Regulation of Biotechnology in Cameroon

[1]Mrs Mary Fosi MBANTENKHU[1], Ms Lilian Munyah NFOR[2]
Technical Adviser N° 1, MINEP - NATIONAL FOCAL POINT, BIODIVERSITY/BIOSAFETY
[2]Environmental Lawyer, - Research Officer No.1 Legal Unit, MINEP.

ABSTRACT

Most developing countries that were parties to the Convention on Biological Diversity participated in the negotiation process of the Cartagena Protocol on Biosafety. Cameroon, a member of the African Union, participated in the negotiations because it has lots of stakes both in the CBD and the CPB. With 75% of its rapidly growing population (16 million inhabitants) relying on agriculture and other biological resources for their livelihood, the issues of food security and public health are high on government's policy agenda. The Cartagena Protocol aims at regulating transboundary movements of Living Modified Organisms (LMOs) that may have adverse impacts on biodiversity and human health. It can contribute to ensure food security levels or produce risks to biodiversity if such LMOs are not well handled. To meet up with its international obligations and to ensure the sustainable management of its biological resources, Cameroon worked within the framework of the Cartagena Protocol and the AU Model Law to develop a national legislation. Contributions from International Organisations such as the OECD, CGIAR and other bilateral partners including financial support of the Global Environment Facility (GEF) through the United Nations Environment Programme (UNEP), Nairobi, enabled Cameroon to be among the pioneers in the African Region in enacting a national legislation on Biosafety. Law No. 2003/006 of 21st April 2003 regulating Safety in Modern Biotechnology in Cameroon, translates the Cartagena Protocol into national realities. Implementation decrees to this law are being finalised to render the law more enforceable. The present paper depicts the historical background, the linkages between the Protocol and the National Legislation and analyses some provisions of the law, which are important to developing countries like Cameroon.

Abbreviations
CBD: Convention on Biological Diversity
CPB: Caragena Protocol on Biosafety
CBL: Cameroon Biosafety Law
FFP: Foods, Feeds and Processings
SCBD: Secretariat of the Convention on Biological Diversity

1. Introduction

In 1954, when traditional biotechnology applications became apparent in Cameroon with the creation by the Cameroon Development Corporation (CDC) of a research centre at Ekona, for the purpose of carrying out research on banana, cocoa and palm, there was no appropriate legislation to adequately cover this area of development. The developers were consequently practising biotechnology applications according to laboratory practices from collaborating institutions. Research activities have since extended to other fields such as animals, fishery, microorganisms etc. Hence, the need for a regulatory instrument to govern these activities.

Since 1986 when cloning experiments were introduced at the Biotechnology Centre at Nkolbissson, modern biotechnology application has been practised in Cameroon at the level of microorganisms, but prior to 2003, there was no comprehensive law specifically regulating this practice. Today, though without much practical experience with genetically modified organisms, there is a comprehensive legislation-Law N° 2003/006 of 21 April 2003 to lay down safety regulations governing modern biotechnology in Cameroon (Biosafety law).

The enactment of the Biosafety Law (CBL) in 2003 is actually a precautionary and/or preventive measure on the part of Cameroon government, because the absence of genetically modified organisms at the moment does not in any way mean that, Cameroon has a future free of GMOs. Also, as party to the1992 Rio Convention on Biological Diversity and its subsequent Protocol on Biosafety adopted in 2000, Cameroon has the obligation to implement the requirements of these international agreements. Thus, in addition to fulfilling a national responsibility to protect hu.nan and animal health, biodiversity and the environment, as well as the well-being of its present and future generations, Cameroon has the same international responsibility in cooperation with other states, including the protection of the common heritage of our globe through its international commitments to regulate transboundary movement, handling and release into the environment of GMOs that may have adverse effects on human and animal health, biodiversity and the environment.

2. International Biosafety Law

The most appropriate international instruments regulating biotechnology at the international level are the 1992 Rio Convention on Biological Diversity, Agenda 21 of the Rio Summit, and the 2000 Cartagena Protocol on Biosafety, the 2002 African model law on Safety in Biotechnology (and the Convention on Plant Genetic Resources for Food and Agriculture).

2.1. Convention on Biological Diversity (CBD)

The CBD in Article 16 (1) on technology transfer emphasised that technology includes biotechnology. In Article 19 (3), the parties are required to "... consider the need for, and modalities of a Protocol setting out appropriate procedures, including in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity". Also, Article 8 (g) of the Convention calls on Parties to establish or maintain means to regulate manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risk to human health.

2.2. Agenda 21 of the Rio Summit

Agenda 21 of the 1992 Rio Summit, in Chapter 16 entitled "Environmentally Sound Management of Biotechnology» on its part recommends the compilation, updating and development of compatible safety procedures into a framework of internationally agreed principles as basis for guidelines to be applied on safety in biotechnology, including consideration of the need for a feasibility of an international agreement and the promotion of information exchange as a base for further development. Hence, the UNEP International Technical Guidelines helped Cameroon in the preparation of its national biosafety law.

2.3. The Cartagena Protocol on Biosafety

Adopted in January 2000 in Montreal Canada, this is the main regulatory instrument at the international level that has the greatest impact on national biosafety regulation, including that of Cameroon. Its objective, which is based on the precautionary approach in Principle 15 of the Rio Declaration on Environment and Development is, "...to con-

tribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movement". . In fact, Cameroon has been part of the process of negotiation of this protocol up to its adoption on the 29 of January 2000; it signed the protocol in 2001 and ratified it in January 2003, and the Protocol entered into force a few months later, in September 2003.

2.4. The African Model Law

The African model Law was published in 2002 by the OAU and is disseminated on the African continent with the aim to guide African countries, especially member states, in their preparation of national biosafety frameworks. However, the African model law on safety in biotechnology is not a binding instrument but it is meant to guide African countries in biosafety legislation. This model law has also been of great help to Cameroon in the drafting of implementation texts on the 2003 Biosafety law, which are being finalised. It is currently being revised.

3. National Biosafety Framework For Cameroon

The main regulatory instrument on biotechnology in Cameroon is Law N° 2003/006 of 21 April 2003, to lay down safety regulations governing modern biotechnology. The Cameroon Biosafety Law attempts to ensure the adaptation of requirements and principles of the CPB into the local context and local perspectives.

3.1 Objectives

The objectives of the Cameroon Biosafety law are,

- To govern the safety, development, use including contained use, manipulation and cross-border movement, including transit of any genetically modified organism that may negatively affect human and animal health, biodiversity and the environment.
- To safeguard products thereof that may negatively affect human and animal health, biodiversity and the environment.

3.2. Scope

The law covers:

a) Safety, development, use including contained use, manipulation and cross-border movement, including transit of GMOs that may negatively affect human and animal health, biodiversity and the environment;
b) Safeguarding of products thereof.

The Cameroon Biosafety law does not apply to:

a) Organisms whose genetic material has been modified using traditional reproduction and coupling methods to develop and nurture plants and animals in natural conditions;
b) Cyto-gentic product of:
   - Genetically modified plant cells where the same result may be obtained through the use of traditional cultivation techniques;
   - Animal cells under cultivation where the genetic material was obtained from individuals of the same species and where the cells could have been produced through natural reproduction and the use of the same type of plants and animal cells;
   - Technique requiring gene therapy involving genetic mutation or cloning except where such genetic mutation is used for health reasons using laboratory techniques to repair certain deficiencies.

4. Cameroon Biosafety Law and Key Issues of a Biosafety Framework

4.1. Precautionary Principle

This is the guiding principle of the CPB. It states: "Where there is a threat of significant reduction or loss of biological diversity, lack of scientific certainty should not be used as a reason for postponing measures to avoid or minimise such a threat". In fact, many interprete this principle to simply mean, «Lack of evidence of harm does not mean evidence of lack of harm».

The precautionary principle has been adopted in the Cameroon biosafety legislation as a basis for risk assessment, in conformity with the CPB. Thus, the Cameroon Biosafety law stipulates in Section 18 (1) that, "Risk assessment in any activity related to genetically modified organisms should take into account the precautionary principle, and be conducted in a suitable manner to guarantee the safety of humans, animals and plants as well as to protect bio-

logical diversity and the environment". Meanwhile, earlier in Section 3 (1), the Law empowers the services in charge of biosafety to prohibit any activity involving genetically modified organisms on the basis of the precautionary principle or new scientific knowledge.

4.2. Advance Informed Agreement (prior informed consent) Procedure

In addition to the precautionary principle, one of the preoccupations of the Biosafety Protocol is the advance informed agreement (AIA) procedure, which applies prior to the first international transboundary movement of living modified organisms for intentional introduction into the environment. The AIA consists of three main steps namely, notification, risk assessment and decision-making. The Biosafety Protocol gives room for exceptions to the AIA procedure in the field of pharmaceuticals, LMOs in transit, LMOs for contained use, and LMOs destined for food, feed, or for processing.

The CBL does not seem to conform entirely with the Biosafety Protocol on the issue of exceptions, for, according to Section 30 of the CBL "The import and export of ALL GENETICALLY MODIFIED ORGANISMS shall be subject to issuance of an Advance Informed Agreement or of a prior informed consent by the competent national administration in collaboration with other services concerned". Once a potential importer or exporter of GMOs or products thereof submits a written notification, the competent national administration has to respond within 90 days following receipt of the notice by:

- Approving;
- Prohibiting the import/export;
- Requesting additional relevant information, in accordance with the provisions of the CBL and the statutory instruments deriving therefrom.

It is important to note that, where, at the expiry of 90 days, the advance informed agreement has not been expressly given by the competent national administration, the application shall be presumed to have been rejected..

4.3. Safety Levels and Safety Measures

Biotechnology applications in Cameroon are classified under four safety levels, and any authorisation to carry out biotechnological activities in Cameroon must mention the safety levels (Section 6 of the 2003 Biosafety Law)

Section 7 requires the user, prior to the initial use of any premises for genetic modification activities, to ensure the following safety measures:

1) The respect of general safety measures such as best laboratory, industrial and production practices;
2) That measures are taken for large-scale sensitisation of the local populations on the hazards related to use, handling or movement of GMOs as well as measures to prevent such risks;
3) That health and phyto-sanitary safety measures as defined by international organisations especially those regarding food safety are applied;
4) That appropriate measures are taken to prevent any negative impact on the environment resulting form the use and handling of GMOs.

4.4. Risk Assessment

Annex III of the Cartagena Protocol on biosafety outlines specific principles of risk assessment and the scientific methodology to be followed. Article 15 of this Protocol on its part, requires that risk assessment should be carried out in a scientifically sound manner, taking into account risk assessment techniques. The Protocol goes on to state in Article 16 (3) that risk assessment should be carried out prior to the first release of a living modified organism.

Cameroon has adopted the principle of risk assessment and has elaborately legislated on it. According to Section 20 (1) of the Cameroon Biosafety law, "Prior to any intentional release into the environment, contained use, import/export, sale/placement on the market of living modified organisms, genetically modified organisms or products thereof, a strict assessment of risks must be conducted". The risk assessment should take into account expert opinion and guidelines drawn by international organisations (Section 18). For this reason, a risk assessment manual is being finalised by an international expert to assist Cameroon in determining the procedure for risk assessment. The Law therefore requires risk assessment to be science-based, taken on a case-by-case basis, and transparent. It should

take into account the precautionary principle. Consequently, lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

The CBL defines the purpose of risk assessment as being to:

- Identify potential risks;
- Assess risk probability;
- Manage risk;
- Analyse the risk-costs benefit ratio; and,
- Examine the efficacy of sustainable alternatives to the introduction of GMOs as well as the precautionary principle.

4.5. Risk Management

Once risk has been identified, the question that follows is whether such risk can be managed. Risk management therefore, would obviously be an issue only in the case of manageable risk. Hence, Article 16 (5) of the Biosafety Protocol is to the effect that, "Parties shall cooperate with a view to:

a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits".

To this effect, Cameroon has taken measures in advance, through its biosafety law to require in Section 25 that, the user of any GMO or product thereof shall propose proportionate risk management measures where there are real or potential risks inherent in the release of the organism or movement of its genes when in contained conditions, or deliberately released into the environment.

4.6. Labelling, Packaging and Marketing

To safeguard ethical and cultural values, and to avoid risk to human and animal health, GMOs or products thereof, intended for intentional release or for marketing in Cameroon are required to be packaged and labelled. The package must bear the wordings:

- "Product based on genetically modified organism ", or
- "Contains genetically modified organism".

Information to be specified includes:

- Distinctive marks of the model or specifications of packaging, irrespective of the container, generally used by the manufacturer of packages;
- Packaging with marks indicating content, donor and consignor;
- Labels with specific colours corresponding to dangerous contents.

4.7. Liability and Redress

Article 11 (1) of the Cameroon Biosafety Law requires that the user shall bear the liability for any damage resulting from the release into the environment of genetically modified organisms. The Cameroon Biosafety Law is not very elaborate on this issue of liability. However, since the holding in February 2004 in Kuala Lumpur, of the Conference of Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety, a process is being initiated for developing international rules and procedures in conformity with Article 27 of the Cartagena Protocol, in the field of liability and redress for transboundary movement of living modified organisms, analysing and taking into account the on-going international law on these matters. Thus, Cameroon may eventually, have to review its biosafety regulation on liability and redress in due course.

On the other hand, the African model law is very elaborate on these issues, and it is submitted that if/when Cameroon decides to consider any regulation on this very burning legal issue, it might have to take into consideration the African model Law.

5. LMOs Intended for Direct Use as Food, Feed, or for Processing

The Cargagena Protocol on Biosafety, in Article 18 (2) (a) on handling, transport, packing and identification, requires each Party to take measures requiring that, documentation accompanying LMOs that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment, as well as a contact point for further information. To this effect, the protocol requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements for this purpose, including specification of the identity of the LMOs and any unique identification, no later than two years after the date of entry into force of the Protocol.

The issue of food or feed has been topically under discussions in the ICCP for several years. There have been remarkable difficulties involved in the efforts to arrive at common grounds by the ICCP with regard to some of the issues encountered in relation to identification of LMOs for direct use as food, feed or for processing. The Protocol however entered into force in September 2003 and the Conference of the Parties, serving as the meeting of the Parties to the Protocol had its first meeting in Kuala Lumpur, Malaysia in February this year (2004). Hence, Parties to the Biosafety Protocol are currently considering the «detailed requirements» for the documentation accompanying LMOs intended for FFPs.

Meanwhile, Decision BS-1/6 of the Conference of the Parties serving as meeting of the parties to the Protocol in Feb 2004 recommends interim measures for Parties that wish to regulate transboundary movement of LMOs intended for direct use as FFPs. According to this decision, a Party may also take a decision on the import of LMOs intended for direct use as FFPs, under its domestic regulatory framework that is consistent with the objectives of the Protocol. The COP-MOP however, request Parties to the Protocol and urges other Governments to take measures to:

- Require the use of a commercial invoice or other documents required or utilised by existing documentation systems, as documentation that should accompany LMOs that are intended for direct use as FFPs, for the purpose of identification by incorporating the information requirements of the first sentence of Article 18 (2) (a);
- Take measures ensuring that documentation accompanying LMOs intended for FFPs clearly identifies that the shipment "may contain" LMOs intended for FFPs, and states that they are not intended for intentional introduction into the environment;
- Require that the documentation includes:
  - The common, scientific and where available commercial names,
  - The transformation event code of the LMOs, or, where available, as a key to accessing information in the BCH, its unique identifier code;
- Require exporters of LMOs that are intended for FFPs under their jurisdiction to declare, in documentation accompanying transboundary movements known to intentionally contain LMOs for FFPs, that the shipment contains LMOs intended for FFPs, the identity of the LMO, and any unique identification, where possible.

As far as Cameroon is concerned, the 2003 Biosafety Law left the issue of regulating GMOs intended for direct use as food, feed, or for processing to "specific norms determined by special instruments". To this effect , the implementation texts to the Cameroon Biosafety Law now in the process of being finalised, have included provisions as interim measures to regulate GMOs intended for direct use as food, feed or for processing, taking into consideration decision BS-1/6 of the Conference of Parties serving as the meeting of the Parties to the Protocol, which was taken in Malaysia in February 2004.

6. Offences and Penalties

Breach of the law in biotechnology applications in Cameroon subjects the offender to penalties, as provided for by Part X of Law N°2003/006 of 21 April 2003, to lay down Safety regulations governing modern biotechnology in Cameroon.

7. Conclusion

With the laws in place, the implementation text to the Cameroon Biosafety Law on the way, and the Biosafety Committee under creation, there remain the need for public awareness, both for biotechnological development, use and for the laws that regulate the practice.

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