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EXPLANATION AND COMMENTS ON THE CAMEROON BIOSAFETY LAW

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This paper is intended primarily as a guide, for use by non-governmental organisations and other public interest organisations.

This paper is comprised of 2 parts. The first part contains general observations concerning the Cameroon Biosafety Law. The second part contains detailed comments and analysis of the provisions of the Cameroon Biosafety Law. This is presented in Table format.

GENERAL

The Cameroon Biosafety Law No 2003/006 titled "Law No 2003/006 of 21 April 2003 To Lay Down Safety Regulations Governing Biotechnology in Cameroon" ("Biosafety Law") was signed by the President of Cameroon on the 21 April 2003, and passed by the Cameroon Parliament during November 2003. Cameroon is a Party to the Cartagena Protocol on Biosafety ("Biosafety Protocol")

The Biosafety Law was probably written in French and translated into English. It is entirely possible that in the course of such translation, the meaning of important concepts and principles have been lost or altered.

Detailed explanations and comments are provided in a Table below. The analysis provided in the Table has been grouped around key issues, namely, **Risk Assessment; Authorisations; Safety Measures; Destruction of GMOs that pose risks; Products of GMOs; GMOs that are pharmaceuticals; Prohibition of hazardous substances connected with GMOs; Contained Use, Field Trials; General/environmental release; Waste and gas treatment; Risk Management; Import/Export of GMOs; Decision-making; Accidental releases and emergency responses; Transit; Liability and redress; Labelling,(identification), packaging and marketing; Transport, handling and packaging; Public Awareness , participation and consultation, Confidential information and access to Information, Offences and penalties; and Enforcement.**

Having regard to the critical analysis provided in the Table below, it is strongly recommended that the Biosafety Law be reviewed in its entirety and a new piece of legislation to be drafted, afresh. Amendments to this Law in a piecemeal fashion will not cure it from its deficiencies, some of which are even flawed in law (e.g. the liability provisions) nor can these be remedied by the promulgation of regulations.

1. The Cameroon Biosafety Law is first and foremost an enabling or framework law. It requires several regulations to be made on key issues, in order for the Law to

become operational and meaningfully implemented. This is fully canvassed in the Table provided below.

2. Generally speaking, the Biosafety Law is cumbersome, convoluted and user-unfriendly. It appears as if the drafters of the Biosafety Law, perhaps under pressure to put in place a biosafety framework, have not paid adequate attention to ensuring consistency, lucidity and detail on key safety issues.

With the result, the Biosafety Law is comprised of a mixed bag of provisions, haphazardly arranged comprising of:

- **reasonably good provisions** (e.g. transit; socio-economic impacts; destruction of GMOs that pose risks);
- **provisions that can do more harm than good** (e.g. safety measures)
- **bad provisions** (e.g. public participation; liability);
- **ambiguous provisions** (e.g. confidential information);
- **provisions that simply water down safety measures** (e.g. genetically modified (GM) pharmaceuticals; products of GMOs; out of court settlements);
- **contradictory provisions on key biosafety issues** (e.g. risk assessment, "safety measures");
- **provisions that raise a number of concerns** (e.g. risk management; risk level setting, "safety attestations") ;
- **provisions that are forward- looking and innovative** (e.g. transport of transgenic animals, insects, material and micro-organisms, packaging and handling of GMOs) ;
- **provisions that implement the Biosafety Protocol** (e.g. components of the AIA procedure for import and export);
- **provisions that fail to fully implement the Protocol** (e.g. Article 23 dealing with public participation and consultation; Article 16 dealing with risk management).

3. Thus, owing to its lack of coherency and clarity on key issues, it is feared that the Biosafety Law may present too many challenges for regulators to interpret and implement the Law in a consistent manner that favours more rather than less stringent protection against the risks posed by GMOs. This situation does not augur well for public confidence in the regulatory system. There can be no doubt that members of the public will have great difficulty in making sense of this law.

4. It appears that anticipated activities involving GMOs in Cameroon may be focussed on 2 key areas in the future. The first, is the role that Cameroon may play as a transit state for GMOs imported into West Africa from the United States, Argentina and Canada. This is reflected in the relatively stringent measures that are imposed for GMOs in transit. Second, Cameroon appears to see itself as producing products of GMOs for the domestic market and for export. This is borne out by the specific provisions that exist for these products, distinguishable from products of GMOs that will be imported into Cameroon.

5. The African Union's African Model Law on Safety in Biotechnology ("African Model Law) does not appear to have influenced the drafting of the Biosafety Law. This is regrettable.

6. The Biosafety Law has not implemented the Biosafety Protocol in its entirety, as is evident from the analysis below.

7. Since the discussion below is concentrated on what is actually contained in the Biosafety Law itself, it is important to make mention here, the issues that have been omitted from the Biosafety Law in its entirety. These omissions relate to (a) powers, functions and decision-making on the part of the competent national authority; and (b) provisions for post-release monitoring.

7.1 The Biosafety Law does not contain discreet provisions dealing with the functions, powers and duties of the competent national authority, which is charged with coordinating the activities relating to the Biosafety Protocol, and tasked with "taking decisions within a national committee made up of services and bodies concerned." This oversight is quite serious, because it is critically important that there is transparency in a biosafety regime regarding the manner in which decision-making bodies responsible for the administration/implementation of the law are to function. Members of the public should know about staffing arrangements, how decisions will be made; and the details concerning the involvement if any, of experts in decision-making. It must also be noted, that the Biosafety Law does not require **decision-making** to be based on the precautionary principle. This is a very serious omission, particularly since the precautionary principle is at the very heart of biosafety decision-making.

7.2 The Biosafety Law has neglected to include post-release monitoring provisions because it has opted for self-regulation. (see Table below dealing with Risk Management). Monitoring is principally the responsibility of government. Post-release monitoring is a critically important component of biosafety regulation of GMOs. The objective of such monitoring is to **prevent risks**. Its other key function is to improve on predictive models to identify risks. Examples of what should be monitored include: environmental effects of on water, soil and bio-organisms; non-target effects that are limited to pre-commercialisation testing on a small spatial sites; multi-year testing of effects; and animal and human health monitoring over a period of time etc.

OVERVIEW OF CAMEROON'S BIOSAFETY REGULATORY SYSTEM

Type of Activity	Explanation and comments/shortcomings
<p>Risk Assessment</p> <p>Chapter III-sections 18-22;</p> <p>Read together with the definition of Risk Assessment in section 5(23);</p> <p>Read together with section 6;</p> <p>Read together with section 42.</p>	<p>Prior to any intentional release into the environment, contained use; import/export, sale/placement on the market of a GMO or <u>products thereof</u>, a strict assessment of the risks must be conducted. (Section 20)</p> <ul style="list-style-type: none"> • The Risk assessment provisions have been largely modelled on those reflected in Annex III of the Biosafety Protocol, dealing with Risk Assessment. • Although the provisions require the consideration of risks posed by products of GMOs, this is limited only to those products that still contain " detectable combinations of genetic material" What this means is that for instance, processed food derived from GM seeds that may not contain detectable combinations of genetic material will not be subject to risk assessment. • Any activity related to GMOs " should " (as opposed to shall) take into account the precautionary principle to guarantee the safety of humans, animals and plants as well as to protect biological diversity and the environment (section 18 read); <p>(a) The most worrying provisions are those contained in section 19 read together with section 6, which aims to <u>classify risks into four different levels of risks:</u></p> <p>Level 1: no risks; Level 2: minor risks; Level 3: slight risks; Level 4: high risks. The issue here is that the government is trying to provide a rationale for the acceptance of certain levels of risks posed by GMOs. The basis for the determination of the acceptability of such risks is not spelt out in the Law except for the references "biotechnology projects that are known to present risks."</p> <p>Section 6(3) specific criteria for defining levels of risks shall be fixed by an implementation decree of the law. This risk characterisation will essentially encompass the risk assessment parameters are essentially the different levels of risks contemplated in section 6 as</p>

	<p>well as those already set out in section 20.</p> <p>(b) The risk assessment parameters set out in Section 20 are astonishingly limited especially when compared to Annex III of the African Model Law and Annex III of the Biosafety Protocol.</p> <p>The Biosafety Law does, however, contemplate the updating of the parameters by the Minister of Environment, after consultation with other competent Ministries (section 21).</p> <p>(b) <u>Equally troubling, is the wording contained in section 20(2) that the risk assessment is required to take place "...taking into consideration on a case-by-case basis, the ecological, socio-economic and ethical consequence, <i>in a scientific manner and on the basis of the precautionary principle, where feasible</i> "</u></p> <p>Why should the application of the PP be only where feasible? Who will decide when it is not feasible? " What criteria will be used to make a determination as to when the PP is feasible? Why should socio-economic and ethical concerns be considered in a scientific manner?</p> <p>This provision seems to be confirming that section 18 (see below) does not create a clear- cut legal obligation that the PP must be taken into account.</p>
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<p>Authorisations</p> <p>Section 25 (authorisations for contained use and release (including field trials))</p> <p>Read together with section 6</p> <p>See also, the comments made for "Field trials" below;</p>	<p>(a) Any activity in the research, development, production, manipulation and marketing of GMOs or products thereof in contained conditions, release into the environment requires approval from the competent national administration (section 25). <u>However, the procedure for applying for such authorisation has to be determined by regulations. This means that until such time as these regulations are made, the operation of the authorisation provisions may be inoperable.</u></p> <p><u>Note also: these provisions do not apply to the import and export/cross border movement of GMOs or products of GMOs-because separate provisions have been created for imports/exports but these do not apply to products of GMOs.</u></p> <p>(b) <u>Very importantly, as already pointed out above, section 6 deals with classifications of safety levels for "biotechnology projects" . Four safety levels are provided for, from 1-4, with safety level 1 presenting no risks to safety level 4 presenting risks or high risks probability for the community and/or the environment.</u></p> <p>(c) <u>Section 6(2) requires that any authorisation to carry out biotechnology activities must mention the safety levels for which the authorisation has been granted.</u></p> <p><u>As already pointed out above, section 6(3) provides that specific criteria for defining levels shall be fixed by and implementation decree of this law.</u></p> <p>Again, until such time as the criteria for defining the safety levels have been established, proposed activities involving "biotechnology projects" –or activities involving GMOs or products thereof, cannot be graded; the corresponding safety measure can therefore not be applied; nor can section 6(2) be complied with and authorisations cannot be issued for activities involving GMOs or products of GMOs.</p>
<p>SAFETY MEASURES</p> <p>Chapter IV, Sections 7, 8 and 9</p> <p>Definition of "user" = any person, institution or body (including companies), responsible for the development or preparation, production, experimentation,</p>	<p>Special sections have been crafted to deal with safety measures to be adhered to by the user of any premises used for genetic modification activities (such as laboratories) industrial and production practises (this can also cover premises where the industrial or production of GMOs take place in the open environment-or where it is no longer under contained use conditions).</p>

marketing and distribution of organisms presenting new traits"

The provisions contained in Chapter IV i.e., reading sections 7, 8 and 9 together, can do more harm than good in the general interpretation and application of the Biosafety Law!

- (a) In regard to the premises concerned, the user is obliged to abide by general safety measures such as laboratory best practise, industrial and production practises. It would have been far more preferable for the Biosafety Law to have spelt out what these refer to by making specific reference to these best practises in a schedule to the legislation in order to provide legal clarity and ensure greater transparency.
- (b) A duty is created for the sensitisation of local population on the hazards related to the use, handling or movement of GMOs and the measure to reduce such risks (section 7). However, this section does not stipulate who has the duty to fulfil these obligations. It is, however, implied that this duty should be performed by the user-which will include industry, whereas, this function should in the first instance, be performed by the competent authority;
- (c) Section 8 deals with the need for safety measure to be set up from levels 1-4 as "recommended internationally for micro-organisms and in genetic engineering ...**provided that organisms whose hazard levels have been determined shall be freely handled after notification of the competent authority. This provision seems to contradict the entire basis for biosafety regulation of activities concerning GMOs under contained use conditions and environmental releases where industrial and production practises entail releases into the environment. Irrespective of the level of risk that is determined for a GMO or an activity related to a GMO, GMOs can never be freely handled. They must always be subject to biosafety measures; strict monitoring and so forth;**
- (d) Additionally, section 9 requires health and phytosanitary safety measures as established by international institutions to be applied by professionals working on GMOs, especially regarding food safety

<p>Destruction of GMOs that pose risks</p> <p>Section 17</p>	<p>Section 17 contains a really important provision. It requires that any GMO 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 regulation. The promulgation of this regulation to operationalise this critically important provision is urgent. At the same time, it must be borne in mind that these provisions are only meaningful if there is monitoring by the Cameroon government-and not self-regulation, as is provided for by this Law. See below on Risk Management.</p>
<p>Products of GMOs</p> <p>Section 19(3)</p> <p>Section 20(1)</p> <p>Section 55</p> <p>Section 43- Under the heading "transportation of transgenic animals, plants and micro-organisms)</p> <p>Cross refer, provisions dealing with import and export/AIA procedure</p> <p>Cross refer-provisions on labelling and packaging for products of GMOs that are imported and those that are produced in Cameroon</p>	<ul style="list-style-type: none"> (a) Products of GMOs are not defined in section 5; (b) A strict risk assessment is required to be conducted for any intentional release; contained use; import/export/sale/placing on the market of a GMO or products thereof section 20(1); (c) Recall, the risk assessment will only be conducted on products of GMOs that contain detectable combinations of genetic material; (d) Recall, the risk assessment is based on the substantial equivalence principle; (e) Recall that authorisation is required for contained use, release into the environment and placing on the market of a product of a GMO. (f) Note that the import and export of products of GMOs do not require authorisation and is not included in the AIA procedure dealing with imports and exports. So, products of GMOs can enter into Cameroon without any authorisation being required. (g) However, products of GMOs that are produced in Cameroon will require authorisation before they are placed on the market. Arguably, while the AIA procedure does not apply to products of GMOs that are imported into Cameroon, authorisation will nonetheless be required for the placing on the market of such imported products of GMOs; (h) Section 43 requires that before "biotechnology products" can be imported or exported, the competent national authority in the exporting country shall issue "to whom it may concern" <u>information attesting the safety of the products concerned</u>. Thus, products of GMOs will flow freely into Cameroon from the US, Canada, Australia, South Africa, Argentina, provided that the competent authorities in the country of export issue a safety attestation. Since the Biosafety Law does not provide for any guidelines for this safety attestation, it could take any form and even contain waivers etc.

	<p>(i) <u>Sneakily, and most importantly, tucked deep in the Law towards the end on page 27 of a 30 page document, section 55 provides the following: "notwithstanding the above provisions, products based on GMOs intended for human and animal consumption, shall be subject to specific norms determined by special instruments"</u></p> <p><u>This provision appears to convey the intention to craft special provisions to deal with products of GMOs and in so doing, render the current provisions on products of GMOs, inapplicable. Arguably, however, for as long as these "specific norms" and "special instruments" do not exist, the current provisions relating to products of GMOs will apply;</u></p> <ul style="list-style-type: none"> • Note, the placing on the market of products of GMOs that are imported will have to be packaged and labelled but not those produced in Cameroon. See below on labelling, packaging etc • The liability provisions contained in the Biosafety law do not apply to products of GMOs.
<p>GMOs that are Pharmaceuticals</p> <p>Sections, 51, 52 and 53</p> <p>Read together with section 20 and 25</p>	<p>(a) GMOs that are pharmaceuticals for animals and humans are included in the definition of GMOs and generally speaking, the provisions dealing with GMOs, such as compulsory risk assessments and authorisations and the provisions dealing with import and export of GMO will apply to GM pharmaceuticals. Additional safeguards seem to have been created for GM pharmaceuticals that are imported into Cameroon, raise a number of concerns</p> <p>(b) In terms of section 52, GM pharmaceuticals that are produced outside of Cameroon and imported into Cameroon will have to be quarantined first at the ports of entry until samples which shall be tested by the competent national administration proves that the said products are not dangerous, before they are placed on the market. <u>In the absence of any proof of danger; the competent national administration shall take responsibility to authorise the release of the products. Why should there be proof of danger as opposed to proof of safety? What about the precautionary principle?</u></p> <p>Although an obligation is placed on the manufacturer to "set up strategies and ensure the follow up of the</p>

	products in order to guarantee their safety to human and animal health as well as to the environment" it is not know what these entail.
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<p>Prohibition of Hazardous substances connected with GMOs</p> <p>Section 22(2)</p> <p>"Substances associated with GMOs" not defined</p>	<p>An important provision exists in section 22(2) that prohibits the cross border movement out of Cameroon, or into Cameroon with the purposes of cross border movements or export out of Cameroon, substances connected with GMOs 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. This may be an attempt to address genetically modified biological weapons. However, these provisions are limited only to cross-border movements and not to the development, production and release into the environment of the substances connected with GMOs.</p>
<p>Contained Use</p> <p>Chapter IV sections 7, 8, 9 dealing with safety measures to be applied at the premises where GM experiments take place, read together with the definition of "containment level", read together with section 6?</p> <p>Sections 13, 14, 15, read together with the definitions of "containment"</p> <p>"works in a contained milieu"</p> <p>Read together with section 20, 25; 26</p>	<p>(a) See above, authorisation required (section 25). (b) See above, Risk Assessment required (section 20(1)) (c) See above, on "safety measures".</p> <p>The Law uses too many different concepts to define what constitutes "contained use" (Chapter 1, section 13, 14 and 15). It conveys the notion that activities involving GMOs under contained use can take place only in a closed system in a laboratory, but it also includes greenhouses. Certainly, however, the intention is to exclude field trials-see below. At the same time, contained use is also synonymous with "containment" and the notion of prevention of release into the environment by the use of physical barriers but it also refers to the use of biological containment measures "with a reduced survival or replication capacity in an open environment."</p> <p>The actual application of the law will have to be closely monitored, particularly since provision is made in section 14(2) for containment measure to be reviewed every 2 years by the user to incorporate new scientific and technical knowledge on risk management waste treatment and disposal. Section 15 also states that containment modalities shall be fixed on the basis of the knowledge and level of risks that GMOs present.</p>
<p>Field Trials</p> <p>Definition: section 5(17)</p> <p>A special Part VIII has been created to deal with "open testing and use of GMOs" contained in sections 40, 41 and 42.</p> <p>Cross refer-section 36 dealing with accidental releases and emergency</p>	<p>(a) "Field trial" is not specifically defined, however, it appears to be covered by the definition of "deliberate or programmed release in the environment" in section 5(17) which is an intentional use of a GMO, other than which is contained.</p> <p>(b) As mentioned above, a Risk Assessment (section 20).</p> <p>(c) Furthermore, authorisation is also required in terms of section 25;</p>

response below

Cross reference, quarantine provisions

- (d) Recall, provisions on safety measures;
- (e) The "appraisal" of projects to conduct research on and develop GMOs in the open, is primarily the responsibility of the user or promoter of the technology (section 41).
- (f) The conducting of independent appraisals by the competent authority is only a discretionary **right** of the competent national administration, as opposed to a compulsory **obligation** (section 41);
- (g) Public consultation must take place; (section 42);
- (h) Section 42 contains a provision that raises some concern. It obliges the competent national administration to issue an **"environmental safety attestation"** after taking into account the comments received at the public consultation. **How can this be done where an independent environmental risk assessment has not been required?** What would the status be of such an "environmental safety attestation"?
- (i) What constitutes public consultation and how this will work, is not spelt out in the Biosafety Law;
- (j) Prior to GMOs being released into the environment, the GMOs must be subject to "appropriate quarantine measures" as fixed by the competent authorities. **This means also that until such quarantine measures are established, no quarantine can take place and therefore no intentional releases can take place either-well at least not in terms of this Law;**
- (k) Where a user wishes to import GMOs into Cameroon or export GMOs from Cameroon with the intention of deliberately releasing GMOs into the environment, it must give the competent authority notice. (Section 27(1) **Again, the information that must feature in such written notice must be laid down in the implementing degree. If these are not laid down, this provision is not operational. Moreover, the acknowledgement of receipt of such notification is to take place in accordance with the conditions laid down in the instruments in force. If no such instruments exist, then these provisions cannot be complied with;**
- (l) Failure to acknowledge receipt of the notification shall not be interpreted as an authorisation;
- (m) Appropriate measures and emergency response plans have to be put in place to properly manage accidents, before GMOs can be released into the environment. Cross refer, comments below on accidental releases and emergency response.

<p>General/environmental Release</p> <p>Definitions-section 5 (17)</p> <p>Read together with sections 20(1) and 25;</p> <p>Read together with section 16</p> <p>Section 32 (socio-economic study required)</p> <p>Read together with section 6; cross refer comments on section 6 under authorisations and field trials;</p> <p>Read together with section 27(1).</p> <p>Read together with Part VI, dealing with emergency response-cross refer, comments below</p>	<ul style="list-style-type: none"> (a) Authorisation required-section 25; (b) Risk Assessment required-section 20(1); (c) Additionally, prior to any deliberate release, a socio-economic study is required to be conducted by the competent national authority to be paid for by the user (section 32). See below. (d) Whereas provision has been made for public consultation for field trials, no such corresponding provision exists for releases of GMOs into the environment for commercial growing! It is critically important that the results of the field trials be subject to public scrutiny, prior to any decision being made for its commercial growing. (e) The provisions of section 6 should apply dealing with levels of risk-see comments above. (f) Where appropriate, the provisions dealing with "safety measures" will also apply; (g) Prior to GMOs being released into the environment, the GMOs must be subject to "appropriate quarantine measures" as fixed by the competent authorities. This means also that until such quarantine measures are established, no quarantine can take place and therefore no intentional releases can take place either-well at least not in terms of this Law. (h) Appropriate measures and emergency response plans will have to be put in place to properly manage accidents before GMOs can be released into the environment. Cross refer, comments below on accidental releases and emergency response. (i) Where a user wishes to import GMOs into Cameroon or export GMOs from Cameroon with the intention of deliberately releasing GMOs into the environment, it must give the competent authority notice. (Section 27(1) <u>Again, the information that must feature on such written notice must be laid down in the implementing decree. If these are not laid down, this provision is not operational. Moreover, the acknowledgement of receipt of such notification shall take place in accordance with the conditions laid down in the instruments in force. If no such instruments exist, then these provisions cannot be complied with.</u> (j) Failure to acknowledge receipt of the notification shall not be interpreted as an authorisation.
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<p>Waste and gas emissions treatment</p> <p>Part VII sections 38 and 39</p>	<p>Although the management and disposal of waste and contaminated effluent containing GMOs or resulting from research and development, manipulation and marketing of GMOs are mentioned in sections 38 and 39, these provisions are "mere bones" in the sense that regulations need to be made to give them "flesh".</p> <p>Similarly, gas and toxic emissions originating from facilities which use GMOs are required to be treated before being released-but the law does not spell out what this treatment entails.</p>
<p>Risk Management</p> <p>Chapter, VI, section 23</p> <p>Recall, definition of "user"</p> <p>Recall, absence of monitoring provisions</p>	<p>No risk management measures are set out in this section at all because the approach the Biosafety Law has taken is one of self-regulation of risks by the permit holder.</p> <p>Section 23 requires the user 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 used in <u>contained use conditions or deliberately released</u> into the environment. <u>This is not in accordance with Article 16(1) of the Biosafety Protocol which creates very clear obligations for Parties regarding the establishment and maintaining of appropriate mechanisms, measure and strategies to regulate, manage and control risks identified in the risk assessment associated with the use, handling and transboundary movement of LMOs.</u></p>
<p>Import/Export</p> <p>Chapter II</p> <p>Read together with the definitions of "Advanced Informed Agreement"</p> <p>Read together with section 27(2)</p> <p>Read together with section 22(2)</p> <p>Read together with section 43(1) and (2)</p>	<p>(a) An Advanced Informed Agreement (AIA) or prior informed consent (PIC) is required to be issued by the competent authority before any GMO can be imported into or exported from, Cameroon. <u>This section (30) does not include the words "products thereof", although these words are included in section 31, dealing with the reaction of the competent authority when it receives an application for an AIA or PIC. This does, however, not cure the fact that products thereof, are excluded from the requirement in the first place that an AIA or PIC is required.</u></p> <p>(b) The reaction by the competent authority to an application for and AIA or PIC within 90 days of receipt of the application, is based on Article 10(3)(a);(b); and (c) of the Biosafety Protocol.</p> <p>(c) <u>The information that the applicant must furnish when giving its notification/making application must be in accordance with the information to be laid out in an implementing degree. Again, unless such information is set out in an implementing degree, the provisions dealing with</u></p>

	<p><u>the AIA for imports and exports of GMOs will not be operational.</u></p> <p>(d) Very interesting, if after the 90 day period, no AIA or PIC is given, <u>the application shall be presumed to have been rejected</u></p> <p>(e) Additionally, section 43(2) requires that GMOs developed within Cameroon can only be exported from Cameroon if the competent authority in the country of export i.e. in Cameroon issues to whom it may concern, information attesting to the safety of the GMO concerned.</p>
<p>Decision-making-Precautionary Principle; Socio-economic considerations etc</p> <p>Cross-refer, comments on field trials (decision-making linked to the furnishing of a safety attestation after public consultation)</p> <p>Cross refer comments on general environmental release</p>	<p>No discreet mechanism exists in the Biosafety Law dealing with decision-making.</p> <p><u>Certainly, there is no provision requiring decision-making to be based on the precautionary principle. This is a fundamental and serious flaw of the law.</u></p> <p>Section 32 deals with socio-economic impacts but these are to be taken into account only, prior to a deliberate release into the environment of GMOs. In these circumstances, a thorough study of the ethical and socio-economic impact on the local population, taking into account a number of factors which is set out in the section. The study is to take into account a range of important issues. The study is to be funded by the user.</p>
<p>Accidental releases and emergency responses</p> <p>Part VI, Section 36 and 37.</p> <p>Read together with section 33</p>	<p>(a) Section 36 requires that before any GMOs can be introduced into the environment and before any activity can take place (as opposed to authorised), appropriate measures and emergency response plans must be put in place to properly manage accidents resulting from the deliberate or accidental release of GMOs.</p> <p>(b) The responsibility to do so is on the persons involved in the production, manipulation and marketing of GMOs in collaboration with the competent services. These services also involve authorities responsible for disaster management in the event of a disaster or imminent danger resulting from deliberate or accidental release representing a threat to human, animal or plant health, biodiversity and the environment.</p> <p>(c) In the event of a disaster or imminent danger as contemplated above, then the competent authority <u>may suspend the activity, including import and export of the GMO concerned pending investigation. The suspension of import/export of the GMO is welcome, but it is not mandatory and somehow, it does not resonate</u></p>

	<p>well with section 17, which requires the destruction of the GMOs in the event of risks to human, animal and plant health and to biodiversity. There is no coherency here, between these 2 provisions.</p> <p>Section 33 specifically requires that the competent national authority, in collaboration with other services concerned, apply emergency response strategies in the event of an accidental release and in order to reduce its socio-economic impact.</p> <p>Section 37 makes the user liable for any damage caused by the accidental release of GMOs.</p>
<p>Transit</p> <p>Section 48 read together with the provisions relating to containment and transport</p> <p>Cross refer section 14 (containment provisions; definition of containment in section 5(31) dealing with "containment level;</p>	<p>(a) Note: the provisions relating to authorisations (section 25) and risk assessment (section 20(1)) do not apply to GMOs in transit in Cameroon;</p> <p>(b) However, section 48 requires that:</p> <p>(i) there be prior informed consent before GMOs at transited through Cameroon (which is specifically excluded by Article 6(1) of the Biosafety Protocol;</p> <p>(ii) that the requirements pertaining "containment" and transport apply to the transit of GMOs (see discussion on contained use above and packaging below);</p> <p>(iii) that the exporter/importer ensure at its own expense, the inspection by the competent authorities;</p> <p>(iv) GMOs in transit can only remain in Cameroon for a maximum period of 60 days after which, they would be 'escorted out of the country" This time period is to be indicated on the documentation accompanying the GMOs.</p> <p>Additionally, transit conditions are contemplated to be introduced by way of regulations.</p>
<p>Liability and redress</p> <p>Chapter V sections 10 and 11 Definition of "user" section 5(47)</p> <p>Read together with section 37</p>	<ul style="list-style-type: none"> • The provisions in this section are flawed in law, and will have to be deleted and this section redrafted. Note, these provisions do not apply to products of GMOs. <p>(a) Section 10 read together with the definition of "user" places an unequivocal duty on the person (including companies) responsible for the development or preparation, production, experimentation, marketing and distribution of GMOs to be responsible for taking appropriate measure to prevent any negative impact on the environment that may result from the use and</p>

handling of GMOs.

- (b) However, liability for damage resulting **from the release of a GMO** is to be borne by the implicated user- section 11(1). "Release of a GMO" appears to be wide enough to cover "placing on the market of a GMO" **RECALL:** Section 37 also makes the user of GMOs liable for any damage caused by the deliberate or accidental release of GMOs. This section is under the heading "emergency response strategies".
- (c) **BUT**, section 11(2) absolves the user from liability for damage **from a use or release when GMOs are seized by an inspector or controller** in the event that certain offences are committed (in terms of section 56) such as non-respect for conditions, restrictions or directives of the Law is contravened or where there is a failure to provide information or any explanation to inspectors. Then in these circumstances, the user is only liable if the user "had anticipated or was in a position to foresee and prevent the damage, and had failed to take acceptable action to that effect"

Section 11 (1) and (2) have thoroughly confused the burden of proof required under the criminal law with strict and no-fault liability under civil law or delict when damages arise. In so doing, these provisions have thus made it possible for an anomalous situation to arise:

Strict liability will apply for any damage resulting from releases of a GMO. However, if an offence is committed in terms of section 56 the Act, and GMOs are seized, then strict liability will not apply, but fault based liability. It is also noted that the Biosafety Law does not deal with seizure of GMOs-only destruction of GMOs that poses a risk.

Additionally, the liability provisions do not cover:

- **Damage resulting from the development and handling; of GMOs;**
- **Redress.**

<p>Labelling (identification), packaging and marketing</p> <p>Chapter IV, section 49</p> <p>Cross refer, section 46 dealing with the labelling of transgenic material for research purposes</p> <p>Section 50</p>	<p>(a) Section 49(1) requires any GMO or products thereof intended for intentional release or marketing in Cameroon, to be packaged and labelled in order to safeguard ethical and cultural values and to avoid risks to human and animal health. However, the details regarding such labelling and packaging are not set out in the law.</p> <p>(b) In terms of section 49(2) <u>GMOs that are produced in Cameroon</u> and placed on the domestic market are required to be labelled as " product based on GMOs" or "contains GMOs". The section also stipulates requirements for packaging for GMOs to ensure that they are distinct. However, these provisions do not apply to products of GMOs!</p> <p>Thus, the placing on the market of GMOs that are imported will have to be packaged and labelled but not those produced in Cameroon.</p> <p>(c) Section 49(3) appears to deal with the documentation to accompany shipments and requires only that there be an attestation that the AIA has been complied with. Since the AIA procedure does not apply to GMOs, we can assume that this provision relates only to GMOs.</p> <p>(d) Section 46 deals with the transportation, handling and labelling of transgenic material between research institutions and contains several identification/labelling provisions as well.</p> <p>Sections 49(3) and 46 will have to be revised to come in line with the outcome of the negotiations under Article 18 of the Biosafety Protocol.</p> <p>There is a stray provision in section 50 dealing with the registration of commercial activities by the distributor of GMOs but this is to be done in terms of regulations that are in force. So until such time as these are promulgated, this section is inoperable. It is unknown what the status of such registration will be, and whether the public will have access to this information.</p> <p>The section also provides that all importers and commercial agents involved in the distribution of GMOs and products thereof, shall pay expenses whose amounts are to be fixed annually by the finance law. It is unknown what these expenses are meant to cover.</p>
<p>Transport, handling and packaging- Part IX</p>	<p>(a) Section 44 deals with the measure that a user is obliged to take regarding the transport and handling</p>

<p>Sections 44, 45, 46, 47 and 48</p>	<p>of transgenic animals, which are essentially designed to ensure that transgenic animals are not released into the environment.</p> <ul style="list-style-type: none"> (b) Section 45 deals with the measures that must be taken during the transportation and handling of transgenic insects-which are designed in principle, to prevent releases into the environment; (c) Section 46 deals with the transportation, handling and labelling of transgenic material between research institutions and contains several identification/labelling provisions as well. (d) The transportation of micro-organisms are to be in accordance with international norms in force (this will include the outcome of MOPI decisions under Article 18 of the Biosafety Protocol) <p>These provisions are welcome, especially since the Biosafety Protocol has not yet elaborated on handling and transport of GMOs.</p>
<p>Public Awareness, participation and consultation</p> <p>Sections 42 read together with Sections 20 and 25; Section 35</p> <p>Cross reference-Section 7 dealing with contained use-regarding the duty on the user to sensitise the local population of hazards posed by GMOs</p>	<ul style="list-style-type: none"> (a) Section 42(1) deals with public awareness and consultation, but it appears in the Part dealing with field trials. This section places an obligation on the competent national administration in collaboration with other services, to sensitise the public and to see to it that a "sufficient number of public consultations are devoted to the use, release, and placing on the market of GMOs and products thereof. See above. (b) Section 42 read together with section 20(1), makes it mandatory that for every application for a field trial, public consultation is required. No such corresponding provisions exist for releases into the environment for commercial growing. (c) However, the Biosafety Law does not stipulate any process for this public consultation, which is a serious omission. (d) Section 35 contains provisions dealing with public awareness, and creates obligations also for industry, which is worrying- (e) Section 35 creates a general obligation on the competent national administration in collaboration with other services to foster and facilitate sensitisation, education and participation of the public essentially on biosafety, but then it also creates an obligation for the person involved in modern biotechnology to "sensitise and educate the public on the risks and the benefits that such organisms entail." <p>The raising of awareness of the public is not the function nor duty of industry and certainly, it is out of place in a</p>

	<p>biosafety law, that industry is legally obliged to educate the public on the benefits of GMOs!</p> <p>This is certainly not in accordance with the provisions, spirit and intentions of Article 23 of the Biosafety Protocol.</p> <p>Note: Article 23(2) requires public consultation in decision-making.</p>
<p>Confidential Information and access to information</p> <p>Chapter VI, section 12</p> <p>Relevant other section: Section 42(1)</p>	<p>Section 12 of the Biosafety Law deals with confidential information only with respect to information obtained by an inspector/controller. It prohibits such persons divulging information obtained during the performance of duties under the law except</p> <ul style="list-style-type: none"> (a) if it is necessary for the effective implementation of the Law and its regulations (but who will decide this?) (b) when ordered to do so by a court for the purposes of legal proceedings; and (c) when the competent authority authorises it. <p>This section does therefore, not address confidential information <u>furnished by the Applicant/notifier to the competent authority</u> (See Article 21(3), (4) and (5) of the Biosafety Protocol.</p> <p>It does also not address the issue of public access to information that cannot be confidential information-such as the information stipulated in Article 21(6) of the Biosafety Protocol.</p> <p>There appears to be a huge legislative lacuna on these important issues, at least in terms of Biosafety Law.</p> <p>Section 42(1) obliges the competent national authority to 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. This is welcome. However, no provision has been made for this register to be placed in the public domain or to allow the public access to such register.</p>
<p>Offences and penalties</p> <p>Part X Section 56 (offences)</p> <p>Sections 60-64 (penalties)</p> <p>Section 65 out of court settlement</p>	<p>Section 56 makes it an offence when there is non-compliance with any condition, restriction or directive under the law; refusal to provide information or any explanation to an inspector etc.</p> <p>Section 59 deals with the process after an offence is committed. It appears that the matter first goes to the competent authority to adjudicate the matter, when an</p>

	<p>opportunity for settlement is also envisaged before the matter goes to court.</p> <p>The penalties for non-compliance are set out in section 65 and these are in 4 categories-the first being the most lenient and the last being the most severe. The first category deals with the violation of a safety measure, the second deals with violations of approvals, authorisations, notifications and emergency measures; the third, with putting GMOs and products thereof into dangerous use; and the last deals with offences related to micro-organisms. Second offenders are liable to twice the maximum penalties.</p> <p>Section 65 provides for out of court settlements-the competent authority is given powers to work out a settlement. These provisions are designed to allow the wrong doer to avoid a prison sentence since it promotes settlement by financial means only. These provisions will not serve as a deterrent to wrongdoers to abide by the provisions of the law as it undermines the "teeth" provide by way of penalties</p>
<p>Enforcement</p> <p>Section 57, 58</p>	<p>Sections 57 and 58 deals with the powers to enforce the provisions of the Law. However, enforcement officers can only be sworn in as such, in accordance with conditions laid down by regulation.</p>