimes conflicting preferences. Finally, the pragmatic model is based on a committee of actors involved in the issue, and membership is wider than an expert group. Each model is subject to criticism, for example, none directly involves citizens' decisions on science and technology policy.

To clarify some terms, actors here means those parties concerned with, and affected by, the GMO rules and rule-making processes. These include government research organisations, universities and the for-profit private sector, directly involved in the development and commercialisation of GM products. It also includes science and technology policy-making bodies, and for-profit and non-profit organisations, such as farmer, consumer and business organisations, pressure groups, and faith-based organisations.

On an individual basis, perspectives on genetic modification could vary considerably within and among organisations but 'actors', as conceptualised here, hold shared values and interests. They want to see solutions to contested issues and have the "power to thwart a solution or decision" (Carlson, 1999, quoted in Matz and Ferenz, 2005: 42).

Actor participation<sup>1</sup> is conceptualised as being able or free to be involved in (or consulted about) GMOs. It relates to the actual act of being involved in, or influencing, decisions and being responsible for the consequences of such decisions. Furthermore, actor participation involves not only deciding on and implementing activities but also making and institutionalising the rules of decision-making. This is particularly important as people's acceptance of authority largely depends on their feeling that it is legitimate and should be accepted. Besides the well recognised benefits of participation (Haas, 2004), the rationale for actor participation is thus its inherent social value.

However, experience suggests that participation does not always guarantee that deliberations or contributions are taken on board. Harrison and Mort (1998: 67) report that, in the 1990s, health and social service managers and professionals in the UK ignored the outcomes of public consultation and user involvement in such areas as mental health and physical disabilities. Consultation and involvement, they argued, were used as "social technologies", a means of legitimising decisions and activities. The point to note is that consultation outcomes are not legally binding unless taken up by the official decision-making bodies, hence Matz and Ferenz (2005) recommend that the consultation process make effective links with official decision-making bodies.

The literature assigns different meanings to governance, including allowing non-governmental organisations and the for-profit private-sector participation in decision-making processes over complex matters such as GMOs (see review in Lyall

It is often argued that conventional government agencies, acting on their own, are insufficiently accountable to public demands, and lack the knowledge and resources to address GMOs and Tait, 2005). It is often argued that conventional government agencies, acting on their own, are insufficiently accountable to public demands, and lack the knowledge and resources to address GMOs.

The governance arrangement is widely understood to fill these gaps by drawing on multiple actors' knowledge and resources, thereby enhancing accountability. Following Hurd (1999: 381), legitimacy is conceptualised as an actor's acceptance of authority, which may emerge from the "substance of the rule or from the procedures or source by which it was constituted". Hurd (1999) underlines that the presence of legitimate institutions as an "authority" produces stability and predictability.

The term biosafety systems harmonisation has no standard definition but, based on interviewees' broader understanding and as discussed here, is used to mean the co-ordination of national biosafety policies, standards and guidelines, aiming to minimise or eliminate differences in the outcome of decisions on GMOs across co-operating states. The benefits from harmonisation are often stated in terms of reduction in regulatory costs and increased trade in GM products. In generic terms, the mechanisms for harmonisation include: an evolutionary process whereby independent systems acquire similarity over time; co-operative harmonisation by means of international legal instruments; or imposition by a stronger economic power (see, for example, Drezner, 2005; Busch and Jorgens, 2005).

Central to biosafety harmonisation, also, are approaches to the regulation of GMOs, North America and the European Union (EU) (see, for example, Paarlberg, 2000; and Nap, *et al.*, 2003). The two approaches have different foci: the North American approach is based on the characteristics of the product, while the EU is concerned with the process by which the product is produced. North America relies on existing laws to determine liability for environmental damage, and harm to people and property. The EU approach regards GMOs as "something new and special" for which existing legislation is not sufficient, thus this approach presupposes new legislation.

The North American approach is broadly considered as pro-GM while the EU is more precautionary, largely because of the significance of anti-GM European consumer preference. The adoption of either approach at the national and/or continent level has considerable implications for biosafety systemsbuilding in Africa, including for the setting up of institutions and allocation of resources for implementing regulation, and trade in GM products.

Finally some key points regarding GMO regulation need further elaboration. First, regulation has a complex agenda. It provides for the necessary resources for overseeing GMOs across the relevant sectors and disciplines, as the development and application of the technology traverses industrial and biological boundaries, involving such spheres as agriculture, food and health. Second, regulation

faces the challenges of reconciling domestic laws and adopting relevant regional and international conventions. Also, with the increasing drive for commercialisation and privatisation, it is the duty of regulation to ensure that public and private interests are balanced, for example, in overseeing how national genetic resources are accessed and used.

# **Evolving GMO governance in Ethiopia**

## Background to the GMO debate and regulation

The debate over modern biotechnology in Ethiopia largely focuses on agriculture and biodiversity, because of its significant role in the economy and society. Agriculture contributes 85%, 46% and 92% of total employment, gross domestic product and expert earnings respectively (Beintema and Solomon, 2003). Predominantly a smallholder farming system dependent on family labour for land preparation and planting, weeding and harvesting, Ethiopia's geographical position, range of altitude, rainfall pattern and soil variability also gives it a wide ecological diversity and a wealth of biological resources. Crop plants such as coffee and teff (an Ethiopian cereal grass) are known to have originated from Ethiopia, and germplasms of such native plants are likely to offer Ethiopia significant economic benefit from their global exploitation, for example, teff for glutenfree diets (Clark, 2005).

However, despite the wide variety of its genetic resources and diverse agro-ecological zones, Ethiopia is prone to periodic food shortages, attributed to recurrent droughts, environmental degradation, and pest and plant diseases. Success at increasing food supply is offset by increases in human population. Productivity-enhancing measures focus on a narrow range of choices — extension programmes, seed improvement measures through conventional methods, and fertiliser applications (Degfe *et al*, 2002).

Decades of agricultural research have produced a small range of technologies, largely biological varieties and breeds, and agronomical practices. The generation of chemical and mechanical technologies such as fertilisers and farm tools has been minimal (Mekonnen, 1995). Consequently, Ethiopia to this day depends on an archaic plough culture. Many actors, notably members of the scientific community, argue for exploring every possible avenue for increasing food production and sustainable agriculture.

Ethiopia is a latecomer to modern biotechnology. Government policy in the early 90s (TGE, 1993) acknowledged the role of biotechnology and promised support. Progress, however, has been limited to pockets of research infrastructure and institutionbuilding activities, such as in the Ethiopian Institute of Agricultural Research, the Institute of Biodiversity Conservation and Addis Ababa University.<sup>2</sup> Biotechnology development in Ethiopia also faces several constraints, including limited R&D capacity owing to a low science base; limited training; difficulties with recruitment and retention of graduates; and limited Government and donor funding. Some donors seem to be reluctant to support R&D before the biosafety framework is put in place.

### Institutionalising the Ethiopian biosafety system

At the time of writing, Ethiopia has not approved its biosafety bill but, following the adoption of the Protocol in 2004, it embarked on the implementation of the Protocol's biosafety framework. To give legitimacy and direction to the emerging institution, implementation started with the establishment of a national Steering Committee (SC), consisting of some 33 representatives from almost as many Government organisations and academia. Among key SC players were the Ethiopian Environmental Protection Authority (EPA), the Ethiopian Institute of Agricultural Research (EIAR), the Institute of Biodiversity Conservation (IBC) and Addis Ababa University (AAU).

Representation to the Committee from for-profit and non-profit organisations was limited, and there was hardly any media and press coverage about genetic modification in general and the process of biosafety institutionalisation in particular. EPA championed the implementation process as, compared to the other actors, it had relatively better knowledge, expertise and infrastructure for overseeing the implementation of regulation.<sup>3</sup> In line with the 'pragmatic' model of legitimising science and technology (S&T) decisions, it appears, the SC was created to exploit expertise and know-how located in different sectors.

Major differences emerged before long, among actors within and outside the SC, over the process of developing the draft bill, its content, and the proposed location of GMO administration. Although views about genetic engineering varied within and among the organisations, in this instance, it was clear that the major split was between EPA authorities on one hand, and on the other, key representatives to the Committee, namely those drawn from EIAR, IBC and AAU.

A steering committee was set up to implement the Protocol's biosafety framework: major differences emerged among actors within and outside the SC, over the process of developing the draft bill, its content, and the proposed location of GMO administration Almost all the EIAR, IBC and AAU scientists interviewed made it clear that their role in the process was at best marginal as (a) legal and technical documents were prepared by EPA lawyers and consultants under its guidance, (b) EPA was made, by default, the competent authority for GMO administration, and (c) EPA proposed the adoption of the 'protective' principles and criteria of the African Model Law on Safety in Biotechnology, which, according to the interviewees, potentially limit the development of useful modern biotechnologies in the country.

Some scientists alleged that their written submissions on the draft bill made hardly any impact. Some noted that, apart from a handful of seminars and discussions, the political space for (and culture of) participation itself was limited. Some also doubted EPA's neutrality in the process and felt that it controlled the biosafety implementation process in advancing its own environmental and biodiversity issues. So a number of interviewee scientists and science and technology policy-makers feared that, if approved, the bill (and EPA as a competent authority) would limit the development of useful modern biotechnologies in the country.

EPA's leadership, however, justified its actions on the grounds that most members of the SC and the other stakeholders did not have the required biosafety capacity to do the job. In justifying their preferred GMO evaluation standards, EPA authorities noted that the Protocol was rather "limited" on GMO effects on "human health and socioeconomic considerations" and that there are no adequate domestic laws to address such potential risks. EPA's central argument is social and economic, focusing on concerns for smallholder farmers and losses of biological resources to multinational companies:

[Some] patent owners are saying 'we will give it free'. But I don't believe that. If patents were to be given free to developing countries, why should they have existed in the first place? TRIPs of the World Trade Organisation ... will make it compulsory for developing countries to respect patent owners ... And when that happens a smallholder farmer, who requires negotiating for the use of patents around the world, couldn't even say 'I will continue as my parents did, I don't want your patented varieties'. [Patents] would put [the developing countries] in a totally new form of colonialism where the only resources we have, our biological resources, will also be controlled by companies in the north. (Egziabher, head of EPA)<sup>4</sup>

Some of the scientists hold similarly robust views, and share some of the concerns of EPA officials. The difference, however, was that many of the scientists see some scope for developing and exploiting GMOs:

Current developments on GMOs focus on pest control and weed control. For the poor farmer with very little land holding but a lot of time to work on [their] farm, or in a situation where hand-weeding is possible, the GMOs out there are not very useful to them. However, GM crops can be useful where the land holding system is larger and where commercial spraying is now destroying biodiversity. (an Addis Ababa University Professor)

Some interviewees suggested that any one organisation with 'particular interest', one way or the other, should not lead on the implementation of the biosafety framework nor become a competent authority. The overwhelming view, however, was that whoever champions the process should be competent, work with other actors, and seek to produce a national consensus over the matter.

Behind this polarised debate, the study found much common ground bridging the differences among the main protagonists of GMOs. For example, most interviewees agreed that commercially available GMOs have little relevance to Ethiopia, as they are not indigenous and drought-resistant staple food crops. The smallholder farmer issues are complex as, for example, segregating GM and non-GM crops on small (sometimes multi-cropped) farms is technically and culturally difficult. They also agree that GMO development is expensive and skillintensive, and that if pursued could be at the expense of conventional R&D. They were concerned that the introduction of GMOs could lead to the patenting of some biological resources of the country.

Yet even stout sceptics see some benefits from the development and ownership of GMOs in Ethiopia. They argue that, to counteract the privatisation of sovereign resources such as germplasm and address the more important issue of equity, GMO development should be undertaken within the public sector. However, the biosafety rule-making and institutionalisation processes were perceived to have failed to find a way through the competing views and concerns over GMOs, leaving sufficiently potent ground for contesting impending decisions on GMO activities.

# **GMO** governance in South Africa

South Africa is the economic and science and technology giant of Africa and has been progressively supporting S&T via attracting foreign direct investment, as well as government investment. Priding itself on its S&T base, South Africa is poised to give leadership in knowledge economy, notably in biotechnology in Africa (GSA, 2001).

Experimentation in, and recognition of, the potential uses of modern biotechnology in South Africa go back to the 1970s but there were no statutory rules and standards to regulate activities until 1990. Interviewees noted that South African scientists took

the initiative and organised themselves under the South African Committee on Genetic Experimentation (SAGEN) in 1978 to advise Government on matters of GMO regulation. The private sector, along with SAGEN, initiated South Africa's biosafety bill development, and in 1994 the Government set up a committee that drafted the GMO Act.

Approved by parliament in 1997, the Act (GSA, 1997) provided policy and regulations for GMO activities. It created, within the Department of Agriculture (DoA), the Office of the Registrar for GMOs. It set up executive and advisory committees and an inspection service. According to the interviewees, the choice of DoA as the entry point for GMO administration (or competent authority) was influenced by some historical developments. First, as the Act was being written, most of the GM products were agricultural (such as crop plants). Second, DoA (unlike other departments) had a fair number of experts in biotechnology. It also has inspectorates and an inspection infrastructure that stretches down to province level.

While the Act was implemented in 1999, South Africa has been approving GM R&D, field trials and commercialisation since 1990. Approval in the period 1990–1999 followed biosafety guidelines developed by SAGEN, commonly known as 'the green bible', and in accordance with existing legislation, notably the Agricultural Pests Act (no 15 of 1983). To date, South Africa is the only country on the continent to have commercialised insect-resistant maize and cotton, and herbicide-tolerant cotton, maize and soya-beans.

Some interviewees noted a number of flaws that led to contestation in the development of GMO regulatory institutions and the GMOs Act. As in Ethiopia, some saw that actors' participation in the early institutionalisation process was largely limited to, and driven by, the developers and suppliers of the technology. After the GMO Act was passed, according to some interviewees, the governance system remained elitist and non-participatory. They noted that six of the eight members of the Executive Committee were drawn from Government departments developing or supplying the technology (the other two members being scientists appointed by the Minister of Agriculture).

Others noted that the system's decision-making criteria rest largely on scientific and technical inputs. In direct contrast to Ethiopia, interviewees noted that the Act gives less consideration to socio-economic and biodiversity issues. In the view of some interviewees, despite passing regulations in 2004, GMO labelling is inadequate, and liability and redress issues are hardly looked at. Some referred to insufficient access to information and lack of transparency of decisions on GMOs. In particular, Biowatch (a South African non-governmental organisation that takes a sceptical view of GMOs) has been exerting pressure to gain access to information on GMO activities in South Africa, leading to, and winning, a landmark case against the Department of Agriculture in February 2005.<sup>5</sup>

Others commented that communication of the science was 'not good', particularly in the early days. Efforts to address this problem came later, after questions were raised and protests mounted. The establishment of agencies such as AfricaBio — a pro-GMOs stakeholders association — and Biowatch have contributed to the debate over GMOs, awareness building, and innovative changes in the system. Finally, the common procedure for capturing non-technical public input into the GMO decision-making process is that applicants put notices in local papers inviting comment/consent from the public on their proposed activities. However, according to the some interviewees, few people read the papers and participate in the process.

It appears that following the 'expert' model of legitimising S&T decisions, the process of institutionalising GMOs in South Africa drew its legitimacy from scientific expertise, independent review and decision-making processes, however criticised they were by the opposition. Pro-GMO actors argued that centring the regulatory body on the DoA has enabled the system to draw on the expertise and knowledge of innovation practices and technology assessment. The system copes well with processing applications and interpreting 'precaution'. Without compromising on safety, they argue, the system has reduced the costs of monitoring and administering GMOs.

The Government has, in some areas, responded to the criticisms levelled against the GMOs governance system. For example, as part of the wider national biotechnology strategy, it has created a Public Understanding of Biotechnology unit to raise awareness levels in the country.<sup>6</sup> Such Government responses to some criticisms are shaping and reshaping the GMOs governance structure; the process is, however, ongoing. On 12 November 2003, South Africa agreed the Protocol. Over 2005–06, it was engaged in developing the second (revised) bill, which, it is hoped, will build on lessons learnt from its predecessor.

# Harmonising biosafety systems in Africa

Promoted by GMO activities, trade and food aid in GM products, a series of declarations and initiatives have been made towards harmonisation of biosafety systems in Africa. Examples of initiatives include:

- The Organisation of African Unity (OAU) (now the African Union (AU)) produced model biosafety legislation for the continent in 2001.
- In 2005, the AU New Partnership for Africa's Development (AU-NEPAD) set up a high-level African Panel on Biotechnology (APB) to develop an African strategy on biotechnology and biosafety.
- The United Nations Environment Programme Global Environment Facility (UNEP-GEF) has

been implementing the biosafety framework of the protocol for the last five years.

• The USA and other developed countries have been providing resources to develop some pan-African biosafety systems.<sup>7</sup>

A closer look at these and other harmonisation drives shows a number of interesting points. Across the region, as interviewees noted, the convergence of national and sub-regional biosafety systems is perceived as desirable, as it is hoped to overcome or minimise differences in the technical contents of rules and decision-making criteria, so that differences in the outcome of decisions on GMOs among nations are minimised or eliminated. Expected benefits are often stated as expanding the pool of biotechnology and biosafety expertise available for the region, reducing regulatory costs, and enhancing trade in GM products.

Harmonisation initiatives are pursued at different levels by multiple actors: at the levels of sub-regional economic blocks (such as the Southern African Development Community), agricultural research organisations (such as the Association for Strengthening Agricultural Research in Eastern and Central Africa), and pan-African science and technology policymaking organisations such as NEPAD. Donors and multilateral organisations provide financial and technical support to these initiatives.

Some of the initiatives lack a mandate and actor participation (in addition to having practical, logistical and financial constraints). Participation is often influenced by donors and professional interest groups. Processes tend to be led by *ad hoc* working groups of scientists, and 'representatives' of nonscientific actors, but some of the actors, notably farmers and consumers, often miss out. Government policy-makers are also conspicuous by their absence.

Lack of co-ordination among the many initiatives means replication of effort. There also exist mismatches between the legal responsibilities of those attempting to produce harmonisation and those supposed to implement it; in other words representatives from a handful of countries attempt to create a system to serve a larger number of countries. Finally, as brought out by the case studies, a significant challenge to the harmonisation agenda is reconciling national biosafety systems that differ with regard to criteria for GMO evaluation and institutional arrangements for governing GMOs.

Turning to the methods of achieving harmonisation, these were unclear as there was no single model to which to converge. Analysis of the empirical evidence brought out three key emerging typologies of biosafety harmonisation: co-operative, voluntary and pro-active. Mapped onto these typologies, in Table 1, are country target/coverage of a mechanism for harmonisation, the basic reference/guidance it draws on and its aims and principal actors, and an assessment of expected convergence. Although not meant to be implemented sequentially,

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The methods of achieving harmonisation were unclear as there was no single model to which to converge: analysis of the empirical evidence brought out three key emerging typologies of biosafety harmonisation: co-operative, voluntary and pro-active

the typologies can be seen as progressive, from co-operation between different national systems, to a voluntary common African position, to a mandatory Africa-wide policy and regulatory regime.

*Co-operative harmonisation by means of the Cartagena Protocol on Biosafety* The Protocol, as an international agreement focusing on the transboundary movement of living modified organisms (LMOs), serves as an instrument of harmonisation providing protection from potential adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking into account risks to human health. Its Article 14.1 allows for Parties to enter into (Convention on Biological Diversity, 2000):

bilateral, regional and multilateral agreement regarding intentional transboundary movements of living modified organisms, consistent with the objectives of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

# Table 1. Emerging typology of the African biosafety systems convergence

	Co-operation	Voluntary convergence	Proactive harmonisation
Target, coverage	Country-by- country	Africa	Africa
Reference and method	Cartagena Protocol on Biosafety	Voluntary model legislation	Directed by AU-NEPAD secretariats
Principal actor	UNEP-GEF	AU	AU-NEPAD
Major purpose	Transboundary movement of GMOs	Ensuring social justice and maintaining biodiversity	Co-development of GM technology and its regulation, intra-Africa trade
Expected convergence <sup>a</sup>	Low-medium	Low	Too early to predict

*Note:* <sup>a</sup> Based on qualitative data assessment and scale of 1–5: low=1–2; medium=3; and high=4–5

At the time of writing, some 39 African countries are party to the Protocol, meaning that they have obligations for the implementation of its provisions.

The UNEP-GEF initiative, focusing on the implementation of the Protocol, aims to build: a "national biosafety framework", developing policy on modern biotechnology, legal and technical documents for implementing such policy; an administration capacity for handling requests; mechanisms for public participation and awareness building; and monitoring and evaluation. The methodical approach inevitably produces some level of correspondence among systems developed on a country-by-country basis.

The Protocol, however, contains optional clauses, such as the application of socio-economic criteria on GMO decisions. When countries use partial or full discretion given by the Protocol, that limits the UNEP-GEF initiative's potency to produce compatible biosafety systems. According to a UNEP-GEF interviewee, the concept of 'harmonisation' gives the impression of centralising laws of sovereign countries. He thus prefers 'co-ordination' to 'harmonisation' as the former is about national biosafety systems recognising each others' products. According to this interviewee, UNEP-GEF's aim is to make countries co-operate and trust each others' systems.

Voluntary harmonisation by means of the African Model Law on Safety in Biotechnology (African *Model Law*) The African Model Law (OAU, 2001) is voluntary model legislation that is legally nonbinding and has no relationship to any international conventions. Its key objectives are protecting biodiversity, ensuring social justice and developing a common African position on GMOs. The African Model Law, taking the protection provided for by the Protocol, allows the use of provisions of the Protocol that are at the discretion of the Parties. Some of its provisions, most importantly its scope and criteria for making decisions on GMOs, exceed the minimum standards provided for by the Protocol. For example, it recommends the application of the discretion given by the Protocol to Parties in Article 26.1 on "socio-economic conditions" (Convention on Biological Diversity, 2000):

The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regards to the value of biological diversity to indigenous and local communities.

Many of the interviewees that argued from industry and market perspectives regarded the African Model Law as "too protective". For example, an interviewee from the African Biotechnology Stakeholders Forum noted that decisions on GMOs have to be based on "circumstances that go beyond religious and traditional beliefs and other norms of a society". According to this interviewee, societal views can distort an issue like GMOs.

The comment, however, was based on the mistaken assumption that practices of regulatory science have some 'universal validity'. Empirical and theoretical research suggests that, even operating under a seemingly common international treaty, there exist some national specificities or identities, such as in institutional practices, judgement of experts and established relationships of trust (Rothstein *et al*, 1999; Jasanoff, 2005).

Moreover, the evidence from Ethiopia demonstrates that some risk, acceptable by scientific standards, could be unacceptable to society if it is inequitably distributed. According to AU personnel, who primarily work on biosafety issues across the continent, not many countries showed a keen interest in adopting the African Model Law. It appears, therefore, that the chance for national systems to converge to the African Model Law at this time is low.

However, it needs noting that the African Model Law, compared to the other major initiatives, has not been sufficiently supported and promoted by donors and pan-African organisations; but consistently criticised by the pro-GMO groups, contributing to its unpopularity. The fact remains that countries such as Ethiopia, using their sovereign rights and operating within the limits of the Protocol, back the Model Law. This results in national differences in standards for evaluating GMOs — a problem that can only be reconciled through more negotiation and understanding among the drivers of the harmonisation agenda.

Proactive biosafety systems harmonisation, the AU-NEPAD approach The AU-NEPAD initiative is about co-development of GM technology and regulatory institutions. It is a proactive initiative that subsequently aims to make the emerging policy and rules mandatory across Africa. According to a senior NEPAD interviewee, whether GMO is relevant to Africa is less important, as NEPAD is pressing on "how to harness biotechnology taking into account the perceived risks".

On the technology development front, NEPAD has identified facilities in member countries, and is capitalising on them by setting up centres of excellence and networks (one each in Nairobi, Pretoria, Cairo and Dakar). The notions of co-operation and centres of excellence are based on an economic rationale — that African countries taken separately are too small to develop a comprehensive national capacity, as the requirements are for high quality and multidisciplinary skills and modern research facilities, and risk management structures (Gaillard, 2003).

Subsequent to knowledge production, many countries, including South Africa and Egypt that are

considered to have better S&T capacity (GSA, 2001; Ayele, 2005), also have limited capacity for commercial exploitation of modern biotechnology, and lack venture capital, entrepreneurial skills and local and foreign markets. So, according to an interviewee from NEPAD, Africa has to look into expanding its own markets for producing and trading modern biotechnologies. This entails harmonising the biosafety systems.

Although evaluation would be premature, the AU– NEPAD initiative seems to have some ingredients for success. The high-level APB is charged with developing an African strategy on biotechnology and biosafety by the highest body on the continent — the AU. APB comprises an interdisciplinary team of scientists, civil society representatives, industrial managers and senior policy-makers (Chege, 2005). Most panel members are personalities well known for their passion, intellectual rigour and global experience; some have supporters from a wide spectrum of views.

The above initiatives suggest that there is widespread optimism about harmonisation, but for different reasons. There seems to be political will on all sides. Reducing differences in the outcome of decisions on GMOs across the continent appears to be the central rationale for harmonisation, although some dominant national actors revert to their preferred continental model as a means of legitimising domestic action.

It is, however, important to remind ourselves of the advantages of harmonisation at this point in time. As many countries have begun to institutionalise biosafety systems, harmonisation is likely to produce relatively limited adjustment costs. Looking from an industry perspective, harmonisation reduces the number and complexity of regulatory regimes, and overcomes different labelling requirements. All these reduce the cost of regulation, enhance trade and investment, reduce the cost of product delivery and perhaps reduce prices to consumers.

Taking the international treaty, the Protocol, as a reference point, it follows from the analysis that barriers to harmonisation emerge as and when national standards exceed the minimum provided for by the Protocol, are not clearly identified and specified, or have no relation to the Protocol. In the case of countries not party to the Protocol, it is possible that national standards could also fall short of the standards provided by it. While none of the interviewees suggested that harmonisation means total convergence of biosafety systems, pioneers of harmonisation should focus on standards that really matter to the key actors, consider why differences occur and how they can be harmonised.

Another challenge to harmonisation can be the disparities in African economies and resource distribution, in effect determining the rent distribution from harmonisation. The case studies demonstrate that countries have different reasons for harmonisation and differing expectations. Some pursue the agenda with a view to creating a larger intra-Africa market for GM products. Others pursue it to combat involuntary transboundary movement of GMOs, emerging from porous borders that encourage illegal trade in GMOs and/or the cross-boundary gene flow to wild species.

Moreover, as African economies differ in size, in the distribution of their human population across activities, and in the size and distribution of their genetic resources, each factor creates an incentive or disincentive for harmonisation. It is also worth noting that much African concern about GMOs is partly to do with potential loss of genetic resources to multinational companies. Some interviewees, interestingly, noted that, if Africa were to own the technology, and reap the benefits thereof, the opposition to it would be much reduced.

### Conclusion

Institutionalising GMOs raises some fundamental questions, including who champions it and for what end, and whether and how actors' views and interests are taken into account. This paper has shown that, in the countries studied and at pan-Africa level, the emerging biosafety systems are perceived as having failed to find a way through the competing views and concerns over GMOs. Analysis suggests a critical consideration of two areas: legitimation, and socio-economic needs and interests.

The paper demonstrates that the process of institutionalising biosafety systems tends to be pathdependent, and institutions already debating or developing policy, or those poised to develop or evaluate a technology, often start the process. In this regard, the case studies brought out some necessary factors that must be present: regulatory skills and knowledge of modern biotechnology, and infrastructure for administration, inspection and monitoring. Institutionalisation could build on some of these factors, rather than 'reinventing the wheel'.

Critically, this paper demonstrates that actors' perceptions of the institutionalisation process are central for legitimacy. Thus, those championing the institutionalisation process of biosafety systems need to have a mandate, from national governments or the AU. The process needs to be inclusive of major actors, with different preferences, as this brings collective ownership of, and accountability for, action. Different viewpoints and social, professional and sectoral interests need to be brought around the negotiation table, as this provides opportunities for understanding the issues better , and enlists trust in governance and support for process implementation (Haas, 2004).

On convergence of biosafety systems, again the legitimacy question has to be answered. Also, harmonisation champions need to recognise that convergence very much depends on compatibility of systems, overcoming major disparities between

economies. Countries and actors want to see how they would benefit, and need to understand why they should forego their own interest (should that be the case) or demand that others do.

The case studies showed that there is little dispute that science is the basis for risk assessment. However, social norms and political interests must not be downplayed, since scientific assessment itself is based on those social and political assumptions (Levidow, 2001). This means, therefore, that it cannot be presumed that systems converge simply because scientific standards appear to be the same.

Furthermore, national systems tend to differ as do the environments giving rise to them (political,

#### Notes

- 1. The analysis in the paper focuses on participation by key actors, as defined here, as opposed to much wider participation by citizens (for detailed review of multiple stakeholders participation see Matz and Ferenz, 2005).
- 2. Woldu and Demissew (2004) provide more information on biotechnology capacity in Ethiopia.
- EPA's team of experts has been led by Dr Tewolde Berhan Gebre Egziabher — Africa's chief negotiator for the Cartagena Protocol on Biosafety.
- 4. Clearly the scope of Egziabher's views on GMOs, biosafety and patenting living organisms is much wider than Ethiopia.
- See <<u>http://www.biowatch.org.za/main.asp?show=13</u>>, last accessed 16 June 2006.
- 6. See <http://www.pub.ac.za/>, last accessed 16 June 2006.
- See Southern African Regional Biosafety Program supported by USAID. Available at <<u>http://www.usaid.gov/</u>>, last accessed 16 June 2006.

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cultural, and economic). As part products of such national systems, GMO laws too differ, in such areas as the scope and range of principles applied and relationships to other domestic laws. Such national system-specific differences highlight the need for more negotiation and understanding among those involved in biosafety systems development at pan-Africa level, to arrive at acceptable standards to actors, even if some of those standards do not necessarily support the interests of all actors. Thus, a central challenge of biosafety system construction and harmonisation is ensuring that the making and implementation of biosafety rules connects with, and represents, the key actors.

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