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POLICY AND REGULATION OF BIOTECHNOLOGY IN FOOD PRODUCTION

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Executive Summary

Modern agricultural biotechnology has become a highly controversial issue, which has polarized the civil society in terms of the potential benefits and risks of the adoption of genetic engineering technologies and resulting products in food and agriculture systems. Africa as a region is grappling with policy and regulatory choices as it tries to position itself in the current global discussions. This paper reviews existing policy and legal instruments and summarizes discussions in the region on genetically modified products. Policy considerations and recommendations are made for further regional dialogues on the burning issue of incorporation of genetically modified products in food and agriculture systems in Africa

ACRONYMS AND ABBREVIATIONS

ABSPII	Agriculture Biotechnology Support Project Phase II
ASARECA	Association for Strengthening Agricultural Research in Eastern and Central Africa
BCH	Biosafety Clearing House
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CORAF/WECARD	Conseil Ouest et Centre Africain pour la Recherche et le Développement Agricole/West And Central African Council for Agricultural Research and Development
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic Acid
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FARA	Forum for Agriculture Research in Africa
GEF	Global Environment Facility
GM	Genetically Modified
GMM	Genetically Modified Microorganism
GMO	Genetically Modified Organism
IFPRI	International Food Policy Research Institute
IPPC	International Plant Protection Convention
IPR	Intellectual Property Rights
LMO	Living Modified Organism
OECD	Organisation for Economic Co-operation and Development
PBS	Program for Biosafety Systems
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TRIPS	Agreement on trade-related aspects of intellectual property rights
TWN	Third World Network
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial & Development Organisation
UNIDO-BINAS	UNIDO-Biosafety Information Network & Advisory Services
USAID	United States Agency for International Development
WHO	World Health Organization
WTO	World Trade Organization

1.0. Introduction

1. Modern agricultural biotechnology[1] encompasses a range of technologies used to unravel and manipulate the genetic make-up of organisms for use in agriculture. It includes a whole range of technologies, including genomics and bioinformatics, marker assisted selection, micropropagation, tissue culture, cloning, artificial insemination, embryo transfer, and genetic engineering or modification.

2. The development of these technologies has enhanced the array of agricultural techniques that can be used to advance food production. However, when the genetic set up of an organism is modified, a thorough risk analysis of the resulting genetically modified organism (GMO) is required to test potential negative effects on its surrounding environment, or to detect the presence of unintended compositional changes that could have adverse effects on human health [3]. Many of the proponents of modern agricultural biotechnology have suggested that the issue should be resolved through the application of sound science[2] and that it would be unethical to ban the use of or inhibit the potential benefits associated with this technology for addressing serious problems related to public health, nutrition, poverty, and the environment [34]. Others, however, have questioned the adequacy of scientific knowledge about this technology and its benefits, and raised concerns regarding its potential risks, claiming that regulatory decisions have been based more on politics than on science.[3] The key trends from these dialogues seem to echo the sentiments of an independent Panel of Eminent Experts on Ethics in Food and Agriculture established in FAO[4]: *"Consideration must be given to the potential benefits for food and nutrition security, and thereby for human health and well-being, on the one hand, and the need to avoid risks to human health, social justice and the environment, on the other. Adequate safeguards must be put in place, to ensure that all concerns are protected, including environmental concerns, while leaving options open for future generations*" [35].

3. In Africa as a region, with very few exceptions, the lack of adequate national or regional biosafety regulatory mechanisms is a subject of great concern. Sensitive debates are going on about the status of biotechnology for international development and particularly its implications on food safety, impacts on biodiversity, ethical issues, trade related issues and consumer concerns [5]. There is a need therefore for policy and regulatory dialogues for a common regional position or harmonized models to assist Governments and policy makers in decisions involving the regulatory measures for GMOs.

4. While developed countries have established their national frameworks to deal with agro-biotechnology and biosafety focusing primarily on domestic priorities and strategies, most developing countries are doing so under less flexible circumstances. They increasingly seem to be expected to set up their national regulatory schemes based on the requests and expectations of their main trade partners. For developing countries, reconciling their trade interests with their responsibility for improving the quantity and quality of agricultural and food products made available to the population and with their commitment to environmental preservation seems to be a difficult task [5]. Developing countries pondering whether or how much to use genetically modified agricultural products must balance many different concerns, ranging from battling domestic starvation and malnutrition and ensuring health and safety, to preserving the environment, fulfilling multilateral trade obligations and protecting and enhancing trade

[1] Biotechnology is any technique that uses living organisms or part thereof to make or modify a product, improve plants or animals, or develop microorganisms for specific uses (www.biodiv.org)
[2] See www.scidev.net
[3] See Third World Network www.twnside.org.sg/
[4] The eminent panel of experts was established to established to advise FAO on key ethical issues of relevance to its work

opportunities [6]. Some policy and regulatory aspects have been analysed and summarized in this paper..

2.0 Current Use, Research and Impending Development of Foods Produced Through Modern Biotechnology

5. Current research and development activities and future projects are targeted mainly at crops, livestock, fish and microorganisms. Programmes are focused in addressing the following:

- Biotic Stresses – Pest and disease resistance, virus resistance;
- Enhanced nutritional value and altered composition of agricultural products;
- Development of processing aids for foods and feeds;
- Reproductive biology;
- Production of vaccines and diagnostic tools to prevent diseases in domestic animals;
- Tolerances to a biotic or environmental stresses [7-18].

6. An overview of the current situation in developing countries can be derived from a first analysis of about 2,000 crop sector entries from 71 countries in FAO-BioDeC[5], a database launched by FAO in April 2003 providing information on biotechnology products/techniques in use or in the pipeline in developing countries [19]. The publication summarises and analyses the information contained in the database as of 31 August 2004. GMO activities (479 records) are ongoing in many countries but unevenly distributed, with Latin America and Asia recording 85 percent of all recorded GMO activities in the developing world (45 percent and 40 percent, respectively). GMO activities aimed at pathogen resistant cultivars form 35 percent of the total activities, followed by pest resistance at 20 percent, quality traits and herbicide resistance each at 16 percent. Most of the commercialized GMOs were acquired from developed countries and are mainly herbicide and Bt resistant cotton, maize and soybean cultivars. From the number of field trials (40 percent of all GMO activities) it can be postulated that in the near future the developing country markets will have new GM crops such as virus resistant papaya, sweet potato and cassava; rice tolerant to a biotic stress (salinity and drought), and even high lysine maize and soybeans with improved oil composition. However, a lot of biosafety capacity building is needed to enable many countries in Africa, Eastern Europe and the Near East to benefit from this technology [19].

3.0 Development of Regulatory and Food Safety Systems in the Area of Modern Biotechnology

7. In order to make informed decisions on the safety of GMOs and GM foods, African governments need substantial human and institutional resources in the disciplines required for the assessment of risks to the environment and for human food[6]. Developing countries have limited expertise in the required regulatory fields of science, as biotechnologists in these countries are generally engaged in research [20]. In most developing countries, these same scientists, are asked to sit on national biosafety committees, and are involved in both risk assessment and policy-making. There are three vulnerabilities in this scenario: (a) when developers are also risk assessors, the potential for conflict of interest is magnified; (b) because most members of the national biosafety committees are recruited on a voluntary basis, they do not devote too much time to this responsibility; (c) because membership of the national biosafety committees generally rotates, there is no continuity in the capacity gained through experience. In addition, there is little or no national experience in the kind of tests and methodologies required

[5] See FAO-BioDec (www.fao.org/biotech/inventory_admin/dep/default.asp)
[6] See UNEP Technical Guidelines for Safety in Biotechnology, Belgian Biosafety Clearing House (www.biosafetyprotocol.be/UNEPGuid/Contents.html)

for an effective risk analysis. This therefore calls for a strengthened institutional capacity building in the regulatory agencies in developing member countries ensuring the independence of the regulatory authorities and the benefit of accumulated experience through time. Regional approaches could provide a cost effective means to overcome the high costs involved in the implementation of institutional and technical measures.

8. Currently there are several capacity building initiatives including the GEF Capacity Building Biosafety Project implemented by UNEP, World Bank and UNDP; FAO biotechnology and biosafety projects; the USAID Project on Agriculture Biotechnology and Biosafety (ABSPII and PBS). FAO implemented biosafety capacity building projects in Kenya and Swaziland, and several additional technical cooperation projects are currently in the pipeline. There are more than 89 multilateral and bilateral initiatives on Biotechnology and Biosafety on the Biosafety Clearing House of the CBD.

9. In addition to initiatives to assist developing countries with National Biosafety Frameworks, other areas of focus are food safety and risk assessment related activities, training activities on data/tools for decision making among others. These activities are spearheaded by UN agencies (FAO, WHO, World Bank, UNEP, UNDP, UNIDO, WTO, UNCTAD), private sector, bilateral and multilateral agreements[7].

10. Capacity-building initiatives must be sustained beyond the life of any externally supported activity. It must become an integral part of the recipient country's development programme and not be a once-off activity [21]. In turn, African countries must participate and take ownership of these development initiatives.

4.0 A Review of Existing National, Regional and International Policy and Regulatory Instruments on Biotechnology in the Africa Region

11. The scientific and policy bases for examining issues and passing judgment on genetically modified products are evolving as rapidly as the pace of technical evolution in biotechnology. Regarding the safety of genetically modified foods and the implications for consumers' health, the CBD through the Cartagena Protocol on Biosafety, FAO, WHO, UNEP and other intergovernmental agencies continue to stress the importance of accurate risk management and effective risk communication, while optimistically pointing out the real prospects of solving major nutrition problems and even preventing food safety problems with specifically developed GMOs [22].

12. At the international level, 15 legally-binding instruments and nonbinding codes of practice address some aspect of GMOs, but none of these on its own is appropriate for the regulation of all sectors [23]. Seven of these are legally binding, namely the UN Convention on the Law of the Sea (1982), the Convention on Biological Diversity (1992), and its Cartagena Protocol on Biosafety (2000), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (1995), the WTO Agreement on Technical Barriers to Trade (1994), the International Plant Protection Convention (1997), the Aarhus Convention (1998). These instruments can be of assistance to African countries in establishing appropriate regulatory structures that deal with potential concerns while, at the same time, promoting harmonization of national regulations for crops, livestock, fish, forest trees and microorganisms whilst meeting international obligations [23]. They also increase, however, the already overstretched capacity needs of developing countries, and present challenges to developing a fully coherent policy and regulatory framework for modern biotechnology in developing countries. [24]. However, as a way of harmonization of the diverse international obligations, the development and enforcement of a regulatory framework for GMOs should be coordinated within cross-sectoral national bodies responsible for enforcing sanitary, Phytosanitary and

[7] See capacity building initiatives under the Biosafety Clearing House, http://bch.biodiv.org

zoosanitary measures in an integrated national biosecurity system. Appropriate national institutions should be developed for these purposes [23]. Models for rationalizing relevant regulatory functions among sectors are appearing in a number of countries[8].

13. Although all these instruments are of relevance, the Cartagena Protocol on Biosafety and the Codex Guidelines are particularly relevant for the objectives of this paper and are hereby described .

4.0.1 The Cartagena Protocol on Biosafety

14. The Cartagena Protocol is a legally binding international instrument that regulates the transboundary movement of living modified organisms (LMOs) resulting from modern biotechnology with the objective of protecting the environment. Its main features include procedures for transboundary movement of LMOs that are intentionally introduced into the environment, and for LMOs that are intended to be used directly as food or feed or for processing (LMO-FFP). The Party of import makes its decisions in accordance with scientifically sound risk assessment. The Protocol sets out general principles and methodologies on how to conduct a risk assessment. Parties to the Protocol must also ensure that LMOs subject to intentional transboundary movement are handled, packaged and transported under conditions of safety and are accompanied by appropriate documentation [25].

15. To facilitate its implementation, the Protocol establishes a Biosafety Clearing-House (BCH) to exchange information, and contains a number of important provisions including capacity building, financial mechanism, compliance procedures and public awareness and participation. The Protocol does not consider however, ethical aspects relating to the use of modern biotechnology [26, 27].

16. The provisions of the Cartagena Protocol extend only to those organisms resulting from modern biotechnology that might cause potential adverse effects to the conservation and sustainable use of biodiversity, with consideration of risks to the human health. The Protocol does not enter, however, into specific measures addressing the safety of foods derived from biotechnology. These measures are addressed by the Codex Alimentarius Commission.

4.0.2 Codex Principles and Guidelines

17. The Joint FAO/WHO Codex Alimentarius Commission is the principal forum in which the food safety aspects of GMOs are considered. Several Codex Committees have dealt with different aspects of matters related to GM foods. In 1999, the Commission established the *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnologies or traits introduced into foods by biotechnological methods [28 - 31]. It should be noted that Codex standards and related texts, while not binding in nature, are recognised as international reference points by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, as far as food safety is concerned.

In July 2003, the Codex Alimentarius Commission adopted the following:

Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology

[8] The combined Portal on Food Safety, Animal and Plant Health developed by FAO, OIE, WHO & WTO among others is a useful resource in terms of guidelines and standards on safety among life forms. See also www.fao.org, www.oie.int, www.who.int, www.wto.org.

18. The purpose of these principles is to provide an overarching framework for undertaking risk analysis of the safety and nutritional aspects of foods derived from biotechnology. The "tracing of product" is referred to in the text as a specific tool to facilitate risk management measures.

19. The key elements of the principles are:

- a pre-market food safety assessment, on a case-by-case basis, for foods derived from biotechnology. The assessment should be based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques. The data and information used in this assessment should be of a quality that would withstand scientific peer review;
- the food safety assessment is based on a comparative analysis with a "conventional counterpart" to ensure that the resulting biotechnology food is no less safe than the foods normally consumed by the population;
- risk management measures should be proportional to the risks identified in the safety assessment and may include measures such as labelling, post-market monitoring and product tracing; and
- the definitions used in the Principles for the [Food Safety] Risk Analysis for Foods Derived from Modern Biotechnology are the same as those in the Cartagena Protocol on Biosafety (CPB), so that the Codex texts on food safety and the CPB text on biosafety and environmental protection are mutually compatible and supportive.

Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants

20. This guideline, which is based on the above "Principles", describes the methodology for conducting a safety assessment specifically for foods derived from recombinant-DNA plants. The basic approach for the safety assessment is the comparative approach based on the concept of "substantial equivalence", thus focusing on the difference between foods derived from recombinant-DNA plants and their conventional counterpart. It pays special attention to the question of allergenic potential of new genetically modified (GM) plant varieties. An annex outlining the evaluation of allergenicity was also agreed[9].

Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms

21. The guideline describes the methodology for conducting safety assessment specifically for foods derived from recombinant-DNA micro-organisms. The basic approach is similar to the guideline of recombinant-DNA plants, however, elements peculiar to micro-organisms were highlighted.

22. The key elements of the guidelines are:

- a detailed step-by-step guidance on how to undertake a safety assessment, including the nature of the data to be collected and the elements in the decision-making process that allows food produced using recombinant-DNA micro-organisms to be considered suitable for human consumption;
- a comparison of the safety assessments undertaken by different national authorities;

[9] See FAO's Food and Nutrition Portal (www.fao.org)

- an option for national authorities to use other countries assessment in line with the Codex guidelines;
- a provision for future food safety assessments that may be undertaken by FAO and WHO, if FAO and WHO decide to undertake case-by-case safety assessments.

23. The Codex Intergovernmental Task Force was dissolved in 2003 after having successfully completed the development of the three documents above. It was re-established by the Commission in 2004, to resume its work. Its meeting in September 2005 identified areas for future work, which included food safety assessment of foods derived from recombinant-DNA animals as well as food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits. The re-established Task Force is expected to complete its work by 2009.

4.0.3 National Biosafety Frameworks

24. A national biosafety framework is a combination of policy, legal, administrative and technical instruments that is set in place to address safety for the environment and human health in the context of modern biotechnology. They are intended to serve as mechanisms for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer. However, establishing such a system has many dimensions and associated challenges and will require investments to build institutional and human capacity for implementing and managing the developed framework. There is neither a single best approach nor standard that reflects national environmental, cultural, political, financial and scientific capacity to build a National Biosafety Framework.

25. Where national biosafety frameworks are in place, they vary between countries according to national priorities and statutory structures. In addition, the different social conditions that prevail in countries make it difficult to typecast the appropriate regulatory systems that should be enforced by developing countries. Notwithstanding the diversity, a number of elements are essential and form the core of many national frameworks. These are:

- national policy and strategy;
- regulatory framework consisting of regulations and/or guidelines;
- mechanism for handling applications and issuing permits;
- system for enforcement; and
- system for information dissemination[10].

26. The impetus to establish regulatory frameworks for biosafety has been pushed further by the need for developing countries who are parties to the Cartagena Protocol on Biosafety to meet their obligations. The projects on biosafety capacity building funded by GEF and implemented by UNEP, UNDP and World Bank seek to assist in addressing this felt need.

27. Recently international food aid has also triggered some form of regulation in those countries that have been faced with food shortages. The need for food aid has also raised the challenge of elaborating a food safety regime as part of the biosafety regulatory framework to facilitate handling emergencies involving food shortages.

5.0 Review of reports of various technical and policy meetings on Biotechnology in Food Production in the African Region

[10] Development of National Biosafety Frameworks, www.unep.ch/biosafety

28. Agricultural biotechnology has been described in several regional consultations as having a potential benefit and posing risks in the quest to address a wide range of public health, nutritional, agricultural, and environmental problems facing the region [32, 33][11]. These conflicting signals have resulted in the banning or slowing of the commercialization or use of GMO products in some countries. It has also disrupted the distribution of food aid in some drought-stricken countries of Africa.

29. A large body of literature has already emerged concerning the development of agricultural biotechnology policy, most of it in the past five to eight years as a result of the intense controversy especially in the Eastern and Southern Africa region. Most of these sources contain verifiable factual information (e.g., dates of meetings, names of participants, topics discussed, and decisions) as reflected in regional policy dialogues and technical meetings[12]. However, they also present selective representations and interpretations of scientific knowledge and health and safety risks, reflecting the views of the authors or the organizations.

30. Technical and policy dialogues in the region have raised the need for scientific and legal considerations and political leadership in policy choices related to GM products and a framework for discussing policy options and trade-offs in African countries.[13]

6.0 Policy Considerations

31. The introduction of a new technology such as genetic modification may depend on the perceived balance between the potential benefits and risks to the environment and human health [5]. In the current atmosphere of heightened expectations and fears in the region, governments have to work within international law to make policies and draw up legislation on a range of issues: intended release of GMO products into the environment, food and agriculture systems; regulatory measures to minimize risks for human health and/or protection of adverse impacts on biodiversity, and support for in-country development of GM products. Governments have to make their decisions based on a number of considerations or policy options including the scientific knowledge of the technology, the potential benefits and risks, the potential benefits of a harmonized approach in the region, and questions of economic and social development [31]. In addition, policy decisions have to be made on national strategies to consider the expected role of GM products in food security and economic growth, considering stakeholder opinions for the development of regulatory instruments, including provisions on liability and redress. The guiding principle for policy and regulation of GMOs should be the use of scientifically sound risk-assessment reviews made on case-by-case basis. [36]. The following issues may have a bearing on the current discussions.

6.1. Mechanisms for Harmonisation & Regional Approaches

6.1.1 Harmonization of Biosafety Regulatory Frameworks

32. At the international level, common standards have been agreed upon that implicitly promote the harmonization of regulatory systems. While the *Codex Principles*

[11] www.isaaa.org
[12] www.asareca.org; www.sadc.org, The South African Biotechnology Strategy among others, www.coraf.org

[13] i. See www.absfafrica.org, www.africabio.com, www.ifpri.org,
ii. Preparatory report on Africa for the UNIDO Biotechnology Conference www.unido.org
iii. Report of the Stakeholder Consultations on Biotechnology and Biosafety, Abuja, April 2004. www.coraf.org
iv. FARA Biotechnology & Biosafety Initiative, www.fara-africa.org

for the risk analysis of foods derived from modern biotechnology and the accompanying Guidelines [29-31] are available to guide the risk analysis in general and safety assessment in particular of GM food, they have no binding effect on national legislation, but do form the basis for harmonization under the SPS Agreement (*SPS*). FAO and WHO are developing, in cooperation with other international agencies and donor countries, training and capacity building tools to assist developing countries to apply Codex texts. International Standards for Phytosanitary Measures (ISPM) provided by the International Plant Protection Convention (IPPC) also deal with pest risk analysis for LMOs. Through the adoption of ISPM No. 11, (2004): *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organism* guidance is provided on analysis of risks of plant pests to the environment and biological diversity, including those risks affecting uncultivated/unmanaged plants, wild flora, habitats and ecosystems, and on evaluating potential phytosanitary risks to plants and plant products posed by living modified organisms (LMOs).

33. On the other hand, the Cartagena Protocol has established legally-binding rules for environmental risk assessment. In addition, OECD & the EU have experience in promoting international harmonization in the regulation of various aspects of biotechnology by ensuring efficiency in the evaluation of environmental and human health safety, through its working group for harmonization in biotechnology and its task force for the safety of novel foods and feeds or through specific Directives [38, 39]. Attempts have also been initiated by ASARECA and recently SADC, CORAF & FARA which could be consolidated into sub-regional and a regional programme.

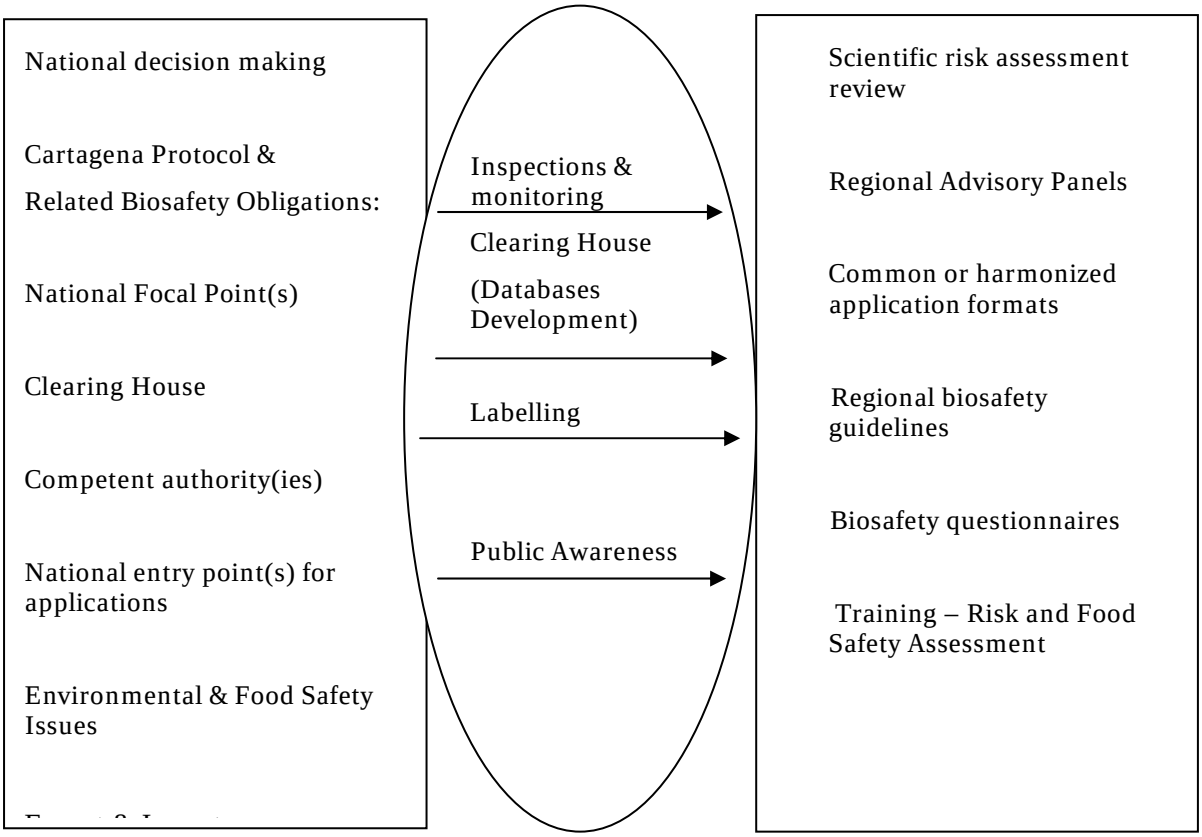
34. Some African countries have sets of agreed principles (regulatory and for risk assessment of GM products) for guidance, and the advantage of learning from the experiences of their forerunners by investigating best practices and adapting them to suit their individual situations.

35. Although agreement has been reached on the scientific principles of environmental risk and food safety assessment, consensus has not been achieved on the extent of data required to comply with these principles or on the role of the data for decision-making. The establishment of a regional/subregional cooperation platform in biosafety would greatly facilitate the implementation of regulatory measures, promote the sharing of resources, synchronize the assessment of foods derived from modern biotechnology, and would expedite information exchange [41]. Moreover, integrating some activities could reduce the overall requirement for new financial resources.

36. Issues raised in an earlier meeting [40] and which have been modified in Figure 1 could be reviewed in regional dialogues as a conceptual framework for harmonization of regulatory frameworks.

Figure 1: Suggested Regional and National Biosafety functions modified from Koch (2001)

National biosafety function- Regional responsibility - Regional biosafety function



37. Harmonization can be achieved at several levels, i.e. some elements of national biosafety frameworks can be implemented at the regional level. For example, the countries of the Association of South-East Asian Nations (ASEAN) have come together to cooperate on various levels including: (i) harmonization of legislation for products derived from modern biotechnology and intellectual property rights; (ii) research and development in biotechnology; and (iii) environmental protection. They have also developed risk assessment guidelines for the region.[14] The Asian BioNet Project, funded by the Japanese Government and implemented by FAO, supported regional collaboration in biosafety capacity building in ten Asian countries.

38. Work towards such harmonization can only move forward through inter-sectoral collaboration at national and regional level, and would require support from several international organizations, regional bodies, regional centers of excellence and related agencies. This calls for multi-stakeholder dialogues on choices for the region.

6.1.2 Regional Approaches to Developments in Biotechnology and Biosafety in Africa

39. Most the sub-regional organizations responsible for food and agriculture in Africa, namely WECARD/CORAF, ASARECA, SADC and North Africa have either initiated or are already implementing a biotechnology and biosafety programme aimed at

[14] www.asean.org

building capacity in biotechnology as it especially pertains to agriculture, and biosafety in the area of risk and food safety assessment among others. The primary goal of these sub-regional initiatives and programmes is to develop and promote regulatory harmonization within the sub-regions by supporting programmes that will build a common approach and understanding among policy makers and the wider public. The programmes also include competitive and commissioned research and development activities by institutions in the sub-regions, through bilateral and multilateral partnerships with the intergovernmental bodies[15].

40. On the regional level, the Forum for Agriculture Research in Africa (FARA)[16], the African Agency for Biotechnology and numerous other institutions have initiated a process to assist in the development and deployment of modern biotechnology for food and agriculture in a safe and efficient manner. A number of challenges have been identified as critical to the development of a regional approach which need to be addressed. They include the following:

- lack of political support for biosafety and biotechnology,
- poor communication among various initiatives which often leads to duplication of efforts,
- inadequate dialogue and, sometimes, conflicting agendas among key stakeholders within initiatives or countries (e.g., Ministries of Agriculture, Ministries of Environment, Councils of Science and Technology),
- absence of key stakeholders groups in initiatives,
- lack of information about the potential benefits of biotechnology for crops grown and eaten by subsistence farmers.

6.1.3 Handling of Food Aid

41. African countries are at different levels of development in the use of biotechnology. Some countries are receiving assistance from international agencies to develop frameworks for and undertake training in the use of this technology. Recently a number of countries in the region accepted genetically modified (GM) food aid, in most cases before biosafety policies and frameworks were in place. Given the high degree of transboundary movement of goods and people in the region, it is important that decisions by individual countries be open for consideration by neighbours. A common position is therefore called for to form a basis for biosafety regimes in the interest of food, agriculture, and natural resources management including food aid in the region. The African Union through the regional technical organizations, the intergovernmental organizations, regional centres of excellence and the NARS should position itself to provide leadership for and guidance to national efforts to help address issues related to handling of GM products including food aid. In addition, African governments should establish a long term policy dialogue in collaboration with the multilateral/intergovernmental agencies involved in technical issues related to GM products such as the FAO, UNEP, WHO, CBD, UNIDO among others on mechanisms and approaches relevant to the handling of food aid involving GM foods or foods derived from

[15] See www.coraf.org, www.asareca.org, www.sadc.org, www.fara-africa.org

[16] FARA has been mandated by the sub-regional organisations (SROs), ASARECA, CORAF/WECARD and SADC/FANR, which are the foundation of FARA, and other institutions such as the FAO, the NEPAD and the AATF, to initiate a consensual process to develop a Biotechnology Biosafety Program. The prime objectives of the FARA-BBI is to "create robust biotechnology and biosafety policies that will stand the test of time, improve the efficiency of processes designed to develop and implement biosafety frameworks, build capacity in negotiations and crisis management skills for an African position in international discussions and raise awareness about the importance of biosafety systems with political leaders thereby facilitating the development and implementation of biosafety legislation" www.fara-africa.org

biotechnology. The World Food Programme has recently adopted, in agreement with FAO, the Operational Guidelines on the Donation of Foods Derived from Biotechnology. It must be recalled, however, that the ultimate responsibility and decision regarding the acceptance and distribution of food aid containing GMOs rests with the governments concerned [42].

6.2 Labelling of GM foods and consumer choice

42. Current debates in the region suggest the need for the establishment of GM food labelling policies to ensure that consumers receive meaningful information. Two broad regulatory approaches for labelling of GM food exist:

- voluntary labelling – which is driven largely by market forces, with no legislative requirements to declare the use of GMOs in food production; and
- mandatory labelling – which requires declaration of characteristics imparted to a food by the use of gene technology (be they health-and-safety and/or process-related), or use of gene technology itself in food production.

43. As of 2004, some form of mandatory labelling standards for foods produced using gene technology had been adopted or planned by over 30 countries worldwide [43] The key issues which need to be dialogued and addressed are options for labelling and setting of thresholds to assist in accessing adventitious presence. There is currently no global consensus on labelling, although the Codex Committee on Food Labelling continues to work towards agreed guidelines. Some progress has been made since the committee started work in this area[17] [46]

6.3 Handling of GM Products

44. Following the recent debate at the Meeting of the Parties to the Cartagena Protocol on Biosafety[18], it is to be noted that an African perspective on article 18 of the Protocol in terms of relevant documentation and templates for GM Products for Food, Feed and Processing needs to be developed. This could address critical questions being raised on handling of GMO imports at the ports. These discussions should look at the development of templates and training to assist port officials in handling of GM products. Common formats could help in assessment, decision making and transboundary movement of GM products.

6.4 Capacity Building: Training of Regulatory Agents

45. Enforcement activities are critical in ensuring safety of GM products and instilling confidence in the regulatory process. An effective regulatory system needs adequate legal authority with well resourced staff to carry out enforcement activities such as conducting inspections, sampling GM products, ensuring that GM products released in the market have undergone the necessary environmental and food safety assessment in accordance with national or international principles and guidelines, monitoring and

[17] The Codex Committee on Food Labelling (CCFL) which since 1991 has intensively debated the nature and extent of labelling for foods produced through biotechnology, at meetings and through working groups. While there is general agreement on the need for food labelling standards addressing health and safety issues arising from the use of gene technology (such as altered allergenicity, composition, nutritional value or intended use), divergent views exist among Member States on appropriate guidelines for process-based labelling of such foods. As positions on process-based labelling are as divergent as national regulatory approaches, progress in achieving consensus is likely to be slow. In 2001, the Codex Alimentarius Commission agreed to a proposal by the CCFL to adopt mandatory labelling of allergens in foods derived from biotechnology in the general food-labelling standard for prepackaged foods. However, there has been little progress by CCFL in addressing other labelling issues.

[18] Report of the Second Meeting of the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP2), www.biodiv.org

limiting environmental problems that may arise, and taking adequate legal action against violators of permit conditions [45]. Therefore critical questions arise on the need to pool regional resources for training of food safety and phyto-sanitary inspectors and environmental protection officers. Certification of regional biosafety and food safety agents and sub-regional/regional laboratories for training, development and validation of detection techniques and harmonisation of protocols for inspection as it pertains to GM products should be prioritised. This could help in building public confidence in issues related to transboundary movements of GM products in the region. Presently only South Africa which has developed such capacity to meet national and regional needs.

6.5. Regulation of GMOs in Food Production: safety issues

46. A lot of debate is going on the use of *substantial equivalence* as a fundamental concept for food safety assessment [46 - 48]. The Codex Alimentarius Commission considers that "substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart". Continuous dialogue is needed at the regional and national level to promote a common approach in GM food safety assessment. Common procedures or harmonization of some areas of concern could help in evolving a regional position in international discussions related to safety of GM products.

7.0. Recommendations and Conclusion

47. The development of policies and regulatory instruments for biotechnology in food and agriculture in Africa is a key issue. There is a need for established pre-market approval and post-release monitoring systems, agreed standards for environmental and food safety assessment, transparency, public participation, establishment of a scientific resource base, independent regulatory authority/decision making apparatus, capacity building, enforcement mechanism and resources. As the region grapples with choices in the handling of GMOs in food and agriculture, the following recommendations are made in addition to issues raised under policy considerations.

7.1. Liability and Redress Issues

48. Liability and redress issues related to GM products are currently the subject of international discussions under the Cartagena Protocol on Biosafety. Africa as a region should initiate activities to elaborate a regime which could facilitate national choices and regional positioning on liability and redress issues.

7.2. Socioeconomic aspects in the use of GMOs

49. Socioeconomic issues arising from the adoption of GMOs in agriculture require an analysis of consequences for specific groups and interests in society. It has been claimed that there are benefits for large-scale farming as opposed to small-scale farming, as a result of better adoption of practices associated with GMOs by large-scale farmers, as well as an ability to deal with IPRs [49]. Some groups analysing trade and agriculture feel that the impact of large-scale production and marketing of GMOs may overshadow potential success stories from a few GM products in developing countries [46]. The State of Food and Agriculture (SOFA) 2003-2004 *Agricultural Biotechnology: Meeting the needs of the poor?* presents a comprehensive survey of the economic literature. This larger body of research shows that small farmers can benefit when they have access to GM crops but that farmers in "non-adopting" countries can be harmed as adopting farmers achieve efficiency gains that they are denied. SOFA argues also that regulation is one of the major factors (among several) influencing whether farmers have access to

GM crops. The evidence also suggests that, despite fears of corporate control of the sector, farmers and consumers so far are reaping a larger share of the economic benefits of transgenic crops than the companies that develop them. The evidence however is based only on about three years of data for a relatively small number of farmers in a few countries on one single crop and event. These short-term gains may not be sustained as larger numbers of farmers adopt the technologies. Time and more carefully designed studies are required to determine what will be the level and distribution of benefits from transgenic crops [1].

50. An analysis of the costs and benefits of GM food and products, and the intended scope of beneficiaries should be undertaken on a case-by-case basis. Cost-benefit ratios can relatively easily be estimated for manufacturers and farmers (who may benefit from certain GM products in the short term). Data developed on regulatory costs will be extremely helpful to African Governments in decision making.

7.3 Intellectual Property Issues

51. Technologies in agricultural research and development have always been considered a major contributor to improving food security. Nonetheless, their successful application will depend on their relevance to poor people, the access to and transfer of proprietary technology to countries in need, and the existence of enabling national and international political and economic frameworks.

52. Many developing countries will need to overcome a number of obstacles before they can take full advantage of what modern biotechnology has to offer. Among them, the proprietary nature of many of the currently applied technologies and products might increase transaction costs, create dependency situations and finally slow down the rate of their adoption in countries where high investments and political decisions have already been agreed.

53. The development of products of modern biotechnology is capital-intensive as proprietary research tools must be licensed from the private sector in many national systems. This situation has caused restrictions on innovations and is a barrier to the availability of the tools of research in both developed and developing countries. If African countries are to rely on importation of new varieties, especially those developed with biotechnology, then allowing more flexible IPR standards makes good economic sense. A different situation raises if there is any intention of reexport nationally produced seed or even grain of varieties bearing transgenic events protected elsewhere.

54. Finally, and as highlighted above, the effect of IPRs on the costs of GM technology is recognized as a potential hindrance to its application in Africa. This concern is shared not only by African authorities but also by international research organizations and some multinational companies. Apart from straightforward negotiations between potential users and IPR owners, in which the IPRs may be acquired through contractual licensing, outright purchase, or partnerships, the need to minimize costs, particularly to deserving poverty-stricken developing countries, may require goodwill arrangements including donations[19]. Several agencies are involved in the brokerage or application of modern technologies for Africa's agriculture.[20]

[19] In view of this, a concerted effort appears to be in the making through the recently established African Agricultural Technology Foundation (AATF). Supported by the Rockefeller Foundation and set up in Nairobi, Kenya, under an African-controlled board, the AATF has an ambitious mandate to link the needs of resource-poor farmers with potential technologies acquired through royalty-free licenses, agreements, and contracts. These activities need to be published widely to get "buy-ins" from countries in the region. It is yet to be seen what impact this approach will have on GM acceptance in Africa and how soon benefits can be felt.

[20] These include the International Service for the Acquisition of Agro-biotech Applications, the African Agriculture Technology Foundation, the Collaborative Agricultural Biotechnology Initiative of the U.S. Agency for International Development and the Consultative Group on International Agricultural Research (CGIAR). The latter's broad mandate

55. The numerous pros and cons of IPRs in biotechnology in agriculture clearly underscore the need for comprehensive policy guidelines, which should promote dialogue and partnerships with the private sector, as a prerequisite for the application of GM technology in food and agricultural production.. Studies and dialogue should be initiated to pick lessons and best practices to help African countries meet challenges related to IPR issues, while at the same time protecting their national interests.

7.5 Research and Development Activities

56. A significant research effort should be made to support analytical methods technology, bioinformatics, environmental studies epidemiology and dietary survey tools to detect impact on biodiversity and health changes in the population that could result from the spread of GMOs. Specific recommendations to achieve this goal include:

- Enhancing the basic knowledge about local ecosystems in order to enable studies of gene flow and of impact on biodiversity of the environmental release of GMOs.
- Focusing research efforts on improving analytical methodology to improve information on toxicological evaluation, nutrient content and food composition data of publicly accessible databases, chemical identification, micro array analysis, metabolic and proteomic profiling in major food crops and whole foods.
- Developing or expanding profiling databases for plants, animals, and microorganisms that are organized by genotype, maturity, growth history, and other relevant environmental variables to improve identification and enhance traceability of GMOs.

57. There is a need for worldwide accessible databases, linked to ongoing efforts in this area, with information on detection and identification methods and reference materials for GMOs and food products derived thereof on the market and in development. Development and access to credible nutritional and food safety data on GM products could facilitate handling of GM Products. Training and use on available databases on environmental and food safety tailored for African needs could help in addressing the issues raised with handling of GM Products. Use of existing databases, continuous development of biological and food data files would assist reviewers in technical assessment of GM products; a notable example is the use of the combined International Portal on Food Safety, Animal and Plant Health[21]. Data from other relevant agencies such as the the BCH of the CBD, the FAO Biosafety resources website, the UNIDO-BINAS site, and the OECD could be helpful.

Conclusion

58. There are advantages to the use of biotechnology including genetically modified products; however, it is not a panacea for alleviating the food security needs in the Africa region. Countries producing or receiving genetically modified products must have a clear and responsive regulatory policy and authoritative body to ensure that scientific risk analysis is carried out and that all possible safety measures are taken through testing before the release and afterwards through close monitoring. Regional and subregional approaches should be strongly considered to deal with certain implementation aspects to

includes mobilization of cutting-edge science to reduce hunger and poverty, improve nutrition and health, and protect the environment.

[21] www.ipfsaph.org

ensure cost-effective biosafety systems. More important, the human rights to adequate food and democratic participation in debate and eventual decisions concerning the new technologies must be respected, safeguarding the consumers right to informed choice [23]. The key aspects of a biosafety framework should include the following:

- Participation of involved stakeholders in the development of national biotechnology strategies and policies of Governments.
- Legislative and policy frameworks that include provisions to address trade-offs across public agencies in various sectors (e.g. agriculture vs. health vs. environment) and stakeholder groups (e.g. farmers vs. consumers)
- Adoption of regional approaches for specific aspects of implementation of biosafety systems.
- Unambiguous requirements for transparent state action and enforceable provisions for vigorous public involvement
- Rigorous risk assessment and management (based on internationally agreed standards, such as the Codex Principles and Guidelines, as regards food safety)
- Clear criteria for selecting products to be submitted for regulation
- Specific measures to reduce the potential food safety risks of GM foods: mandatory (rather than voluntary) pre- and post-market testing of new products
- Greater standardization of testing methods and decision making criteria
- The use of newly emerging broad-spectrum profiling techniques to detect unintended compositional changes
- Consideration of the diverse contexts in which a given GM product may be consumed when developing, testing, labelling, and exporting or importing GM foods

59. In addition to the above, the following recommendations are made to help strengthen the development of policies and regulatory frameworks related to the GMOs in food and agriculture production in Africa;

1. Development of policies on IPR that consider the national needs and capabilities, including cost implications, while keeping in mind the international context in which the country operates, particularly in terms of products intended for domestic consumption and products destined to reach international markets.
2. Capacity building initiatives and funding led by African governments to provide the skills for policy development, enactment of laws, human and material resource development and implementation of technologies for increased agricultural production and food self-sufficiency,
3. Promotion of multi-stakeholder partnerships at national and international level including multinational companies, international agencies, national research institutions and universities, companies, and nongovernmental organizations, for enhancement of technology transfer to address food security in Africa, including South-South collaboration programmes,
4. Creation of awareness of the role of biotechnology and its potential impact on food security for African countries. Therefore, it will be advantageous to encourage networking and the use of local groups in advocacy and awareness creation efforts aimed at developing an informed society.

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