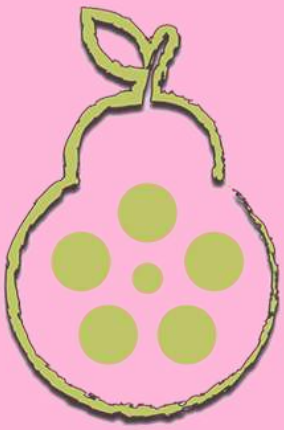
Manual on Biosafety Risk Assessment and Risk Management for Cameroon



Compiled for the Cameroon National Biosafety Committee
April 2004

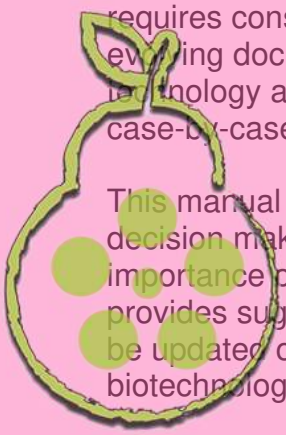
Preface

This manual has been compiled as a guidance document for regulators and developers of genetically modified organisms (GMOs) in Cameroon. It is designed to give a logical framework to stakeholders wishing to assess the safety of GMOs and incorporates the requirements of the Cartagena Protocol on Biosafety. Risk assessment and risk management form one part of a functioning national biosafety framework and need to be seen in the context of the other structures. The UNEP/GEF implementation project has identified the following five key areas of a national biosafety framework:

1. Policy;
2. Regulation;
3. Administration;
4. Inspections and compliance;
5. Public participation.

Risk assessment and risk management fall within the administrative handling of applications.

Biotechnology is a rapidly developing field and so the safety questions being asked about GMOs are not fixed. Each new GMO in each new release environment requires consideration of new safety concerns. As such, a biosafety manual is an evolving document. It needs to be broad enough to cope with the challenges of new technology and yet practical enough to empower biosafety officers to undertake case-by-case assessment of each new GMO and genetic modification (GM) activity.



This manual for Cameroon provides general input on the role of biosafety in GM decision making, the processes used in risk assessment and risk management, the importance of clear risk communication and how to administer GM applications. It provides suggestions for public participation in GM decision-making and will need to be updated on a regular basis to take into account new developments in biotechnology and biosafety.

The document draws strongly from the biosafety manuals listed below and these are all recommended reading for biosafety officers and stakeholders:

- A Workbook for technical training. Biosafety and risk assessment in agricultural biotechnology. 2002. Agricultural Biotechnology Support Programme. Institute of International Agriculture. Michigan State University. PL Traynor, R Frederick and M Koch. http://www.iia.msu.edu/absp/biosafety_workbook.html
- Resource book for implementation of biosafety in East Africa. 2004. BIO-EARN. Kampala, Uganda. http://www.bio-earn.org/biosafety-manual.html
- Crop biotechnology. A working paper for administrators and policy makers in sub-Saharan Africa. 2002. L Kitch, M Koch, I Sithole-Niang. FAO, Box 3730, Harare, Zimbabwe.
- UNEP/GEF Biosafety guidance http://www.unep.ch/biosafety/resources.htm
- FAO International Standards for … Pest risk analysis … including analysis of environmental risk and living modified organisms. ISPM No.11. http://www.fao.org/newsroom/en/news/2004/43684/index.html

Muffy Koch
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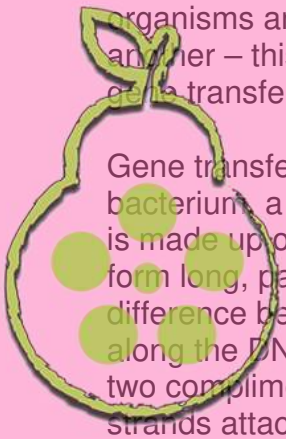
1. Introduction to biotechnology and GMOs

Genetic modification is under debate worldwide. In North America the technology has been introduced with minimum concern, but in much of Europe and the developing world there has been significant opposition to the implementation of genetically modified (GM) crops and foods. As genetic modification is a new tool in the field of biotechnology, it is important to understand its context in order to make informed decisions about GM technology, GMOs and GM products.

1.1 Biotechnology

Biotechnology is not new. It is the use of living systems to produce useful products. Three thousand years ago the Egyptians and other early civilizations were baking bread, making wine and brewing beer with the aid of yeast. About 500 years ago agriculture and food processing was strengthened by the use of selection and breeding to obtain the best organisms for milk and cheese production, brewing, agriculture etc. Selection and breeding is achieved by identification and movement of good characteristics (genes) for improved production in local growing environments. Out of this developed landraces and improved varieties of microbes, plants and animals. In the last 30 years it has become possible to improve organisms and processes by the transfer of single genes from one organism to another – this is referred to as molecular biotechnology, genetic modification or gene transfer.



Gene transfer is possible, because no matter what organisms are modified, e.g. a bacterium, a worm, a mouse, a plant or a human being, their genetic material (DNA) is made up of just 4 molecules: **A, C, G** and **T**. The A, C, G and T building blocks form long, parallel strands with sequences that are unique to each organism. So, the difference between organisms is the order of these A, C, T, and G building blocks along the DNA strands - called the genetic code. Each DNA molecule is made of two complimentary strands of A, C, T, and G sequences. The complimentary strands attach to form the spiral staircase structure (or double helix) which we associate with DNA.

The ability to move genes between organisms became possible with the discovery three new technology tools:

1. enzymes that cut DNA at specific places,
2. mechanisms to insert genes into organisms and
3. technology to grow a whole organism from a single cell (tissue culture).

These tools make it possible to isolate single genes and move them from a donor organism to a recipient organism. Because DNA structure is identical, it is possible to move genes between species, overcoming natural species barriers controlled largely by sexual compatibility.

Thus, not all biotechnology is genetic modification. The term ‘GMOs’ is used for organisms that have received new genes, or for organisms that have had some of their own genes modified using molecular techniques. These processes are not inherently dangerous, but the resulting GMOs may have characteristics that change their impact on their environment, which includes human and animal health. As these changes could be hazardous, it is customary to check the safety of all GMOs

as they are being developed and before they are released for testing and general use.

1.2 Implications for society

The adoption of gene transfer is so fast that economists have predicted a rapid move from the information economy into the biological economy over the next quarter century. Gene transfer is used worldwide to produce medicines, health care products, food processing aids, food supplements, environmental remediation tools, sustainable industrial resources and new materials. However, it is the more recent introduction of GM crops that has raised considerable outcry including the need for effective biosafety measures to ensure that GMOs will not impact negatively on the environment.

In keeping with international conservation agreements, protocols have been established to ensure that national governments can:

- investigate the use of biotechnology tools for sustainable and equitable use of genetic resources (Agenda 21);
- assess environmental impact of GMOs before they are approved or rejected for use in local environments (Cartagena Protocol on Biosafety) and
- ensure high food and feed safety standards in the resulting products (CODEX Alimentarius).

All of these agreements encourage capacity building and sharing among member nations and open and transparent exchange of information on GM activities and products.

1.3 Implications for nations

In order to access, test and regulate the use of GMOs, governments need to establish national frameworks that can set policy, strategy, regulation and administrative processes to ensure the safe and effective use of appropriate GM products. Most developed countries already have these structures in place and most developing countries are in the process of developing the national biosafety frameworks needed to undertake these functions.

2. Biosafety in the context of decision making on GMOs

The biosafety recommendations on the safety of a GMO are just one of the sets of data that national decision makers take into account when reviewing an application for an activity with a GMO. Applications could be for development, import/export, testing or general use. In developed countries, biosafety is often the primary data used in decision making, but in many developing countries issues such as socio-economic impact, public input and national imperatives are also taken into account before decisions are made.

Thus, many national biosafety frameworks make a clear distinction between decision-making and advisory bodies in their national biosafety frameworks. The policy towards genetic modification is the major determinant as to whether the technology will be tested and used in any country. Worldwide these national policies vary considerably (Paarlberg, 2000), Table 1.

Table 1: Biosafety Policy options for GM crops

	Promotional	Permissive	Precautionary	Preventive
Biosafety	No careful screening, only token screening, or approval based on approvals in other countries	Case-by-case screening for demonstrated risk, depending on intended use of product	Case-by-case screening also for scientific uncertainties owing to novelty of GM process.	No careful case-by-case screening; risk assumed because of GM process
Food safety and consumer choice	No regulatory distinction drawn between GM and non-GM foods when testing or labelling for food safety	Distinction made between GM and non-GM foods on some existing food labels but not so as to require segregation of market channels	Comprehensive positive labelling of all GM foods required and enforced with segregated market channels	GM food sales banned, or warning labels that stigmatise GM foods as unsafe to consumers required

(Adapted from Paarlberg, 2000.)

2.1 Biosafety Regulation

Decisions about GMOs are usually taken within a national biosafety framework that is established for this purpose. In establishing this framework countries initiate a national policy on the use of modern biotechnology that guides how decisions about GM activities should be taken. The policy together with development of a national biosafety framework should follow extensive consultation to ensure public awareness and input into the development process. Consultation between national departments responsible for environment, agriculture and health will ensure that the framework bridges across ministries and is efficient, cost-effective and can be implemented.

An interim framework is sometimes implemented using biosafety guidelines and an existing permit system for approvals (e.g. a plant pest Act). This is used for administering applications and decision-making while the legislation for the final framework is being modified or developed. Implementing the biosafety

administration process is facilitated by capacity building in both the handling of GMO applications and biosafety review training. Reasonable fees charged to applicants can help cover the costs of an efficient review process.

In developing the biosafety framework, it is important to note that as GMOs become part of every aspect of our economies and lives, less and less regulation will be needed. As such, the legislation needs to be flexible to deal with changes in regulatory approach and technology developments. While early applications will be from international applicants, the development of local GMO products to address local needs is highly likely. This should be taken into account during development of the national biosafety requirements. Over-burdensome requirements that extend well beyond the assessment of safety can make the approval process too expensive for local technology developers.

2.2 Factors considered in national decisions

Countries individually decide whether to develop, import, or deploy GMOs and the products made from them. Such decisions take into account national policies for agricultural research and development, and the potential role of biotechnology in meeting national goals and objectives in food production, food security, trade, and related areas. Decisions regarding the use of this technology and its products are based, in part, on a determination of the risk they may pose to the environment or to human health. Of necessity, the safety of each GMO needs to be determined on a case-by-case basis, as each GMO poses different impacts in the release environment, offers different benefits and replaces or improves upon different conventional technology.

However, once the safety of the GMO has been assessed with respect to food, humans and the environment, many countries consider wider input before making a final decision on commercialisation. Here, public acceptance or concerns will give some indication of the acceptance the GMO will have locally. In addition, the decision-makers may wish to consider the potential impact on trade, labour, food security, small business development, sustainable development and poverty alleviation. Under environmental impact assessment it is often necessary to take into consideration the benefits of a new technology and also the impact of not using the new technology. These are just some of the socio-economic factors that may be important in the final decision. When basing import decisions on non-safety issues it is important also to investigate the implication of this decision under international trade laws. All factors that are considered and those that lead to the final decision should be carefully laid out in a decision document that is freely available to the public.

Of necessity, the ‘products of’ GMOs are assessed before commercial use permission is given. It goes without saying, that reviewers cannot assess the safety of a GM food crop or animal without first assessing the safety of the food, feed and fibre products used from that crop or animal. However, adding the regulation of ‘products of’ GMOs to legislation is a practical nightmare, because it then subjects all non-living GM products to the full risk assessment required for living GMOs. This is impractical to implement and unnecessary duplication if the safety has already been assessed in the original approval for use.

2.3 Regional biosafety

The final decision on the implementation of any GMO will be a national decision. However, GMOs are living organisms and will move and reproduce unless these activities are specifically curtailed. Good planting material moves freely between neighbouring countries in Africa and the impact of this on neighbouring countries and the environment needs to be considered when decisions for general use of GMOs are taken. Regional platforms for scientific biosafety assessment would facilitate this process.

2.4 International biosafety agreements

Two pieces of international legislation impact directly on how countries handle GMOs. The Cartagena Protocol on Biosafety (CPB) is an international protocol negotiated under the auspices of the 1992 Convention on Biological Diversity. Its primary aim is to protect biodiversity by ensuring the safe and responsible 'development, handling, use, transfer and release of any Living Modified Organism.' The Protocol addresses trans-boundary movement of living GMOs. Under the terms of the CPB, exporting member countries must obtain an advance informed agreement for GMO importation before shipment. Such agreement is conditioned on the recipient country's performance of an environmental risk assessment. The CPB includes guidelines for assessing environmental impact and provides a central biosafety clearing house (BCH) of information on GMO products, export decisions and biosafety data.

Parties to the Protocol assume certain responsibilities with respect to the use of living GMOs. They are obliged to designate a focal point for liaison with the CPB secretariat, and one or more competent authorities to carry out the risk assessment provisions. These include development and implementation of regulations to manage the safe use of living GMOs.

The CODEX Alimentarius Commission is an international working group that sets standards for food safety, quality and labelling. It functions under the Food and Agricultural Organisation (FAO) in Rome. The CODEX Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology was formed to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology. The proposals are currently issued in draft form and are under discussion between member countries. Signatories to CODEX will be required to bring their national labelling legislation into line with the new CODEX labelling guidelines when these enter into force.

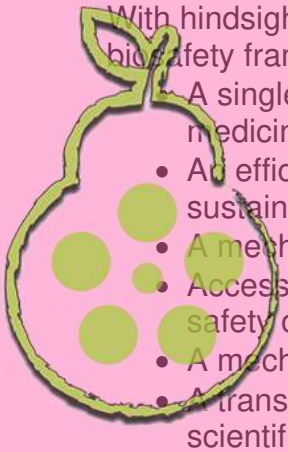
3. Administration of applications for GM activities

Countries choose a biosafety administration system that best suits their existing regulatory environment. In developing countries this is often a centralised office which coordinates biosafety input from a number of ministries. Centralising the administrative function makes the regulation less expensive and promotes sustainability and efficiency.

The biosafety administration office is tasked with the handling of applications, the production and updating of guidance documentation, the recording of biosafety activities and decisions, addressing enquiries and implementing the biosafety regulations, including coordination of risk assessment, decision making, permit issuing, inspections, appeals and public participation.

3.1 Components of a biosafety system (Adapted from Kitch *et al.* 2002)

When faced with applications for activities with GMOs, governments need to implement an effective biosafety framework to ensure a science-based review of the safety issues and a review of other factors important in making a national decision. With hindsight, the following components are considered desirable in a national biosafety framework:



- A single entry point for applications, or multiple entry points (agriculture, medicine, industry) with a single, harmonised biosafety review centre;
- An efficient biosafety administration for processing of applications that is sustainable and grows with demand;
- A mechanism for ensuring confidential handling of commercial information;
- Access to a trained pool of scientific expertise to independently assess the safety of each application on a case-by-case basis;
- A mechanism for public input into applications;
- A transparent national decision making body that can take into account the scientific risk assessment recommendations, the benefits, the public input and any national needs and priorities when making decisions;
- Issuing of a decision document that clarifies the safety issues of each GMO, the conditions attached to specific releases and the reasons why decisions were made;
- An inspectorate that can monitor compliance with release conditions.

3.2 Administrative steps in processing GMO applications

When applications for GMO activities are received at the biosafety administrative office they need to be processed in a manner that is efficient and meets the needs and expectations of applicants and the obligations of international agreements. The following basic steps are used in most biosafety administrative systems:

- Acknowledge receipt of the application;
- Assess whether the application meets the requirements of the regulations;
- Assess whether the applicant requires approval for the proposed activity;
- Assess the nature of the GMO;

- Select a group of scientists with the correct expertise to review the safety of the proposal (about 5 scientists are needed for each proposal, depending on what the GMO is and what it will be used for);
- Publicise the application and call for public input;
- Schedule a meeting for the scientific group to review the application, missing data, the possible risks and acceptable risk management procedures;
- Where information is missing or clarification is needed, request the information from the applicant or schedule a meeting between the applicant and the scientific review panel;
- Receive recommendations from the advisory committee and forward these to the national decision-making body;
- Call a decision-making meeting when the scientific and public input is available;
- Receive the decision and prepare a decision document on the findings of the review;
- Make decisions publicly available;
- Notify the applicant and issue a permit where necessary;
- Schedule an inspection of the release site during and after the activity;
- Review the inspection reports;
- Ensure that activity reports are received.

3.3 Resource requirements for national biosafety (Adapted from Traynor *et al.* 2002)

Scientifically sound safety assessments and measures for handling GM crops and products safely require human, financial, and information resources as well as an adequate infrastructure. The following resource requirements are usually required:

Managers
In the course of implementing biosafety, management responsibilities are commonly placed on individuals who have little or no prior experience in this area. New managers will need skills in:

- Priority setting;
- Resource acquisition and allocation;
- Coordination with multiple agencies;
- Meeting management;
- Communications across many sectors;
- Information access and management;
- Handling of confidential or proprietary information.

Government officials and decision makers
Political support will determine whether a functional biosafety system can be established and put into operation. Thus it is vitally important to have ministry officials and their science advisors well informed on the role of biotechnology in development and the role of the biosafety system in bringing safe and beneficial products to all citizens.

Officials having formal responsibility for biosafety and who take decisions on proposed releases are, in essence, the gatekeepers who determine what biotechnology products, if any, will be allowed, and when. Those having regulatory