AgBioForum, 14(2): 71-82. ©2011 AgBioForum.

Identified Gaps in Biosafety Knowledge and Expertise in Sub-Saharan Africa

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Adoption of genetically modified (GM) crops has the potential to contribute toward alleviating the dire food security situation in sub-Saharan Africa (SSA). However, whether current or future GM crop technologies will be appropriate for countries in SSA will depend upon a number of issues, not least of which is the perceived safety of these products. Several countries in SSA however lack the necessary technical capacity to conduct or review risk assessment dossiers for GM crops and also to monitor for compliance. Biosafety regulatory capacity therefore needs to be enhanced and this requires substantial human and institutional resources. This study is an assessment of the current biosafety needs in SSA. It identifies gaps in biosafety knowledge and expertise in the region and makes proposals for possible training/support programs that could help toward addressing them.

Key words: biosafety, biotechnology, capacity building, genetic engineering, genetically modified organism (GMO), sub-Saharan Africa (SSA), research and development (R&D), transgenic.

Introduction

It is estimated that the human population in sub-Saharan Africa (SSA) increased from around 590 million to more than 760 million in the decade from 1995 to 2005 (Department of Economic and Social Affairs, United Nations, 2009). This, coupled with problems such as erratic rainfall, prolonged droughts, and agricultural pest problems has resulted in severe food insecurity (Mataruka, 2009). SSA is the most food-insecure region in the world (Food and Agriculture Organization of the United Nations (FAO), 2009a), with up to 265 million people living in hunger (FAO, 2009b). Domestic food production in many countries of SSA has failed to keep pace with rising food demand and thus has necessitated increases in food imports (FAO, 2009a). Adoption of genetically modified (GM) crops has the potential to contribute towards alleviating the dire food security situation in SSA (FAO, 2009c).

GM crops have been the most rapidly adopted technology in the history of agriculture and food biotechnology (Halpin, 2005; Huang, Pray, & Rozell, 2002). The global cultivated area of GM crops is reported to have increased from 1.7 million hectares in 1996 to 134 million hectares in 2009, an approximately 80-fold increase. Of the global total of 14 million farmers who planted GM crops in 2009 (up from 13.3 million in 2008), more than 90% or 13 million (up from 12.3 million in 2008) were resource-poor smallholders in developing countries. By the close of 2009, 25 countries were growing GM crops commercially, of which only three were African: Burkina Faso, Egypt, and South Africa (James, 2010).

Although most African countries have not yet begun to plant GM crops for commercial production, research is in progress in a number of countries (Karembu, Nguthi, & Ismail, 2009; Morris, 2011). However, whether current or future GM-crop technologies will be appropriate for countries in SSA will depend on a combination of agricultural, health, environmental, social, and economic factors (Sengooba et al., 2009). Clearly, one of the primary concerns will be the safety of these products (Jaffe, 2004; Singh, Ghai, Paul, & Jain, 2006). The effective and safe use of GM-crop technologies requires appropriate policies and processes to guide national decision-makers. The ability to perform and utilize risk assessments (also called product safety assessments) requires appropriate technical expertise, reliable sources of science-based information, and the mechanisms to deliver credible, verifiable information to a broad array of stakeholders with varying perspectives and concerns (Sengooba et al., 2009; Singh et al., 2006).

Several developing countries, however, lack the technical capacity needed to review safety assessments and to monitor for compliance (Johnston, Monagle, Green, & Mackenzie, 2008). In Africa, the biosafety regulatory capacity of many countries is limited by the lack of trained personnel as well as an absence of coherent regulatory instruments and institutions for risk assessment and management in relation to genetic engi-

Table 1a. Number of survey questionnaires sent and returned in SSA, by contact type.[a]

Contact type	No. of questionnaires sent	No. of questionnaires returned	% of questionnaires returned
Academic	112	29	25.9
Capacity building	145	28	19.3
Government	260	45	17.3
Other	220	43	19.5

[a]*Some individuals were classified into more than one contact type.*

neering. Furthermore, where instruments have been formulated and adopted by governments, there are often weak institutional arrangements for the enforcement of regulatory procedures (Clark, Mugabe, & Smith, 2007; Kingiri & Ayele, 2009). The limited technical capacity to carry out transgenic research and development (R&D) and to implement biosafety regulatory systems in Africa has been attributed in part to stagnating levels of government investment in agricultural research (Johnston et al., 2008; Morris, 2011). Capacity building represents the main challenge to the safe application of such modern biotechnologies in developing countries, as well as in the implementation of the related biosafety frameworks (Araya-Quesada, Degrassi, Ripandelli, & Craig, 2010; FAO, 2009d). Biosafety regulatory capacity therefore needs to be enhanced and this requires substantial human and institutional resources.

Considering that there are significant variations in human and institutional capacity across different regions of the developing world (Araya-Quesada et al., 2010; Johnston et al., 2008), a national or regional assessment of biosafety capacity and needs is required in order to be able to effectively target biosafety capacity-building interventions. Currently, more than 40 countries in SSA are signatories to the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD; Secretariat of the Convention on Biological Diversity, 2003), an international agreement which aims to

> "contribute to ensuring the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that might have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health…" (Article 1, p. 3).

The CPB also requires that there be cooperation in the "development and/or strengthening of human resources and institutional capacities in biosafety" (Article 22, p. 17) for the effective implementation of the protocol, and that such cooperation should include

> "scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety" (Article 22, p. 18).

Acknowledging that methods of delivering capacity building should be tailored to specific demand-driven needs (Araya-Quesada et al., 2010), the present study aims to define the current biosafety needs in SSA by identifying gaps in biosafety knowledge and expertise to ultimately result in characterizing possible training and support programs best aligned toward addressing those needs. It is expected that such information will be useful to actors involved in ongoing and future initiatives, including trainers, beneficiaries, governments and donors, to help design capacity-building programs that are responsive to country or regional needs and priorities.

Materials and Methods

For this qualitative study, a database of contact information of approximately 700 individuals either based or working in SSA and involved in biosafety and biotechnology R&D was constructed. These contacts were specifically selected on the basis of their position facilitating their awareness of current biosafety matters in their country, as experienced by both sides of the regulatory interface (e.g., National Focal Point for the Cartagena Protocol on Biosafety, National Focal Point for the Biosafety Clearing House, chairperson or member of the National Biosafety Authority (NBA) or National Biosafety Committee (NBC), project leader of major GM product development initiative, government biosafety inspector, head of university department carrying out biotechnology R&D, etc.; Table 1a). Following the creation of the database, a survey form was prepared that contained questions related to general aspects of biosafety and the genetically modified organism (GMO) regulatory framework in the recipient country, as well as the composition and training needs of any established

Table 1b. Number of survey questionnaires sent and returned in SSA, by region.

Region	No. of questionnaires sent	No. of questionnaires returned	% of questionnaires returned
Eastern Africa	313	71	22.7
Middle Africa	54	9	16.7
Southern Africa	102	14	13.7
Western Africa	155	22	14.2
Total	**624**	**116**	**18.6**

NBA or NBC. The format of the questions was of two types: (a) a closed system of multiple-choice answers requesting specific or quantifiable information, for example, the current stage of national biosafety legislation toward promulgation, the composition of the NBAs or NBCs in terms of gender, age group, experience, and qualifications of the members, etc.; and (b) open questions where the respondent was free to compose their reply, for example, to identify the type and range of biosafety information thought to be lacking by respondents, key issues that periodically arise during risk assessment, current training needs of the NBC members, etc. Pre-existing data from various sources (e.g., published legislation, reports, news articles, etc.) was included prior to dispatch in order to help reduce any burden on the recipient, and respondents were urged to confirm, add to, or update the information so the survey results were as complete and current as possible. As the survey form was written in English, respondents were also informed that they could reply in French, if that was their preferred language. The questionnaires were sent out by email to all database contacts in March 2009, and partially or fully completed forms were received back in April-May 2009.

Inconsistent and conflicting responses to several questions were identified, especially for those countries where feedback was received from multiple contacts with divergent competencies. Much time was then spent obtaining key supplemental information from a multitude of erudite sources, primarily recent scientific and technical literature. This was followed up with consultations (face-to-face or telephone communication) of major active and informed stakeholders during the period of July 2009 to January 2011, which helped clarify the situation across the subcontinent. The gathered information was then summarized by category to help characterize locally-identified needs at both the national and regional levels. Both the terminology referring to the regions of sub-Saharan Africa (United Nations Statistical Division, 2008) and the three-letter country codes (ISO alpha-3; International Organization for Standardization, 2006) used in this study are as designated prior to the recent split of Sudan into two separate countries. Therefore, though Sudan is usually considered as part of Northern Africa, for the purposes of this study only, it is considered as a whole and as part of Eastern Africa.

Results and Discussion

In total, 624 questionnaires were sent out to individuals across 48 countries in SSA, and 116 were returned, either partially or fully completed, which resulted in an overall response of 18.6%. Although seemingly quite low, this level of response is consistent with typical response rates of postal surveys (20%; Kelley, Clark, Brown, & Sitzia, 2003). Proportionally, academia (either in universities or national research institutes) generated the most respondents (Table 1a), and Eastern Africa was the region from which the most responses were received (Table 1b). This is consistent with this region being the most active in terms of biosafety and biotechnology; and therefore, it was also the region that had the most contacts in the database. At the country level, most contacts were identified (and consequently most responses obtained) from Kenya (KEN), followed closely by South Africa (ZAF; also an active country in terms of biosafety and biotechnology applications). In contrast, as shown in Table 1b, Middle Africa was the most difficult region in which to identify appropriate contacts; and therefore, it is also the region with the lowest response rate. The paucity of contacts might denote a lower formal involvement of stakeholders in biosafety and biotechnology activities, or/and the poorest information system. In fact, there were 12 countries (Benin [BEN], Cape Verde [CPV], Chad [TCD], Congo [COG], Cote d'Ivoire [CIV], Djibouti [DJI], Equatorial Guinea [GNQ], Gambia [GMB], Mali [MLI], Mauritania [MRT], Sao Tome and Principe [STP], and Seychelles [SYC]) for which either no contacts were found or no responses were received. The biosafety situation in these countries therefore proved very difficult to discern, and heavy reliance was upon the results of a few informed contacts and the published scientific and technical literature.

Assessment of Biosafety Needs in Sub-Saharan Africa

Legislative Issues. Although 12 countries have developed biosafety regulatory frameworks which describe how biosafety issues regarding risk assessment, management, and decision-making will take place (Forum for Agricultural Research in Africa, 2011), many lack adequate financial, human, and infrastructural resources to make these frameworks functional. This echoes the findings of our study that determined that the majority of countries across the sub-continent have limited human-resource capacity for developing and implementing national biosafety measures. To date, only 14 countries (Burkina Faso [BFA], Cameroon [CMR], Ethiopia [ETH], KEN, MLI, Mozambique [MOZ], Malawi [MWI], Mauritius [MUS], Namibia [NAM], Senegal [SEN], Togo [TGO], Tanzania [TZA], ZAF, and Zimbabwe [ZWE]) have biosafety legislation in place that provides them with the opportunity for informed decision making with respect to the products of modern biotechnology. Draft bills have recently been adopted by parliament in two other countries in SSA (Ghana [GHA] and Nigeria [NGA]), but these are yet to be promulgated into law by the executive arms of their governments. In addition, we found that 28 countries in SSA do not yet have an operational NBA or NBC, and for those that do exist, the study identified a paucity of members with specific biosafety expertise.

There is a pressing need for those countries with draft bills to push toward finalization of their biosafety legislation. A comprehensive biosafety legal framework serves to strike a balance between: (a) ensuring the development of biotechnology, (b) protecting the environment, and (c) safeguarding the interests of consumers (Wafula, Persley, & Karembu, 2007). In addition, enactment of biosafety legislation and a strong regulatory system are important in developing public confidence and ensuring that commercial releases of potentially beneficial products are carried out in a safe and responsible manner (Jaffe, 2004; Takeshima, 2010; Wafula et al., 2007). Laws and regulations are also vital to deal with any transboundary movement of GMOs, a major objective of the CPB. In the absence of appropriate legislation, there are protracted delays in assessing GM products, and by extension, any eventual authorization. Such delays, caused by the lack of judicial and political decisions, can result in undesirable situations, such as the illegal planting of GM crops as has happened elsewhere in the world, for example, southern Brazil when soy bean seeds were smuggled in across the border from Argentina (Pelaez, 2009). Also, the lack of legislative instruments might result in the complete prohibition of the application of modern biotechnology until such time that there is sufficient political will to resolve the situation.

The absence of biosafety laws exposes countries to regulatory gaps and is a major weakness undermining the legitimacy and credibility of any national biosafety systems. Therefore the enactment of biosafety laws is fundamental in providing adequate legal authority and enforcement (Wafula et al., 2007), as well as assisting the instillation of confidence in the public at large that biosafety issues are given due consideration.

The identification of the needs for training in legal drafting and the development of sectoral guidelines came primarily from those countries that either had experience with GMOs, or had drafted a biosafety bill and then experienced the bill being delayed at several stages of its development due to shortcomings linked to the lack of knowledge/expertise in legal drafting. Such gaps in expertise could result in further unsatisfactory draft bills, e.g., lacking in clarity, consistency and practicality, and containing disproportionate clauses, being presented to parliament. In the case of GHA and NGA for instance, due to *inter alia* flaws in the initial text, the draft bills had to be revised several times before gaining parliamentary approval (E.A. Okoree & R.A. Usman, personal communication, 2011). In those countries where the biosafety law requires public participation in decision-making, there is a need to inform the public of their expected role and to create mechanisms to provide them with the necessary information to facilitate their interactions. Areas pertinent to biosafety legislation in which capacity-building interventions were deemed necessary by respondents therefore included: legal drafting and development of sectoral guidelines; public awareness of, sensitization on, and dissemination of, existing biosafety laws; and setting up institutional structures, such as national biosafety bureau.

Regulatory Issues. The study demonstrated that there is little experience in many countries with regard to preparing or processing applications for import, export, and transit consignments for commercial purpose, as opposed to imports for research purposes; areas which might require capacity-building training intervention.

In some countries (e.g., KEN, TZA, Uganda [UGA]), risk assessment evaluations require that information on decisions pertaining to previous applications on similar products be provided (Linacre & Cohen, 2006). Although information on previous in-country

applications is readily available to the NBA or NBC, information concerning related applications elsewhere in the world is less so. Such information should therefore be consolidated and linkages to such information made readily available for applicants and regulators alike. In addition, the study found that members of the NBCs come from a variety of professional backgrounds, but, except in ZAF, many have not had significant experience in risk assessment and hence would benefit from exposure to training programs on the basic elements of risk assessment as well as more advanced training programs involving the evaluation of risk assessment dossiers. Manuals on standard operating procedures (SOPs) for risk assessment in environmental safety and food safety are also limited in availability. It is necessary that such information is generated or collected when available and the necessary SOPs developed.

A number of countries in SSA are working toward the development of similar transgenic crop products (Karembu et al., 2009). Although a few countries might have made significant strides in the R&D of such crops, other countries are just beginning and might not have developed sufficient technical capacity to evaluate the crops under development. Information sharing between countries could therefore be immensely beneficial. For example, the Virus Resistant Cassava for Africa (VIRCA)[1] project has been actively conducting R&D of GM cassava in a number of countries in SSA. In KEN, VIRCA conducted mock confined field trials (CFTs) between August 2006 and April 2008 and has been successful in developing biosafety-compliant protocols for handling cassava mosaic virus resistant GM cassava from the glasshouse to the CFT, including post-harvest restriction and monitoring (Mallowa et al., 2008). It would be useful for information on such protocols to be widely shared with other countries wishing to develop similar products in order to avoid duplication of efforts (regenerating information that already exists) and to ensure efficient utilization of economic resources. Resource use would be optimized at the regional level.

Many of the transgenic crops currently under development will need to undergo a number of CFTs in order to generate the data necessary to submit to regulatory authorities, and to fully characterize the prospective product. However, it is important to reiterate that this critical development stage cannot proceed in the absence of a biosafety regulatory framework. The study indicates that apart from BFA, KEN, UGA, NGA, and ZAF, the remaining respondent countries still lack experience in compiling and evaluating CFT applications. However, even those countries which have recently begun to regulate CFTs reported the need for further training as, in their experience, issues had arisen with respect to scale, the number of locations and post-trial monitoring periods for which they felt under-prepared. Many applicants reported being able to effectively develop measures to handle accidental releases, although it was suggested that further training is needed to help them to predict areas where contingencies can be specified and thus factored into risk management (A. Kagundu, personal communication, 2010).

GMO sampling and detection capacity is considered critical for the effective regulation of GM products (Miraglia et al., 2004), as well as to be able to meet technical requirements deriving from international obligations (FAO, 2009d). The study found that GMO detection capacity is lacking in a number of countries (including KEN and ZWE; A. Mafa & J. Kanya, personal communication, 2010). Scientists from various countries in Southern Africa have previously emphasized the need to support and strengthen GMO detection laboratories to curb the influx of undesirable GMO products and enhance the capacity of the region to verify the GM content of food imports and exports (Tsiko, 2009). In the Southern African Development Community (SADC), only South Africa has commercialized the production of GMO crops, yet there is a growing influx of GMO products in the region from South Africa and industrialized nations such as the United States, Canada, and other Western countries that often donate food aid to drought-prone parts of the region (Tsiko, 2009). It is therefore necessary that issues pertaining to GMO monitoring and traceability issues, GMO inspection and control, and the amelioration of emergency measures against accidental release are included in biosafety training programs in the region.

Baseline Scientific and Technical Information. In general, there is a great deal of existing information that is relevant to the risk assessment of GMOs, including basic ecological information and experience with both modified and non-modified organisms (Craig, Tepfer, Degrassi, & Ripandelli, 2008). However, there is considerable national and regional variation in emphasis, and in the amount of information required by different competent authorities (Craig & Tepfer, 2007). Furthermore, because risk assessments are carried out on a case-by-case basis, necessary supporting information

1. *http://www.danforthcenter.org/science/programs/international_programs/virca/*

Table 2. Biosafety information identified as lacking by various countries in SSA.

Specified information gaps	Countries (number of countries)
Effect on non-target organisms	GHA, KEN, Sierra Leone (SLE), ZAF, Sudan (SDN), UGA, Zambia (ZMB) (7)
Baseline agronomic data for major African crops	Burundi (BDI), ETH, KEN, NGA, ZAF, TZA (6)
Food safety data (allergenicity and toxicity)	GHA, KEN, MOZ, NGA, TZA, ZWE (6)
Gene flow parameter data	GHA, KEN, NGA, SLE, SDN, ZWE (6)
Molecular characterization data	Central African Republic (CAF), KEN, MOZ, TZA, UGA, ZWE (6)
Status and current spatial distribution of existing genetic diversity	ETH, KEN, Rwanda (RWA), SEN, SDN, ZWE (6)
Data on, and protocols for, the identification/detection/tracing of GMOs and products	CMR, Guinea Bissau (GNB), KEN, Madagascar (MDG), SEN (5)
Agricultural impact	Botswana (BWA), NGA, TZA, UGA (4)
Environmental impact (especially from previous African evaluations)	GHA, SEN, ZMB (3)
Pest resistance to GM crops	KEN, SLE, UGA (3)
Mitigation measures	MOZ (1)
Precise land use / land cover data	BFA (1)
Risk / benefit analysis	KEN (1)
Socio-cultural considerations	NGA (1)

varies, and there are often limitations to information available for particular organisms and receiving environments, especially in the developing world. In cases where such information does not exist it is usually necessary to generate further empirical data, for example, through laboratory or field studies (Craig et al., 2008).

Echoing concerns of Morris (2011), the study found that there is a lack of basic scientific and technical information required to perform a comprehensive and reliable risk assessment of GM products in many countries in SSA. The type of information identified as lacking by respondents in specific countries (Table 2) included, for example, baseline agronomic and ecological data of major African crops, data on the distribution and hybridising ability of crop-related wild species, factors increasing GMO-hybrid fitness, population dynamics of any non-target species in the areas of future cultivation, information on molecular characterization, food safety data, and protocols for the identification and detection of GMOs, etc. There is also a lack of information with regard to issues of pollen dispersal (distance, viability), stability of trait expression in the environment, and expected performance of the transformed varieties (A. Kagundu, personal communication, 2010). The dearth of such scientific information was considered critical by interviewees in their ability to perform credible risk assessments. Therefore, the provision or local generation of such information is of great importance in enabling the regulatory frameworks in these countries to make informed and science-based decisions regarding GMOs.

Craig et al. (2008) provide a detailed description of the type of information pertaining to molecular characteristics that might be required in order to perform a risk assessment. The study found that most plant varieties under development in SSA are generally well described at the phenotypic level, however many of the descriptions do not include a genetic or molecular characterization (A. Kagundu, personal communication, 2010). In determining any potential risks associated with the cultivation of a GM crop, it is usually necessary to acquire sufficient data to characterize the modified plant and permit a comparison with the unmodified counterpart (Shewry et al., 2007; Stewart, Richards, & Halfhill, 2000); hence the need to have the requisite data for such comparisons to be made. It has previously been pointed out that though a positive policy environment exists for technology development, much more needs to be done to generate requisite data on risk assessment and management, especially for crops indigenous to the subregion (US Department of Agriculture [USDA] Foreign Agricultural Service [FAS], 2009). However, when such data does exist, it has been reported that little or no sharing of information among stakeholders occurs (USDA FAS, 2009). Cases have been identified where the lack of specific technical information has hindered risk assessment and therefore decision-making. For example, with regard to the development of virus-resistant

Table 3. Issues that might or do arise during risk assessment in various countries in SSA, as identified by interviewees.

Issues	Countries (number of countries)
Environmental Safety Assessment	
Gene flow	Angola (AGO), BWA, BFA, BDI, CMR, CAF, Comoros (COM), Democratic Republic of the Congo (COD), ETH, Gabon (GAB), GHA, Guinea (GIN), GNB, KEN, Lesotho (LSO), Liberia (LBR), MDG, MWI, MUS, MOZ, NAM, Niger (NER), NGA, RWA, SEN, SLE, Somalia (SOM), ZAF, SDN, Swaziland (SWZ), TZA, TGO, UGA, ZMB, ZWE (35)
Invasiveness	AGO, BWA, BFA, BDI, CMR, CAF, COM, COD, ETH, GAB, GIN, GNB, KEN, LSO, MDG, MWI, MUS, MOZ, NAM, NER, NGA, RWA, SOM, ZAF, SDN, SWZ, TZA, TGO, UGA, ZMB, ZWE (31)
Impact on non-target organisms	BWA, BDI, CMR, CAF, ETH, GAB, GHA, GNB, KEN, LSO, LBR, MWI, MUS, MOZ, NAM, NER, NGA, RWA, SEN, SLE, ZAF, SDN, SWZ, TZA, TGO, UGA, ZMB, ZWE (28)
Others:	
• Secondary environmental effects as a	BWA (1)
• Modification of ecological balance	COD, MDG, TGO (3)
• Epigenetic effects including gene-silencing	ETH (1)
• Impact on biodiversity	KEN, ZAF (2)
• Long term environmental impacts	TZA (1)
• Potential to produce hazards in the environment	LBR (1)
Food/feed safety	
Allergenicity	AGO, BWA, BFA, BDI, CMR, CAF, COM, COD, ETH, GAB, GHA, GIN, GNB, KEN, LSO, LBR, MDG, MWI, MUS, MOZ, NAM, NER, NGA, RWA, SEN, SLE, ZAF, SDN, SWZ, TZA, TGO, UGA, ZMB, ZWE (34)
Toxicology	AGO, BWA, BFA, BDI, CMR, CAF, COM, ETH, GAB, GHA, GIN, GNB, KEN, LSO, LBR, MWI, MUS, MOZ, NAM, NER, NGA, RWA, SEN, SLE, SOM, ZAF, SDN, SWZ, TZA, TGO, UGA, ZMB, ZWE (33)
Others:	
• Digestibility	BWA, MOZ (2)
• Gene transfer and epigenetic effects	ETH (1)
• Risk of resistance to antibiotics	MDG (1)
• Substantial equivalence	NGA(1)
• Consumption patterns, exposure	ZAF (1)
Agricultural sustainability	
Weediness	BDI, CMR, CAF, COM, ETH, GHA, GIN, GNB, KEN, LSO, LBR, MOZ, NAM, NER, NGA, RWA, SLE, SOM, ZAF, SDN, SWZ, TZA, TGO, UGA, ZMB, ZWE (26)
Pest resistance development	AGO, BWA, BDI, CMR, CAF, COM, ETH, GAB, GHA, GIN, GNB, KEN, LSO, LBR, MWI, MOZ, NAM, NER, NGA, RWA, SEN, SLE, SOM, ZAF, SDN, SWZ, TZA, TGO, UGA, ZMB, ZWE (31)
Chemical inputs	**Nutrition**
Higher costs	CMR, ETH, GNB, KEN, LSO, MWI, MOZ, NAM, NER, NGA, RWA, SEN, SLE, SOM, ZAF, SDN, SWZ, TZA, TGO, UGA (20)
Others:	
• Effects on crop or domestic animal gene pools; Relevancy to address food security issues	ETH (1)
• Change in farming systems	KEN, ZAF (1)
• Access to the technology; Impact on traditional knowledge, heritage, & cultural practices; Impacts on trade, labor, & transboundary movement	ZAF (1)
• Erosion of local varieties or germplasm; Export contamination; Loss of market competitiveness	SDN (1)

Table 4. Aspects of biosafety that interviewees identified as a part of—or what would be part of—their decision-making processes.

	Countries (number of countries)			
Issue	**Eastern Africa**	**Middle Africa**	**Southern Africa**	**Western Africa**
Cost-benefit analyses in risk assessment	BDI, ETH, MDG, MWI, MOZ, RWA, SDN, TZA, UGA, ZMB, ZWE (11)	CAF, CMR (2)	BWA, NAM, SWZ, ZAF (4)	LBR, NGA, SEN, SLE, TGO (5)
Integration of socio-economic issues in decision-making	BDI, ETH, KEN, MDG, MWI, MUS, MOZ, RWA, SDN, TZA, UGA, ZMB, ZWE (13)	CAF, CMR (2)	BWA, LSO, NAM, SWZ, ZAF (5)	GHA, GMB, GIN, GNB, LBR, NGA, MLI, SEN, SLE, TGO (10)
Public participation	DJI, Eritrea (ERI), ETH, KEN, MDG, MWI, MUS, MOZ, RWA, SYC, SOM, SDN, TZA, UGA, ZMB, ZWE (16)	CAF, CMR, GAB (3)	BWA, LSO, NAM, SWZ (4)	CIV, CPV, GHA, GIN GNB, LBR, MLI, NER, NGA, SEN, SLE, TGO (12)
Risk calculation	BDI, ETH, MDG, MWI, MUS, MOZ, SOM, SDN, SWZ, UGA, ZMB, ZWE (12)	CAF, CMR (2)	BWA, LSO (2)	GIN, GNB, LBR, NGA, SEN, SLE (6)

transgenic cassava, there is a lack of information pertaining to the biosafety of G5, a protein from the bacteriophage M13 that has been transferred to cassava, (T. Alicai & S. Mallowa, personal communication, 2009). In another example, regarding the development of transgenic biofortified sorghum, a number of countries have indicated the lack of environmental impact assessment data (J. Mutisya, personal communication, 2009). Insufficient data was also reported with regard to confinement distance, pollen flow, and containment mechanisms for transgenic sugarcane in Mauritius (A. Dookun-Saumtally, personal communication, 2009). The development of mechanisms to generate or access necessary baseline data will obviate any stalling derived from data insufficiency during regulatory procedures. A number of additional issues that interviewees indicated that might or do arise with respect to environmental safety assessment, food or feed safety and agricultural sustainability are outlined in Table 3.

Training Needs. From the above, it is apparent that training in risk assessment is still required in the region. With regard to environmental and food safety, responses from at least 58% of the countries considered issues related to non-target organisms, invasiveness, gene flow, allergenicity and toxicity as important considerations during their risk assessments, while responses from at least 54% of the countries raised agricultural sustainability issues related to weediness and pest resistance development (Table 3). It was therefore requested that significant focus be given to the means of addressing these concerns in future risk assessment training offerings. Respondents from across the sub-continent reported that additional issues would form part of their biosafety decision-making, such as cost-benefit analyses, the integration of socio-economic issues, public participation and risk calculation, among many others (Table 4). It would be necessary that these are also included in general risk assessment training modules for the region. A summary of the training needs identified is given in Table 5.

Table 5. Training needs for various countries in SSA.

Key competencies, knowledge, and skills required
1. Audit of risk assessment reports and risk management plans.
2. Compliance requirements under the CPB.
3. Conducting socio-economic assessments.
4. Development of standard operating procedures (SOPs).
5. Ex-ante socio-economic impact assessment.
6. Field trial techniques (location, post-trial monitoring, etc.).
7. General biosafety knowledge and basic elements of risk assessment.
8. GMO sampling and detection.
9. Handling dossiers for import, export and development of GMOs.
10. Harmonization of biosafety related sectoral laws and policies.
11. Integration of socio-economic issues in decision making.
12. Learning from experiences of other countries, e.g., through study tours.
13. Legal drafting and development of sectoral guidelines.
14. Mitigation measures.
15. Post-release monitoring.
16. Preparation of GMO applications and dossiers.
17. Public awareness and sensitization.
18. Regulatory training (legal policy, enforcement, inspection, etc.).
19. Review of GM applications and dossiers.
20. Risk assessment and management.
21. Setting up institutional structures such as National Biosafety Bureau.
22. Sources of information for biosafety risk assessment.

Other Pertinent Issues. Due to the relative dearth of practical knowledge of rDNA biotechnology and its related issues (e.g., socio economic implications) among decision-makers, researchers, and the general public across the sub-continent, there is a vital need to increase their general awareness. This might be done through a variety of means, for example, through participation in training workshops, study tours, and academic specialization in the required fields, such that they might play a fuller and more considered role in the decision-making process. Our study also indicated the requirement for capacity-building interventions to help increase: public understanding of biotechnology and its safe use, understanding ethical and socio-economic concerns, and training scientists in molecular biology. Suggestions were also made for study tours by members of NBCs to countries demonstrating best practices in GMO regulation because such study tours are believed to have been instrumental in ensuring the passage of the biosafety law in Kenya (Karembu, Otunge, & Wafula, 2010).

Conclusion

As noted previously, there is a large disparity in the functionality of the biosafety regulatory systems found in SSA. These are most evident when considering, among other things, the status of their regulation, technical and scientific knowledge, and previous access to training opportunities. It was noted that a significant proportion of countries in Eastern Africa (>50%) reported information gaps in a number of key areas as opposed to countries in Middle, Western and Southern Africa. When investigated further, information deficits were reported only from those countries across the sub-continent that were already active in GMO R&D and have experience in regulating GMOs in the earlier stages of R&D. Many countries might therefore not be able to identify information deficits (and most likely experience deficits too) until they become active in GMO R&D or regulation. This is also likely to be relevant when assessing the scope of future training needs.

From our survey it is evident that with regard to the development and implementation of biosafety legislation, capacity-building needs might vary depending on the stage of its development in each country. However, with regard to actual risk assessment of GM crops, the issues that have been reported to likely arise appear fairly homogeneous across countries with only marginal variations (Table 3) even though there is wide variation in terms of biosafety regulatory structures, systems, and implementation procedures (Falck-Zepeda, 2009). General risk-assessment training programs can therefore be useful across the sub-continent and do not have to be regionally specific. However, it is clear that the time for general introductory courses on biosafety is passing and there is a greater need for more in-depth, sustainable training linked to areas of professional responsibility (Johnston et al., 2008). Issues pertinent to risk assessment such as cost-benefit analyses in risk assessment, integration of socio-economic issues in decision-making, public participation, and risk calculation could form part of general risk-assessment training modules for the region, considering that they were highlighted across the sub-continent. It is noted however, that the inclusion of broader socio-economic considerations into GMO biosafety analyses continues to be controversial and is an ongoing discussion within international agreements and other international fora (Falck-Zepeda, 2009). Their inclusion might actually become an obstacle to the adoption of potentially valuable technologies for developing countries facing higher barriers in terms of biosafety regulatory compliance due to resource constraints (Falck-Zepeda, 2009). This highlights the need for capacity building in *ex ante* impact assessment. Some practical tools for biosafety regulators to estimate the value of GM seed technologies under data scarcity have recently been developed and made available (Demont, Rodenburg, Diagne, & Diallo, 2009; Dillen, Demont, & Tollens, 2009), with the latter reported to severely cut the cost of large-scale, *ex ante* impact assessment when time and resource constraints are present.

This study has identified a number of key areas relevant to biosafety in which capacity-building efforts could be directed. However, when attempting to address biosafety needs, the fact that SSA is a very diverse region in terms of biosafety proficiency should not be ignored. With respect to the provision of risk assessment material or training, it is apparent that the identified needs are fairly homogeneous across the sub-continent and detailed risk-assessment training programs that take into consideration all of the key issues identified in this survey could go a long way toward enhancing the ability of countries in the sub-continent to carry out effective biosafety risk assessment. Although a country-level or sub-regional approach to capacity building in biosafety has been variously advocated, the outcome of this study indicates that this might only be necessary with regard to efforts to develop or implement biosafety legislation. Furthermore, it takes both time and resources to create tailor-made capacity-building programs. It is hoped that such capacity-building efforts will enhance the ability of countries in SSA to be able to effectively regulate the

development or commercialization of GMOs. In addition, the presence of operational regulatory systems should provide confidence to the general public that the opportunities offered by modern biotechnology are being managed effectively.

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Acknowledgments

This study was carried out as part of a biosafety capacity-building project for sub-Saharan Africa, being implemented by the ICGEB. This report is based on research funded by the Bill & Melinda Gates Foundation. The findings and conclusions contained within are those of the authors and do not necessarily reflect positions or policies of the Bill & Melinda Gates Foundation nor the ICGEB.

The authors are grateful to the anonymous reviewers for their constructive comments, which resulted in the improvement of this article. In addition, the authors are indebted to the following individuals for information provided in personal communications.

- T. Alicai, Virus Resistant Cassava for Africa (VIRCA) Project, Uganda
- Y. Boodoo, National Focal Point (NFP) of the Cartagena Protocol on Biosafety (NFP-CPB) and NFP-Biosafety Clearing House (NFP-BCH), Mauritius
- A. Dookun-Saumtally, Mauritius Sugar Industry Research Institute, Mauritius
- R. Ebegba, NFP-BCH, Nigeria
- C. Egesi, National Crops Research Institute, Nigeria
- M. Fosi, NFP-CPB, Cameroon

- D. Gharwe, Tobacco Research Board, Zimbabwe
- D.L.S. Hafashimana, National Competent Authority (NCA), Uganda
- C.Z. Kabore, NCA, Burkina Faso
- A. Kagundu, National Biosafety Committee (NBC), Kenya
- J. Kanya, University of Nairobi, Kenya
- J. Lemgo, Food and Drugs Board, Ghana
- H.K. Macharia, National Biosafety Authority (NBA), Kenya
- A. Mafa, NBA, Zimbabwe
- S. Mallowa, BioCassava Plus Project, Kenya
- M. Mbengashe, NCA, South Africa
- B. Mkoko, National Research Council, Malawi
- J. Mutisya, Kenya Agricultural Research Institute, Kenya
- L. Neves, Eduardo Mondlane University, Mozambique
- E.A. Okoree, NFP-BCH, Ghana
- K.T. Tengue, NFP-CPB, Togo
- C. Theka, NCA, Malawi
- M. Traore, NFP-CPB, Mali
- R.A. Usman, NFP-CPB, Nigeria
- A. Zacarias, National Institute of Agronomic Research, Mozambique