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LAW NO. 2003/006 OF 21 APRIL 2003 TO LAY DOWN SAFETY REGULATIONS GOVERNING MODERN BIOTECHNOLOGY IN CAMEROON

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**The National Assembly deliberated and adopted,
The President of the Republic hereby enacts the law set out below:**

Chapter I

GENERAL PROVISIONS

Article 1:

This law shall govern:

- (1) The safety, development, use including contained use, manipulation and cross-border movement, including the transit of any genetically modified organism that may negatively affect human and animal health, biodiversity and the environment.
- (2) The safeguarding of products thereof that may negatively affect human and animal health, biodiversity and the environment.

Article 2 :

- (1) This law and its subsequent regulatory instruments shall not apply to organisms whose genetic material has been modified using traditional reproduction and coupling methods to develop and nurture plants and animals in natural conditions.
- (2) Unless the genetically modified organisms are of the same species, this law and its subsequent statutory instruments shall not apply to the cytogenetic production of :
 - (a) genetically modified plant cells, where the same result may be obtained through the use of traditional cultivation techniques;
 - (b) animal cells under cultivation, where 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 plant and animal cells.
- (3) It shall also not be applicable to techniques requiring gene therapy involving genetic mutations or cloning, except where such genetic mutations are used for health reasons using laboratory techniques to repair certain deficiencies.

Article 3 :

- (1) The services in charge of bio-safety may prohibit any activity involving genetically modified organisms on the basis of the precautionary principle or new scientific knowledge.
- (2) The terms and conditions of such prohibition shall be laid down by regulations.

Article 4 :

The objective of this law shall be to:

- 1- Ensure safety and ethics in modern biotechnological research and development and lay down the procedure for cross-border movement of genetically modified organisms;
- 2- Provide a mechanism for assessing, managing, communicating and controlling the risks inherent in the use, release and cross-border movement of genetically modified organisms or those having new traits as a result of modern biotechnological activity that may negatively affect the environment, and by extension the conservation and sustainable use of biological resources. This shall be achieved by taking into consideration the risks to human, animal and plant health and their socio-economic effects and by fully developing the benefits of biotechnology, as opposed to traditional technology.

Chapter II

DEFINITIONS

Article 5 :

(1) Advance informed agreement”:

Consent or authorisation given by the competent national administration, following notification by an applicant and before any intentional release, to an importer or exporter permitting him to carry out cross-border movements of a living modified organism, an organism bearing a new trait or a genetically modified organism or products thereof, within or across the country.

(2) Competent national administration:

The national authority in charge of coordinating activities related to biosafety. It shall be responsible for carrying out the administrative duties prescribed by the Cartagena Protocol on the prevention of biotechnology risks. It shall take its decisions within a National committee made up of the services and bodies concerned.

(3) DNA (Deoxyribonucleic Acid):

The molecule bearing the genetic information of most organisms, made up of 4 nitrogenous bases and a phosphate sugar medium.

(4) Recombinant-DNA:

DNA constituted by in vitro fusion of the DNA fragments from different organisms.

(5) Public Hearing:

Meeting with the local or neighbouring population through which they can react, after having been duly informed of any activity on the environment which, according to them, could adversely affect human or animal health or the environment.

(6) Biosafety:

policies or procedures adopted with a view to guaranteeing the application, without environmental risks, of modern biotechnology in medicine, agriculture, industry and the environment, and to forestall human health and environmental safety hazards.

(7) Modern biotechnology:

- application to nucleic acids of in vitro techniques including the recombination of the deoxyribonucleic acid and the direct introduction of nucleic acids in cells or bodies;
- cellular fusion of bodies not belonging to the same taxonomic family, which overcome the natural obstacles of reproductive physiology or recombination and which are not the techniques used for the reproduction and selection of the standard type.

(8) Cell:

The smallest morphological unit of living organisms, capable of growing and reproducing autonomously.

(9) Centre of origin of diversity:

Place or area of localisation of the source or diversity of a species.

(10) BIC:

Biosafety Institutional Committee.

(11) Placing on the market or release of transgenic products for commercial purposes:

Sale of products containing or constituted from substances with new traits.

(12) Clone:

Noun-group of genes, cells or organisms from the same ancestor, which are genetically identical.

Verb: to reproduce identical DNA sequences or whole cells using genetic manipulation techniques.

(13) Containment:

Prevention of the release of genetically modified organisms outside the laboratory. Physical containment is achieved through the use of special procedures and purpose-built installations. Biological containment is achieved through the use of specific varieties of organisms with a reduced survival or replication capacity in an open environment.

(14) Applicant:

A natural or legal person, or a national bio-safety institution wishing to import/export genetically modified organisms.

(15) Release:

Introduction in the environment or in the market of genetically modified organisms.

(16) Controlled/intentional release:

Introduction of an organism presenting new traits in an environment in which risk management measures have been applied.

(17) Deliberate or programmed release in the environment:

Intentional use of genetically modified organisms which is other than contained.

(18) Accidental release:

Involuntary release resulting from accidents, emigration/immigration, human activities and from transport by air, land or water, etc.

(19) Donor:

Organism or cell used as a source for extracting the DNA intended for insertion in another organism (host).

(20) Packaging:

Grouping of components of a virus, during the replication process of the virus, to form a complete particle of the virus.

(21) Environment:

- all the natural or artificial elements and the bio-geochemic equilibriums in which they are involved, as well as the economic, social and cultural factors which foster the existence, transformation and development of the environment, living organisms and human activities.
- natural abiotic resources such as the surrounding air, surface waters, underground water, soils, land surface, wildlife and plants, and the interactions between the elements which all form an integral part of the cultural heritage and specificities the landscape under Cameroon’s jurisdiction.

(22) Labelling:

The logo, content, marks, characteristics and other indicators of the presence of genetically modified organisms or products thereof.

(23) Risk assessment:

Measures aimed at evaluating the damage likely to be caused, the probability of damage being caused, and the impact of the damage evaluated. In other words, risk assessment is an estimation of risks and their consequences.

(24) Familiarity:

The fact of being adequately informed to be able to determine whether a release is with risk or not, or to indicate risk management strategies.

(25) Gene:

A basic hereditary unit of deoxyribonucleic acid (DNA), which determines the structure of a protein or a ribonucleic acid (RNA) molecule and the manifestation of a hereditary feature.

(26) Genome:

All the DNA of a given organism.

(27) Risk management:

Measures applied to ensure the safe manipulation of an organism. Risk management conditions often change according to the risk assessment. A high risk experiment, for example, may be managed owing to the application of appropriate containment measures aimed at reducing risks. The assessment of low risks may indicate to what extent the risk assessment procedure may be streamlined or eliminated.

(28) Inspector/Controller:

An accredited and sworn official of the competent service, who is well specialised in disciplines relating to biotechnology/biosafety, and whose duties consist in verifying, assessing, managing and ensuring the follow-up of risks, and control with a view to granting a prior approval and/or authorisation with full knowledge of the facts on notifications and release in the environment of genetically modified organisms and products thereof. He shall, in addition, be responsible for identifying offenders, formulating and/or proposing appropriate sanctions.

(29) Micro-organism:

An organism which can be seen only through a microscope.

(30) Transboundary movement:

Movement of genetically modified organisms or products through national borders.

(31) Containment level:

The level of physical containment offered by a laboratory and which is based on the installation plan, the equipment and the procedures used. Physical containment levels range, according to the classification of the genetically modified organism, from 1 to 4, with level 4 being the highest.

(32) Notifier:

Any natural person or corporate body, or a national biosafety institution which notifies the competent service of the use, and the export/import of genetically modified organisms.

(33) Nuisance:

The ability of an organism to be harmful to human healthy and/or the environment.

(34) Organism:

A biological, microscopic or non-microscopic entity capable of multiplying.

(35) Organism with new trait:

An organism developed by genetic modifications whose genetic structure resulting from the said modifications is not likely to be reproduced naturally.

(36) Genetically modified organism:

An organism whose genetic material has been altered following a process which cannot be replicated naturally through mating and/or natural recombination, and which has the capacity to replicate and to transmit the same genetic material.

(37) Transgenic organism:

An organism whose cells, including germinal cells, contain foreign DNA. The production of transgenic animals is conducted by inserting foreign genes in newly fertilised eggs or embryos.

(38) Living modified organisms:

A living organism which possesses a new combination of genetic material obtained through modern biotechnology.

(39) Parent (wild variety):

Mother cell or organism of a genetically modified organism.

(40) Pathogenic:

Capable of causing disease.

(41) Precautionary principle:

In case of suspicion of serious threat, or of irreversible damage, the absence of scientific proofs should not be a pretext to delay the taking of preventive measures.

(42) Recombination:

Presence or production of descendants having genetic combinations other than those present in parents.

(43) Risk:

Combination of the consequences of danger, if it occurs, and the probability that the consequences will arise.

(44) Raising public awareness:

The fact of educating and informing the public about risks and the safety measures relating to genetically modified organisms.

(45) Gene therapy:

Treatment consisting in replacing the defective gene in an individual or animal suffering from a genetic disease.

(46) Works in a contained milieu:

Genetic modification operation conducted so as to avoid release outside the laboratory of genetically modified organisms.

Physical containment is achieved through the use of special procedures and installations. Biological containment is achieved through the use of special varieties of organisms having new traits which present a low capacity of survival or replication in a non-contained milieu. Transboundary movement includes transit.

(47) User:

Any person, institution or body (including companies), responsible for the development or preparation, production, experimentation, marketing and distribution of organisms presenting new traits.

Within the meaning of this law, any member of the general public who buys and/or uses an organism shall not be a user, unless the said organism is used under specific conditions.

(48) Contained use or use in a contained milieu:

Any operation in which genetically modified organisms are used in some other way in a close system in which physical barriers are employed, either alone or together with physical and/or chemical and/or biological barriers, and which limit contact between the said organisms and the potential receptive environment, including human beings.

(49) Vector:

An agent capable of reproducing itself and used in the transfer of foreign DNA in a host cell.

(50) Virus:

A sub-microscopic infectious particle, comprising genetic material (DNA or RNA) and protein, and which can reproduce only within the cell of an organism (plant, animal or bacterium).

Chapter III

CLASSIFICATION OF SAFETY LEVELS

Article 6:

- (1) Biotechnological activities shall be classified under (four) 4 safety levels as follows:
- **Safety level 1** - Biotechnological projects that are known to present no risks to the community and the environment.
 - **Safety level 2** - Biotechnological projects that are known to present minor risks to the community and/or the environment.
 - **Safety level 3** - Biotechnological projects that are known to present slight risks to the community and/or the environment.
 - **Safety level 4**
- (1) - Biotechnological projects that are known to present risks or high risk probability for the community and/or the environment.
- (2) Any authorisation to carry out biotechnological activities must mention the safety level (s) for which the authorisation has been granted.
- (3) Specific criteria for defining safety levels shall be fixed by an implementation decree of this law.

Chapter IV

SAFETY MEASURES

Article 7:

- (1) Prior to the initial use of any premises for genetic modification activities, general safety measures such as best laboratory, industrial and production practices must be rigorously respected by the user. Measures must also be taken to ensure large-scale sensitisation of the local populations on the hazards related to the use, handling or movement of genetically modified organisms, as well as on the measures to prevent or reduce such risks.

Article 8:

Safety measures shall be set up from levels 1 to 4, as recommended internationally for micro-organisms and in genetic engineering and in conformity with the laws in force, provided that the organisms whose hazard levels have been determined shall be freely handled after notification of the competent authority.

Article 9:

Health and phytosanitary safety measures defined by international institutions must be applied by professionals working on genetically modified organisms, especially those regarding food safety.

Chapter V

IDENTIFICATION OF RISKS AND LIABILITY

Article 10:

Users shall be responsible for ensuring that appropriate measures have been taken to prevent any negative impact on the environment that may result from the use and handling of genetically modified organisms.

Article 11:

- (1) Liability for any damage resulting from the release of genetically modified organisms shall be borne by the implicated user.
- (2) When an inspector or controller seizes such an organism as stipulated in section 56 of this law, the user concerned at the time of use or of the release thereof shall not be liable for any damage caused, except where the latter had anticipated or was in a position to foresee and prevent the said damage, and had however failed to take acceptable action to that effect.

Chapter VI

CONFIDENTIALITY

Article 12:

No one shall be authorised to divulge information obtained in the performance of his duties as an inspector/controller or in the implementation of this law and subsequent regulatory instruments, except:

- where such information is necessary for the effective implementation of the provisions of this law or related regulatory instruments;
- for the purpose of legal proceedings within the framework of this law and subsequent regulatory instruments, where a competent court of law so rules;
- where he is authorised by the competent authority to do so.

PART II

CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS

Chapter I

CONTAINED USE

Article 13:

Any research, development or use of genetically modified organisms or products thereof must first be conducted in a closed system.

Article 14:

- (1) To prevent risks to human health and the environment, containment shall be guaranteed by use of physical, chemical and/or biological barriers in laboratories, greenhouses and any other facility specially equipped for containment of plants, animals, insects, fish and other genetically modified micro-organisms.
- (2) Containment measures shall be periodically reviewed every two years by the user to incorporate new scientific and technical knowledge on risk management waste treatment and disposal.

Article 15:

Containment modalities shall be fixed on the basis of the knowledge and level of the risks that the genetically modified organisms presents.

Chapter II

QUARANTINE

Article 16:

Genetically modified organisms destined for intentional release in the environment must, prior to such release, be subject to appropriate quarantine measures as fixed by the competent authority, in conjunction with other authorities concerned.

Article 17:

Any genetically modified organism or product thereof which poses risks to human, animal and plant health, as well as to biological diversity and the environment, shall be destroyed under conditions fixed by regulations.

RISK ASSESSMENT

Article 18:

- (1) Risk assessment in any activity related to genetically modified organisms should take into account the precautionary principle, and conducted in a suitable manner, to guarantee the safety of humans, animals and plants, as well as to protect biological diversity and the environment.
- (2) It should take into account expert opinion and guidelines drawn up by relevant international organisations.
- (3) Lack of scientific certainty or agreement by scientists should not be interpreted as reflecting an acceptable risk level.

Article 19:

- (1) Risk assessment shall aim to classify risks according to appropriate levels as defined in section 6 of this law. The purpose of the assessment shall be to:
 - identify potential risks;
 - assess risk probability;
 - manage risks;
 - analyse the risk's cost-benefit ratio;
 - examine the efficacy of sustainable alternatives to the introduction of genetically modified organisms, as well as the precautionary principle.
- (2) Risk assessment shall be undertaken on a case-by-case basis. The type and level of details concerning the information required may vary in relation to the living modified organism, its end use and the probable host environment.
- (3) Risks associated with living modified organisms or products thereof, that is transformed products from living modified organisms that contain new detectable combinations of genetic material resulting from modern biotechnology, should be considered in the on text of risks associated with non-modified organisms or parent organisms on the probable host environment.

Article 20:

- (1) Prior to any intentional release to 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.
- (2) It shall include the following parameters:
 - specificities of the organisms with novel traits, taking into consideration:
 - its biological and reproductive characteristics;
 - the biological and reproductive characteristics of the recipient or host organisms;
 - the trait transmitted through genetic modification or by the vector;
 - marker trait and sequencing;
 - the centre of origin, if it is known;
 - the availability of domesticated or wild parents in the host environment.
 - intended use, that is, the specific application of the contained use, intentional release or placement on the market, as well as the intended scale and any procedures for the management and treatment of wastes;

- the potential recipient environment, taking into consideration on a case-by-case basis, the ecological, socio-economic and ethical consequences, in a scientific manner and on the basis of the precautionary principle, where feasible;
- the potential hazards, knowledge or experiences available on the organism;
- indication as to whether the genetically modified organism released shall be used as human or animal food.

Article 21:

The assessment of risks shall be conducted in accordance with the following principles:

- financial responsibility for risk assessment shall be borne by the applicant for the notification or the notifier,
- information necessary for risk assessment such as reports of previous tests in open environment, the sites of such tests, data, etc. shall be provided by the notifier or the importer/exporter, for transboundary movement of genetically modified organisms or products thereof;
- the minimum criteria for the parameters for risk assessment shall remain those defined in section 6 above, subject to any updates of those parameters on instruction of the minister in charge of the environment, after consulting with other competent ministries.

Article 22:

- (1) Requirements in respect of useful information for notification shall include all reports and risk assessment documentation, and shall specify the safety requirements for accidental release and emergency.
- (2) It shall be forbidden to move to other countries or to engage in importation and movement activities whose purpose is to relocate or export substances connected with genetically modified organisms likely or able to degrade the environment or cause irreversible change in the ecological balance of biological diversity, or whose hazardous nature to human, animal and plant health is proven.

Chapter IV

RISK MANAGEMENT

Article 23:

It shall be incumbent on the user of any genetically modified organism or product thereof to 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. In order to guarantee the stability of genomes and traits in the environment, specialists in risk assessment shall be responsible for ensuring that any genetically modified organism or product thereof, imported or locally produced, is monitored in proportion as the case may be, to its life-cycle or reproductive period before it is put to the intended use.

Article 24:

In the case of importation of genetically modified organisms or products thereof, the exporter or promoter shall bear the cost providing the technical and financial support necessary for risk assessment and management so as to enable the competent authority to accomplish such tasks.

Chapter V

APPROVAL AND AUTHORISATION

Article 25:

Any activity in the research, development, production, manipulation and marketing of genetically modified organisms or products thereof in contained conditions, or intended to be released shall be subject to approval by the competent national administration in collaboration with the other services concerned. The procedure for applying for authorisation shall be determined by regulations.

Article 26:

All applications for approval for activities in the research, development, production, manipulation, use and movement of genetically modified organisms and products thereof shall be subject to payment of charges the amounts of which shall be determined by the finance law.

PART III

DELIBERATE AND ACCIDENTAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Chapter I

NOTIFICATION

Article 27:

- (1) The user shall be bound to give written notice to the competent national administration of his intention to import or export genetically modified organisms before undertaking to effect any deliberate release.
- (2) The information that must feature on the written notice shall be laid down in the implementing decree of this law.
- (3) The applicant shall be held legally responsible for the correctness of the information provided.

Article 28:

- (1) In the event of accidental release of genetically modified organisms resulting in an adverse impact on human, animal or plant health or on the biodiversity and the environment, and that could have been prevented in accordance with the criteria laid down by the competent national administration or the BIC, the user, persons or institutions informed of such accidental release shall immediately pass over such information to the competent national administration, indicating the place where the said release occurred, detail information on the actions taken and the authorities notified.

- (2) The fact that the competent national administration is informed shall in no way relieve the user of any obligation binding him, by virtue of ordinary law or duty, to give notice to persons likely to be affected.

Article 29:

- (1) The competent national administration shall acknowledge receipt, in writing, of the notice to move genetically modified organisms across borders to the notifier or applicant in accordance with the conditions laid down in the instruments in force.
- (2) Failure to acknowledge receipt of the notification on the part of the competent national administration shall in no case be interpreted as being an authorisation to effect any transboundary movement whatsoever.

Chapter II

ADVANCE INFORMED AGREEMENT OR PRIOR INFORMED CONSENT

Article 30:

The import or export of all genetically modified organisms shall be subject to the issuance of an advance informed agreement or of a prior informed consent by the competent national administration in collaboration with the other services concerned.

Article 31:

- (1) In case of an application for an advance informed agreement or of a prior informed consent by a potential importer/exporter of genetically modified organisms and products thereof, the competent national administration shall be bound to respond within a time-limit of 90 (ninety) days following receipt of the notice by:
- approving, with or without conditions, the importation or exportation, indicating how the decision applies to the subsequent importation/exportation of the same genetically modified organisms;
 - prohibiting the importation/exportation;
 - requesting additional relevant information, in accordance with the provisions of this law and the statutory instruments deriving therefore;
 - informing the applicant that the time-limit for notification indicated in this section has been extended by 60 (sixty) days for the purpose of reaching an informed decision.
- (2) The information given for purposes of notification shall be provided as specified under section 27 (2) above.
- (3) Where, at the expiry of the 90 (ninety) days time-limit, the advance informed agreement or the prior informed consent has not been expressly given by the competent national administration, the application shall be presumed to have been rejected.

PART IV

SOCIO-ECONOMIC CONCERNS

Article 32:

(1) Prior to any deliberate release of genetically modified organisms into the environment, a thorough study of their ethical and socio-economic impact on the local population must be conducted by the competent authority in collaboration with the government services concerned.

Such a study shall include the effects on:

- the traditional market and export earnings;
- health;
- production systems;
- ethical, moral and social considerations;
- the actual economic value of traditional species likely to be affected by the introduction of the genetically modified organisms.

(2) Funding of the study shall be provided by the user.

Article 33:

Appropriate emergency response strategies must be applied in the event of accidental release and in order to reduce its socio-economic impact by the competent national administration in collaboration with the other services concerned.

PART V

INSPECTION, CONTROL, EDUCATION AND PUBLIC AWARENESS-BUILDING

Article 34:

- (1) Within the meaning of this law, inspection and control shall refer to the set of operations designed to ensure safety and verify compliance of activities on genetically modified organisms and products thereof in accordance with the norms and procedures in force.
- (2) The duty of inspectors and controllers shall be to check the functioning of establishments responsible for modern biotechnology and to ensure compliance with this law.
- (3) The modalities for inspection and controls shall be laid down by regulations.
- (4) Expenses arising from the discharge of inspection and control duties shall be borne by the competent national administration.

Article 35:

The competent national administration shall, in collaboration with the other services concerned, foster and facilitate the sensitisation, education and participation of the public with regard to the safe movement, manipulation, and use of genetically modified organisms concerned in relation to the conservation and sustainable management of biodiversity, taking into consideration the risks on human health. It shall require that any person involved in modern biotechnology should sensitise and educate the public on the risks and benefits that such organisms entails.

PART VI

EMERGENCY RESPONSE STRATEGIES

Article 36:

- (1) Before introducing any genetically modified organisms or any activity related thereto into an open environment, appropriate measures and emergency response plans shall be put in place to properly manage accidents.
- (2) Response strategies and emergency plans shall be implemented by all persons involved in the production, manipulation and marketing of genetically modified organisms, in collaboration with the competent services, in order to properly manage emergency cases resulting from the deliberate or accidental release of genetically modified organisms and products thereof in their possession.
- (3) In the event of a disaster or of imminent danger resulting from the deliberate or accidental release of genetically modified organisms representing a threat to human, animal or plant health, biodiversity and the environment, the competent national administration shall inform the authorities responsible for disaster management and the services involved. The said administration shall also provide advice on the appropriate emergency response strategies.
- (4) In situations like the one referred to in sub-section (3) above, the competent national administration may suspend the activity, the importation/exportation of genetically modified organisms concerned, pending an investigation on the causes of the accident.

Article 37:

The user of genetically modified organisms shall be liable for any damage caused by the deliberate or accidental release of such organisms.

PART VII

WASTE AND GAS EMISSIONS TREATMENT

Article 38:

The management of waste resulting from research and development, the manipulation and marketing of genetically modified organisms shall be in compliance with the provisions of the laws in force.

Article 39:

- (1) Waste and contaminated effluents containing genetically modified organisms shall be inactivated using approved means before the final discharge. Waste disposal shall be in conformity with the laws in force.
- (2) Gas and other toxic emissions originating from facilities which use genetically modified organisms shall be treated before being released into the environment.

PART VIII

OPEN TESTING AND USE OF GENETICALLY MODIFIED ORGANISMS

Article 40:

- (1) Any test or application of genetically modified organisms in the open by users must be done in a way as to ensure the safety of the local community and the environment.
- (2) The procedure for conducting tests in the open shall be laid down by regulations.

Article 41:

Projects to conduct research on and develop genetically modified organisms in the open must be appraised by the user or promoter of the technology. However, the competent national administration may carry out an independent appraisal if it deems it necessary. This shall apply to all genetically modified organisms such as plants, animals, micro-organisms and viruses, including the reproduction stages where recovery is neither envisaged nor guaranteed.

Article 42:

- (1) The competent national administration shall, in collaboration with the other services involved, see to it that the public is sufficiently sensitised and that a sufficient number of public consultations devoted to the use, release and placing on the market of genetically modified organisms and products thereof, are held; the competent national administration shall open a national biosafety register containing all information relating to the use, release and placing on the market of all new modern technology-derived substances.
- (2) Any application for the open testing of genetically modified organisms requiring risk assessment shall be subject to a public consultation. The competent national administration shall issue an environmental safety attestation after having taken account of comments made at the public consultation.

PART IX

TRANSPORTATION, IMPORT/EXPORT AND PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISMS

Chapter I

TRANSPORTATION OF TRANSGENIC ANIMALS, PLANTS AND MICRO-ORGANISMS

Article 43:

- (1) For biotechnological products to be imported or exported, the competent national administration in charge of biosafety in the exporting country concerned shall issue, to whom it may concern,

information attesting the safety of the products concerned.

- (2) Genetically modified organisms developed within the national territory and designed for export shall be subject to the same procedure.

Article 44:

- (1) Users shall, in accordance with the provisions governing the transportation of transgenic animals, take sufficient measures to:
 - prevent the escape of animals, given such possibilities as accidents on the way so that they are not crossed with domesticated indigenous populations;
 - be sure that they are well identified and that they reach their destination as intended;
 - ensure that the process is supervised by a competent biologist with experience in the management of stock breeding-related problems;
 - institute accounting procedures that will ensure that the number of animals shipped remain same at delivery.
- (2) Only cages and containers approved by the competent national administration may be used for transportation.
- (3) Exporters/importers shall contact the competent national administration for directives related to the purchase of cages approved by airline companies for the transport of specific non pathogenic animals.

Article 45:

During the transportation of transgenic insects and their pathogenic agents, the following measures shall be taken:

- the insects must be put in an unbreakable locking container clearly labelled and hermetically sealed in order to avoid leakages;
- the locking container must be put in another container clearly labelled and properly sealed for transportation;
- the insects shall be transferred from the container to another container immediately they arrive at their destination;
- all the transport equipment shall be decontaminated by autoclave after the transported insects are transferred into new containers;
- accounting procedures shall be set up to ensure that the number of containers and insects exported are the same upon delivery.

Article 46:

- (1) Any transgenic material to be transported within and between institutions, shall first be put in a primary container, such as polythene bags for seeds and placed in unbreakable secondary containers.
- (2) The outer container shall also be labelled to show that it contains transgenic material. The label shall bear the address of the sender to be contacted in case of loss or damage of the parcel. The labels on the parcels of seeds shall indicate the quantity transported.
- (3) Complete transgenic plants shall be covered with nets and devoid of flowers before they are transported. They may be transported in pots, placed in boxes or racks. The plants shall not be transported when they start bearing seeds.
- (4) Accounting procedures shall be set up to ensure that the number of plants or containers exported are the same upon delivery.

Article 47:

Micro-organisms shall be transported in accordance with international norms in force and shall not, for any reason, be transported in personal luggage by public or private transport.

Article 48:

- (1) Any person or company transporting genetically modified organisms through the national territory in transit to other countries shall inform the competent national administration far in advance, and comply with the national requirements relating to containment and transport, as laid down in this law.
- (2) The competent national administration shall grant the prior approval with full knowledge of the facts before the transit is effected.
- (3) Moreover, the following safety measures must be respected:
 - every importer/exporter of genetically modified organisms transiting through the national territory, shall ensure that the imported/exported genetically modified organisms has been inspected, at his expense, by the competent services;
 - All the genetically modified organisms transiting through the national territory shall be granted a period of 60 (sixty) days during which they shall be escorted out of the country.

This period shall be indicated on the documents accompanying the escorted containers, and certified by the competent national administration in collaboration with the other authorities involved at the exit or entry ports.

- (4) Transit conditions shall be laid down by regulation.

Chapter IV

LABELLING, PACKAGING AND MARKETING

Article 49:

- (1) Any genetically modified organisms or products thereof intended for intentional release or marketing on the national territory shall be packaged and labelled in order to safeguard ethical and cultural values, and to avoid risks to human and animal health. (2) All the genetically modified organisms perfected and marketed on the national territory shall be packaged and labelled by the producer and sender as follows: “Product based on genetically modified organisms”, or “contains genetically modified organisms”, in compliance with other supplementary norms defined by the competent national administration in collaboration with the other authorities involved. The following information shall be specified:
 - 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.
- (2) Moreover, the consignor shall fill in and sign two copies of a manifest. The said manifest shall attest to the respect, by the sender, of the requirements of the advance informed agreement.

Article 50:

The distributor of genetically modified organisms shall regularly register his commercial activities in accordance with the regulations in force. All importers and commercial agents involved in the distribution of genetically modified organisms and products thereof shall pay expenses whose amounts shall be fixed annually by the finance law.

Article 51:

Recombinant-DNA vaccines and other pharmaceutical products manufactured through genetic modification and marketed on the national territory shall be subjected to the same safety norms provided for in this law.

Article 52:

Recombinant-DNA products and other imported pharmaceutical products shall be quarantined at entry ports until samples which shall be tested by the competent national administration shall prove that the said products are not dangerous, before they are placed on the market. In the absence of any proof of danger, the competent national administration shall, in collaboration with the other services involved, take the responsibility to authorise the release of the products. Consequently, the manufacturer shall set up strategies and ensure the follow-up of the products, in order to fully guarantee their safety to human and animal health as well as to the environment.

Article 53:

The method of work in the field of Recombinant-DNA vaccines and other pharmaceutical products manufactured through genetic modification shall be determined by regulation.

Article 54:

With regard to genetically modified organisms perfected on the basis of genetic resources taken from the national heritage, the provisions of the regulations in force relating to access to genetic resources and sharing of benefits shall be applied *mutatis mutandis*.

Article 55:

Notwithstanding the above provisions, products based on genetically modified organisms intended for human or animal consumption shall be subject to specific norms determined by special instruments.

PART X

REPRESSION AND SETTLEMENT

Chapter I

OFFENCES AND PENALTIES

Section I

OFFENCES

Article 56:

Offences against this Act or its regulations apply:

- failure to comply with a condition, restriction or direction provided by this Act;
- refusal to provide information or any explanation to an inspector or controller in the discharge of their duties;
- posing as a sworn inspector or controller.

Article 57:

(1) Without prejudice to the prerogatives granted to the prosecution and judicial police officers of general competence, sworn inspectors and controllers of the competent national administration in charge of

biosafety or other services concerned shall be responsible for the investigation, establishment and repression of offences against the provisions of this law.

- (2) The officers referred to in 57 (1) above shall be sworn in before competent courts at the request of the authority concerned, in accordance with the conditions laid down by regulation.
- (3) In the discharge of their duties, sworn officers shall put on professional identity cards.

Article 58:

- (1) (1) Any offence that is established shall be subject to a regular report.
- (2) Investigation and establishment of offences shall be carried out by 2 (two) officers who shall co-sign the report. The report shall be valid until the contrary is proven.

Article 59:

- (1) Any report on the establishment of an offence shall be transmitted immediately to the competent national administration in charge of biosafety who shall notify the accused. The accused shall, within a period of 20 (twenty) days, with effect from the date of notification, be free to contest the report. Beyond the above mentioned period, no protest shall be accepted.
- (2) In case of protest within the time-limit indicated in 59 (1) above, the claim shall be examined by the competent national administration in charge of biosafety.

Where the accused's claim is right, the matter shall be closed.

Where the claim is unfounded and no settlement is carried out, the competent national administration in charge of biosafety shall, in conjunction with the authority in charge of classified establishments, take the matter to court in accordance with the regulations in force.

Section II

PENALTIES

Article 60 :

Whoever is found guilty of violating the safety measures provided for in section 7, 9, 13, 14, 20, 22 and 55 of this law, shall be punished with imprisonment for from 6 (six) months to 2 (two) years or with fine of from 100,000 to 1,000,000 CFA francs or with both such imprisonment and fine.

Article 61:

Whoever violates the approval, authorisation, notification and urgent intervention measures provided for in section 25, 26, 28, 30 and 36 above shall be punished with imprisonment for from 2 (two) to 5 (five) years or with fine of from 1,000,000 to 5,000,000 CFA francs or with both such imprisonment and fine.

Article 62:

Whoever is found guilty of putting genetically modified organisms and products thereof into dangerous use shall be punished with imprisonment for from 5 (five) to 7 (seven) years or with fine of from 5,000,000 to 10,000,000 CFA francs or with both such imprisonment and fine.

Article 63:

Whoever is found guilty of an offence committed in relation to a micro-organism shall be punished with imprisonment for from 7 (seven) to 10 (ten) years or with a fine of from 10,000,000 to 100,000,000 CFA francs or with both such imprisonment and fine.

Article 64:

Any second offender, shall be liable to twice the maximum of the penalties provided for above.

Chapter II

SETTLEMENT

Article 65:

- (1) The competent national administration in charge of biosafety shall have full powers to work out a compromise. To this end, the accused must refer the matter to the authority concerned.
- (2) The amount of money paid as settlement shall be determined in consultation with the authority in charge of finance. The said amount shall not be less than the minimum amount of the corresponding penal fine.
- (3) Under pain of nullity, the settlement procedure shall be carried out before any possible court proceeding.
- (4) The method of collecting and allocating the proceeds of the settlement shall be determined by regulation.

PART XI

SUNDRY AND FINAL PROVISIONS

Article 66:

Income from taxes, authorisation fees, seizure expenses, compensations, public auction sales or private negotiations of genetically modified organisms or products thereof seized shall be allotted and shared in accordance with conditions laid down by regulation.

Article 67:

- (1) Authorisations or permits for exploration and development, movement or marketing of genetically modified organisms which are still valid, in use and in conformity with the protection of the environment shall remain valid until they expire. The promoters of the said activities shall declare their existence to the competent national administration.
- (2) The renewal of such authorisations shall be carried out in accordance with the provisions of this law and the statutory instruments thereof.
- (3) Without prejudice to the provisions of paragraph 67(1) above, holders of authorisations granted before the promulgation of this law, shall comply with the safety measures provided for in this law.

Article 68:

All previous provisions repugnant hereto are hereby repealed.

Article 69:

This law shall be registered, published according to the procedure of urgency and inserted in the official gazette in English and in French.

Yaounde, April 21, 2003

Paul Biya
The President of the Republic,