NIGERIA'S NATIONAL BIOSAFETY MANAGEMENT AGENCY, ACT 2015

In Whose Interest?

-A Review

UNITY AND FAITH, PEACE AND PROGRESS

Nigeria's National Biosafety Management Agency, Act 2015 - *A Review* is a report by Health of Mother Earth Foundation (HOMEF).

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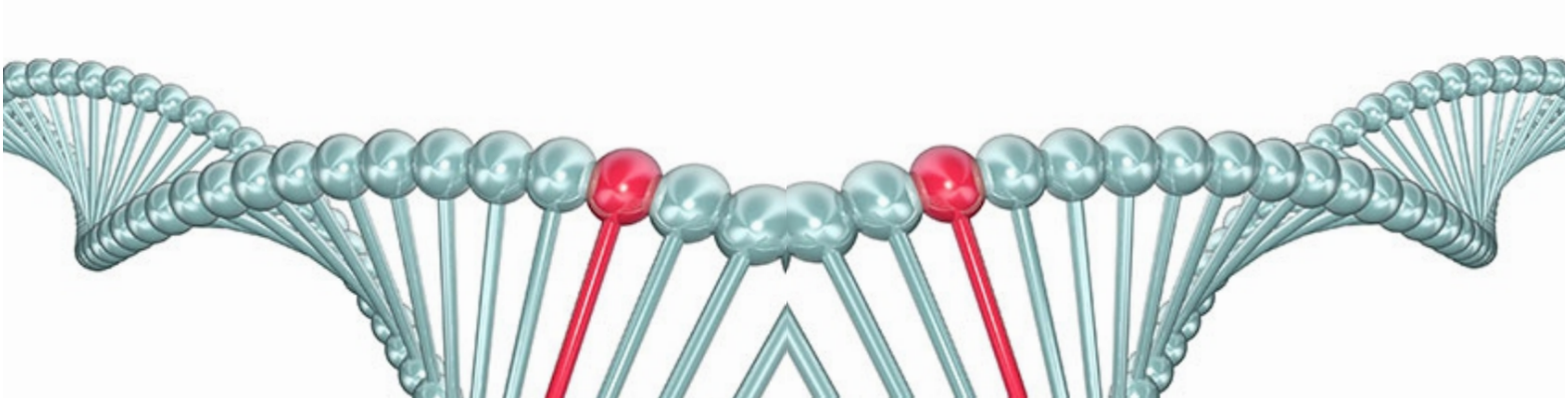
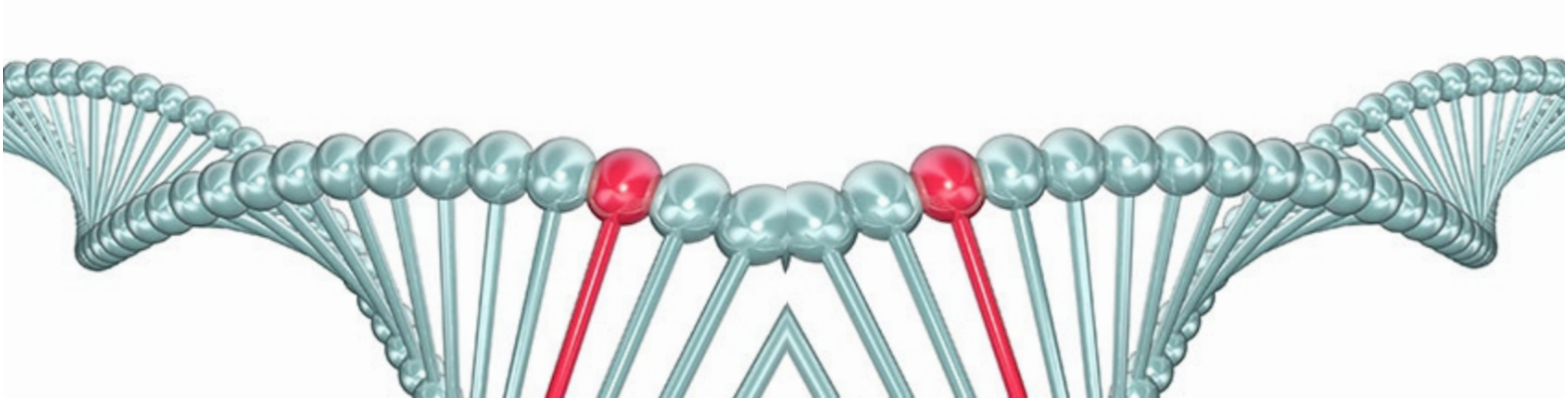
December 2015



About Health of Mother Earth Foundation (HOMEF)

HOMEF is an environmental/ecological think - tank and advocacy organisation. We work to bridge the yawning gap between policy/decisions made by governments and the actual needs at the grassroots. HOMEF recognises that policies are often top down and actions based on such can distort the possibilities of meeting actual needs.

We recognise that the global crises the world is experiencing have impacts on our nation and that these manifestations have systemic roots. Pressures on nations manifest in pressures on the environment and the current paradigm of development and growth based on competition will lead to the critical destruction of biodiversity and continued destructive extraction of natural resources, disrespect for Mother Earth as well as dependency on risky technologies.



CONTENTS

1.0 Introduction

The National Biosafety Management Agency Act, 2015, was signed into law in the last week of the administration of President Goodluck Jonathan. In spite of the far-reaching importance of biosafety matters to citizens of Nigeria, the process that led to the passage of the Biosafety Bill and its eventual signing into law was trailed by controversies and complaints from key stakeholders including farmers, consumers and civil society groups.

We note that with the coming of this Act, the issue of who regulates this critical sector has become more worrisome than ever before. This is so because public officials and agencies that should ensure the safety of our peoples and environment by ensuring sufficient safeguards are the persons and entities promoting the opening up of our environment to genetically modified organisms (GMOs) and, possibly other technologies, without regard to the precautionary principle.

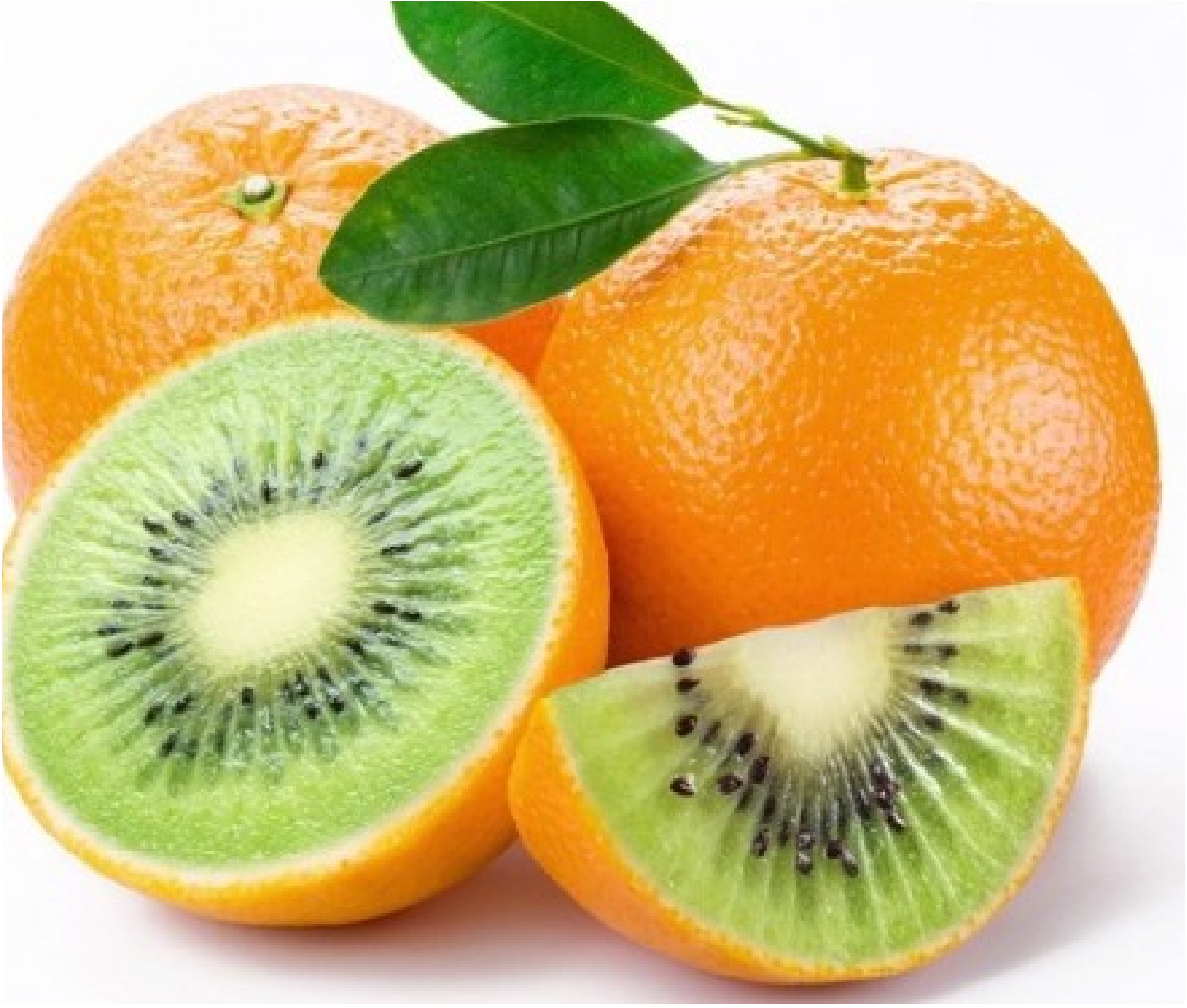
This report is a product of consultations with stakeholders and experts and presents a broad overview of GMO issues and a critical examination of the The National Biosafety Management Agency Act itself. It raises policy issues that would help in urgently improving the Act before harm is inflicted on our environment and peoples.

2.0 GMOs and the Quest for Nigeria

Genetically Modified Organisms (GMOs) are products of genetic engineering also known as genetic modification (GM). Genetic engineering or modern biotechnology is a technology that allows scientists to create plants, animals and micro-organisms by manipulating genes in a way that is not possible via traditional or natural processes. GM technology is not simply an extension of conventional agriculture as it is radically different from traditional plant and animal breeding.

Genetic engineering involves the artificial manipulation of seeds at the cellular level, and allows DNA from one type of organism (such as an animal) to be introduced into another unrelated organism (such as a plant). A fish and a tomato would not crossbreed in nature, but in the laboratory scientists can take a gene from a fish, insert it into a tomato, and essentially create an entirely new organism. The technology is not as exact as it may appear and results from genetic manipulation can at times vary vastly from intended outcomes. It should be noted that, usually it is genes of commercial interest that are transferred.

Once these man-made organisms are released into the environment and the food chain, they reproduce, contaminate natural varieties and cannot be recalled. And because the technology is fairly young, the long-term effects of GMOs on the environment are yet to be fully known.



The benefits of GM crops: what is real and what is hype?

Civil society groups in Nigeria and around the world have engaged in a thorough global evaluation of the performance and the impacts of GM crop releases around the world since 1996. These efforts have been aimed at providing an accurate picture of the global spread and impacts of these crops and organisms, and to help separate the hype from reality. Friends of the Earth International's reports titled "Who Benefits from GM Crops?"[1] help answer two crucial questions as to what benefits GM crops have brought to the world and for whom.

Since the introduction of genetically modified crops close to two decades ago the biotech industry has fought tooth and nail to ensure the spread of these crops around the world. This effort has not yielded the expected results because the crops have not provided the benefits touted by the biotech industry and because industry promoted hype has largely failed to convince both the farmers and the consumers.

1. FoEE. Who benefits from genetically modified crops? 30 April 2014 www.foeeurope.org/who-benefits-gm-crops-industry-myths-240414

Genetically modified crops have been withdrawn either due to safety and health concerns as well as for contamination. Examples include Monsanto's withdrawal of its genetically modified (GM) maize, LY038 in Europe due to safety concerns. Additionally, more than 1,000 farmers from Texas, Louisiana, Mississippi, Arkansas and Missouri, in the U.S.A, have sued Bayer AG, based in Leverkusen, Germany, for allegedly contaminating their farms with Genetically Modified (GM) rice seeds. [2]

2006 marked the fist time independent monitoring and testing was undertaken at the regional level by African civil society groups, which confirmed contamination of the food chain by GMOs in West Africa. This was with regard to release of unapproved Liberty Link Rice 601[3]. A round of monitoring activities was undertaken in Nigeria, Cameroon, Ghana and Sierra Leone by local chapters of Friends of the Earth Africa, after the US Department of Agriculture (USDA) revealed on August 18, 2006 that GM rice unapproved for human consumption had contaminated commercial rice seeds. The samples obtained in Africa were sent to an independent laboratory in the United States and tests confirmed the presence of the illegal GM rice in nine samples. These samples were from Ghana and Sierra Leone. A follow up testing in 2007 found the illegal rice in Ghana and Nigeria.

More than 15 countries in Europe identified the experimental GMO in their rice[4] supplies, and imports were tested to prevent further contamination.

2 IATP. US rice farmers sue Bayer CropScience over GM rice US Rice. August 28, 2006 .http://www.iatp.org/news/us-rice-farmers-sue-bayer-cropscience-over-gm-rice

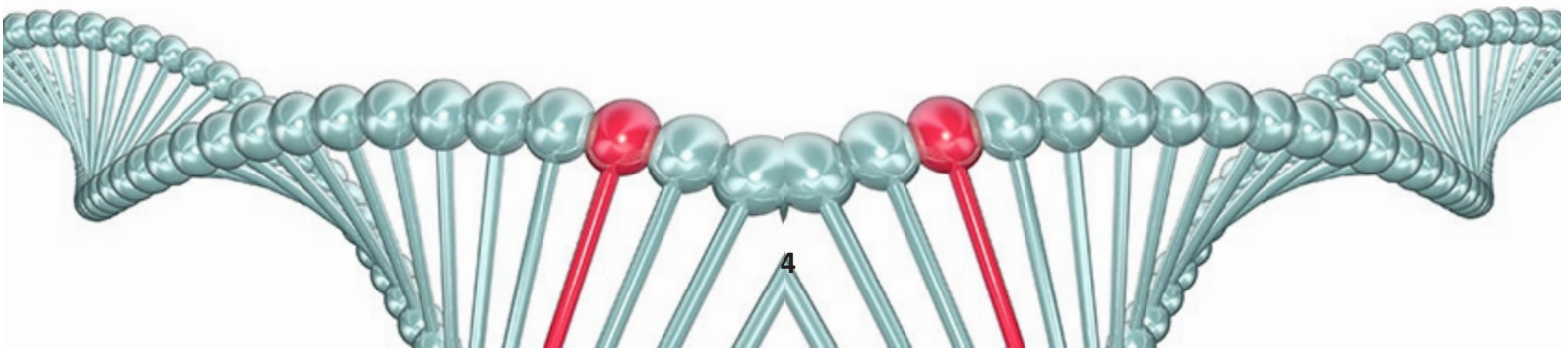
3 ACBio. African Groups Condemn US Decision To Authorize Illegal GM Rice Sent To Africa. Nov 4, 2006. http://acbio.org.za/contaminated-us-rice-must-be-recalled-from-africa/

ERA/FoEN. Open Letter to the United States Agency for International Development (USAID) and the World Food Programme (WFP): Africa Will Not Accept Being the Dumping Ground For GMOs : Contaminated Food Aid Must be Recalled From Africa. 4 December 2006 http://www.eraction.org/publications/open_letter.pdf

FoEE. West African food aid contaminated with GM rice24 November 2006 https://www.foe.co.uk/resource/press_releases/west_african_food_aid_cont_24112006

4 Lobbywatch. StarLink Genetically Engineered Corn in the Food Supply. February 16, 2005, http://www.lobbywatch.org/archive2.asp?arcid=4912 https://www.,humboldt.org.ni/transgenicos/denuncia_englishfeb16.htm ,

FoEI. GM Rice: a new threat to our food supply. September 2006 GM Rice: http://stopogm.net/sites/stopogm.net/files/GMRicethreatsupply.pdf



Mexico, Japan and several other countries around the world took similar measures with some suspending long grain rice imports from USA

The most dramatic GM crop failures have happened in the cotton-growing regions of India, where over 300,000 farmers have committed suicide. From reports, the farmers committed suicide after they became indebted as yields did not match their investment in procuring seeds and chemical inputs.

Commercial production of GM crops is largely confined to four crops: soya, maize, oilseed and cotton. Over 90% of the total area is in just six countries - US, Brazil, Argentina, Canada, China and India account of 95% of the area grown. When the biotech industry seeks to indicate the spread of the technology, the countries they classify as biotech mega-countries are those that have GM crops on up to 50,000 hectares of land. In 2008 it was reported by industry sources that 125 million hectare of GM crops were grown in world which amounted to just 2.6% of farmed land. It is important to note that the proportion of the world's farmers actively growing GM crops is about 1% (13.3 million as stated by the biotech industry out of a total of 1.3 billion).[6] The failure of Bt cotton to eliminate poverty among small-scale farmers in Makathini Flats, South Africa showed the limits of the push of this technology.[7]

The main conclusion of analysts is that modern biotechnology has not addressed the main agricultural problems and challenges facing farmers in most countries of the world and have not proven to be superior to conventional crops.
In addition, the great majority of GM crops cultivated are used as high-priced animal feed to supply rich nations with meats. To claim that GM crops hold the key to food security in Africa and to solving the hunger question is nothing more than industry hype and myth aimed at profit maximization.

More than four out of every five hectares of GM crops are engineered to withstand the application of proprietary herbicides sold by the same company that markets the GM seed, and have little of any relevance to farmers in developing countries who often cannot afford to buy these chemicals. Clearly GM crops today have not benefited small-scale farmers, which constitute the farming majority in Africa. [8]

ISAAA. Pocket K No. 16: Global Status of Commercialized Biotech/GM Crops in 2014. See at http://www.isaaa.org/resources/publications/pocketk/16/
ISAAA. Global status of Commercialized biotech/GM Crops ... – isaaa. January 2015 https://www.isaaa.org/resources/publications/briefs/.../isaaa-brief-41-2009.
GRAIN. Bt cotton in South Africa: the case of the Makhathini ... - Grain - April 2005 https://www.grain.org/.../492-bt-cotton-in-south-africa-the-case-of-the-m..
ACBio. Cottoning on to the lie: the introduction of genetically modified cotton in Africa will harm, not help, smallholder farmers. June 2015 http://acbio.org.za/wp-content/uploads/2015/06/GM-Cotton-report-2015-06.pdf
FoEI. Who Benefits from GM Crops? - Biosafety Information Centre. January 01, 2007

It is instructive to note that recently a total of 19 European Union countries have opt-out of growing genetically modified crops within all or part of their territories.[9] Scotland government has just banned GM crops. Scotland banned the growing of Genetically Modified (GM) crops in an effort to preserve its "clean, green status" as announced Rural Affairs Secretary Richard Lochhead.[10]
Also Wales and Bulgaria had also joined the massive EU waves of GMO bans. [11]

Recently, the Burkina Government took a bold step to ban GM Cotton in Burkina Faso.[12] When Nigeria pushes for genetically modified crops, one crop they try to push is Cotton and they often cite the example of Burkina Faso as having made giant strides with the technology. Instead of becoming rich as proclaimed by promoters of the technology, farmers in Burkina have come to the realisation that the BT Cotton brought them less productivity and less income than their traditional cotton varieties. The Burkina Government has now taken the bold step to ban GM Cotton in Burkina Faso. This is a clear indication that Nigeria cannot afford to gamble with this clearly failed path.

The Nigerian Market

Nigeria is the most populous country in Africa with an estimated population of about 170 million. It accounts for close to 50% of the West African population. With this numerical strength the biotech giants no doubt imagine that Nigeria is the market to grab for its GM products. In a report by the USDA Foreign Agricultural Service titled “Nigeria Biotechnology Agricultural Biotechnology 2007,” Nigeria was said to be “a food deficit country,” and imported about $3 billion worth of agricultural commodities in 2006. A mere importation of food items does not necessarily amount to food deficit? There is no country in the world that does not import some foods for one reason or the other. It does appear that all the USDA was trying to say was that Nigeria is facing a food crisis and that the biotech industry has answer the food question in Nigeria.

9 www.biosafety-info.net/article.php?aid=423
Ecowatch. It's Official: 19 European Countries Say 'No' to GMOs. October 5, 2015
http://ecowatch.com/2015/European-union-ban-gmos/

10 Jurist. Scotland government bans GM crops11 August 2015
http://jurist.org/paperchase/2015/08/scotish-government-bans-gm-crops.php
http://ecowatch.com/2015/10/01/wales-bulgaria-gmo-bans
12 GM Watch. Burkina Faso dumps GM Bt cotton - GM Watch Jun 9, 2015
www.gmwatch.eu/news/latest.../16219-burkina-faso-dumps-gm-bt-cotto
Natural Society. West African Country Dumps Monsanto's GM Cotton, Seeks Compensation Joining the expanding list of GMO rejections. June 10, 2015 : http://naturalsociety.com/west-african-country-dumps-monsantos-gm-cotton-seeks-compensation/

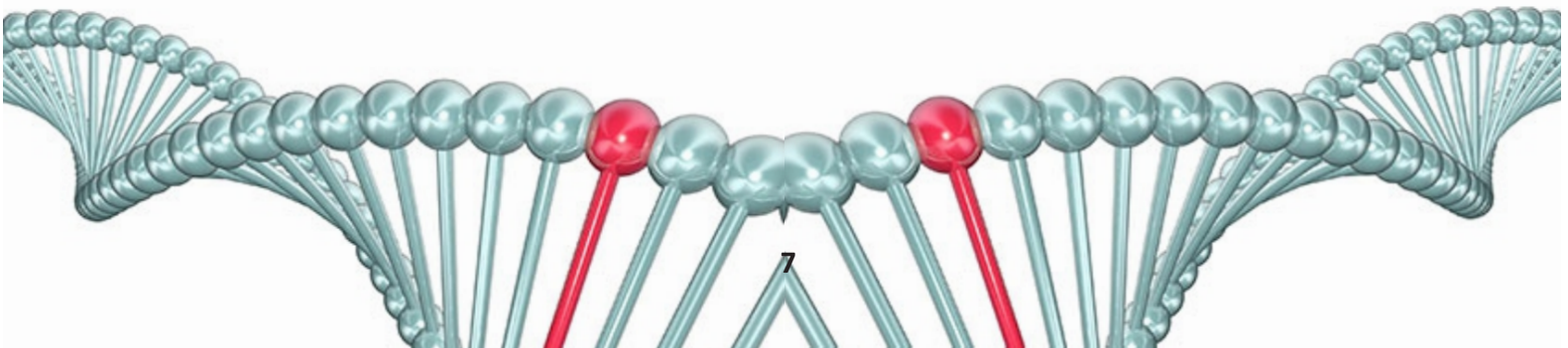
The dispute over hunger, malnutrition and GMOs has been made on many fronts in the past. The clearest case of resistance was recorded in 2002 when Zambia refused GM maize as food aid through the World Food Programme (WFP).[13] Zambia firmly rejected GM maize and did eventually overcome the food crises without succumbing to the pressures of donors who insisted that a hungry man had no choice. Zambia raised the banner of dignity and sovereignty on behalf of our Continent. The World Food Programme was surprised that any one raised issues with the GM food aid, because they had been giving out GM grains in food aid without questions in the past. The truth is that there is always a beginning of demands for accountability and for doing the right thing. For Africa, Zambia led the way.

Later on, in 2004 both Angola and Sudan came under intense pressure to accept GM maize when they faced food shortages. These nations insisted that if they were to accept GM maize they had to be milled and not whole grains. The obvious reason was that whole grains would inevitably be planted and would contaminate the environment.

It is also instructive to note that The Danforth Center made it public knowledge that "We need to start making plans for how these product developments are going to be carried out in four countries of interest and how these products are going to meet the regulatory requirements of those countries." They were simply looking for countries that have big markets for their products. Nigeria, one of the world's largest producers of cassava tubers - with over 34 million metric tons produced annually since 2004 and consumed by millions of people, became their spot.[14]

The systematic attempt by this Center to break down Africa's regulatory resistance to GM crops received a boost when on the 9th of January 2009, the Bill & Melinda Gates Foundation awarded the Donald Danforth Plant Science Center a $5.4 million grant.[15] According to the report "the funding will help the centre secure the approval of African governments to allow field testing of genetically modified banana, rice, sorghum and cassava plants that have been fortified with vitamins, minerals and proteins. These crops are mainstays in the diets of millions in developing countries around the globe."

13 BBC NEWS | Africa | Famine-hit Zambia rejects GM food aid: 29 October, 2002
http://news.bbc.co.uk/2/hi/africa/2371675.stm;
BBC NEWS: Zambia refuses GM 'poison'eptember, 2002
http://news.bbc.co.uk/2/hi/africa/2233839.stm
The Economist.
Better dead than GM-fed? | Sep 19th 2002|The Economist
http://www.economist.com/node/1337197
14 The Green Room. "Gates Foundation Funds Lobbying for Gm Crops for Africa," Friday, 9 January 2009.
http://theonlygreenroom.blogspot.com/2009/01/gates-foundation-funds-lobbying-for-gm.html,
http://www.seattleg lobaljustice. org/agra- watch
15 ibid



Two critical crops have received intense attention by the biotech industry in Nigeria: cassava and cowpea. Experimentations and field testing have been carried out on these crops and perhaps others too, with no public information on outcomes or next steps. Are Nigerians being fed with GM crops already with no prior information and no option of choice?

Nigeria does Not Need GMOs

Efforts to introduce GMOs into Africa have made rather sluggish progress, to the chagrin of the biotech industry. Efforts through food aid and small-scale farmers have not yielded much fruits. Current efforts are being made through the concept that Africans lack key vitamins and that children are malnourished stunted and prone to becoming blind. The idea being sold is that nutrition is a product of the laboratory. To say that this is a false platform is to say the obvious. Sadly, many African countries have signed up to the concept [16]as well as accepting uniform seed laws to which they were not parties in their negotiations.

It is important that government respects the right of peoples to define their own food and agricultural practices and choices. The experience with the commercialization of GM crops abroad and its failed promises clearly show that it will not be in the interest of our people to accept GM crops in our country.

16. Kirtana Chandrasekaran and Nnimmo Bassey. 7 June 2013. G8's new alliance for food security and nutrition is a flawed project. London: The Guardian. http://www.theguardian.com/global-development/poverty-matters/2013/jun/07/g8-new-alliance-flawed-project

It will be problematic to our agriculture and land tenure systems. We call on our government to be conscious of the fact that the future is assured only by sustainable agricultural practices. Such will not be found in the laboratories of profit-driven biotech industry.

In April 2008, the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD),[17] made up of over 400 scientists and development experts, published its report based on 4 years of deliberation and scientific, social science and economic analyses. The report's key findings, amongst others, called for far greater emphasis on agro-ecological approaches to food production. IAASTD concluded that feeding the world will continue to be by smallholder farmers and not through industrial agriculture. It stated that the place of modern biotechnology would be minor.

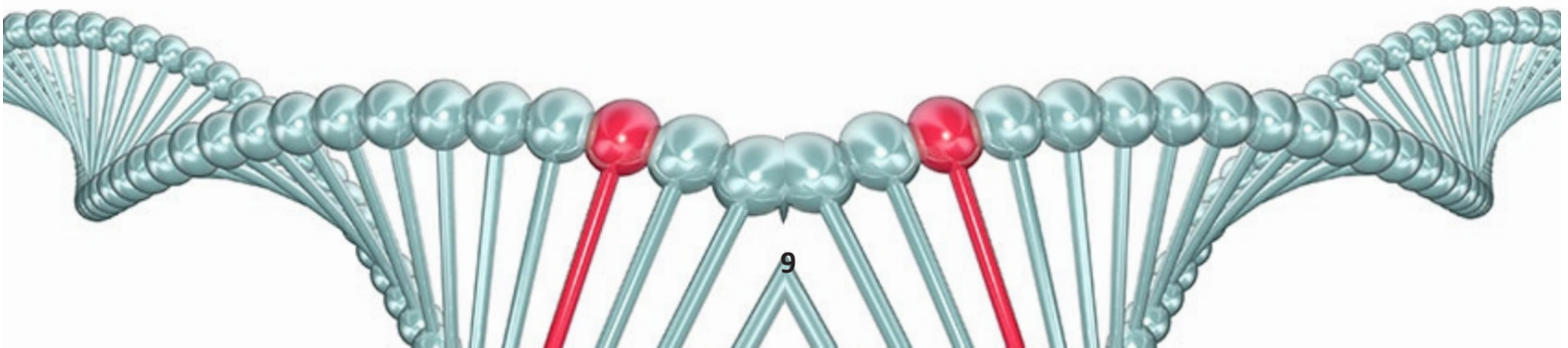
GM crop proponents including the USDA are urging Nigeria to double its "efforts to fast-track the creation of an enabling environment for biotechnology" in other words accelerate the development of their biosafety laws" to allow the introduction of GM products in our country.[18] Biosafety laws are made to regulate GMOs, and to assess comprehensively the environmental, health, socioeconomic, and cultural impacts of the introduction of GMOs before making any release or acceptance of an imported GM product the result of such rules includes the right to say no and to ban and restrict GMOs.

What Nigeria needs is a strict Biosafety law and this should best be based on the African Model Law as the minimum standard. With this in mind, this review/memo and our comments on the Nigerian Biosafety Management Agency Act 2015 is a means of encouraging our Legislators and Government to take a critical look at the current Act and to act as necessary, to comprehensively review it and ensure that Nigeria does not become a laboratory for the testing of unproven technologies and/or a dumping ground without recourse to the precautionary principle.

The bottom line is that the interest of Nigerians must be uppermost in issues of biosafety and corporations and multinational companies should not be allowed to dictate corporate-driven food and agricultural policies that undermine sustainable agriculture and our food future.

17. IAASTD. Agriculture Crossroads Agriculture Crossroads - UNEP . 2009 http://www.unep.org/dewa/agassessment/reports/IAASTD/EN/Agriculture%20at%20a%20Crossroads_Global%20Report%20(English).pdf

18. Mariann Bassey Orovwuje : Nigerian biosafety bill: in whose interest? 15 June 2011 http://www.gmwatch.org/component/content/article?id=13254Emeka



3.0 Comments on Nigerian Biosafety Management Agency Act 2015

The sections referred to in the comments hereunder are those of the Nigerian Biosafety Management Agency Act, 2015. For ease of reference we have appended the Act to this review.

3.1 General Comments

The National Biosafety Management Agency Act seems to have been drafted in a hurry. It seems as if the intention of the Nigerian government was to just get the Agency up and running in order to enable the Agency to put in place a biosafety regime. Enormous amounts discretionary powers have been vested in the Agency with not enough mandatory duties in the operational provisions to ensure that the Agency will perform a stewardship role to ensure that GMOs do not pose harm to human and animal health, society and the environment.

The Act has a number of grammatical errors and evidences sloppy drafting. In fact, some provisions do not make sense at all and in other places, references are made to the incorrect sections and to sections that do not in fact exist. The Act can, however, only come into effect when a number of measures are in place, including, regulations, criteria, plans and strategies relating to the application process, risk assessment and management and decision making. Much work will therefore have to be done to fill the many gaping holes left in the law. This should deal with at the very least the following:

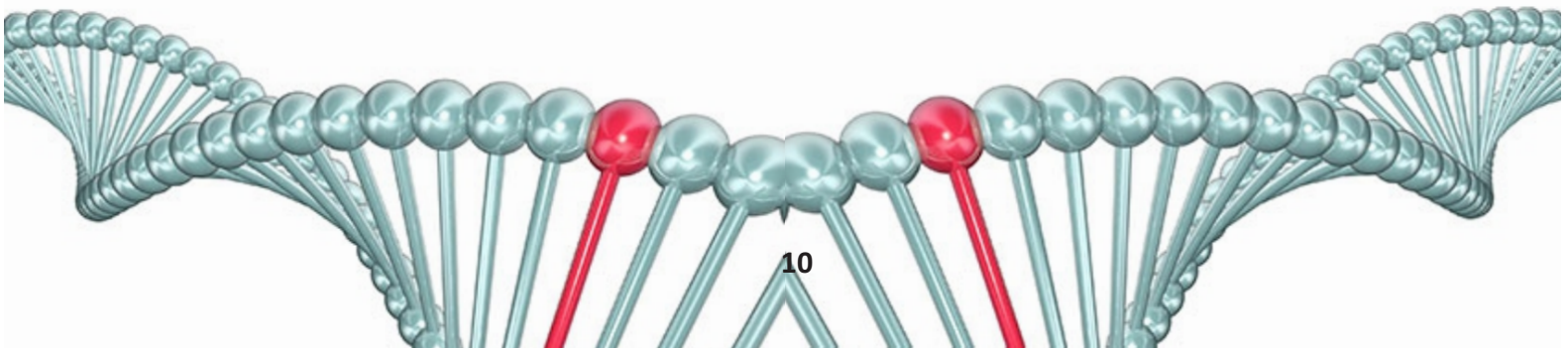
- Access to information;
- Public consultation and participation
- Liability and redress
- Labelling and the right to know
- Decision-making; and
- Appeals and reviews.

Overall, we think there are serious deficiencies with the absolute decision making power of the Agency, with insufficient checks and balances, which should be built in.

There is also a lack of clarity with regards to the different procedures, if any, for GMOs for planting, Living Modified Organisims for Food or Feed, or for Processing (LMO-FFPs), GM pharmaceuticals, GM animals, GMOs in industrial use etc. At least we still a bit confused about it.

Food safety, which is a very important issue, is only addressed in one provision, which gives the power to the National Agency for Food and Drug Administration and Control. This needs to be rectified.

There is a lot of inconsistent use of language and different articles do not fit together.



Section 10 (1) (d) The Composition of the Governing Board is arbitrary. We have representatives from the private sector, National Biotechnology Development Agency (NABDA), Industry, Trade and investment and the Biotechnology Society of Nigeria.

Why should they be part of the Governing Board, when it is really their conduct, their technology and products the law is aiming to regulate? We believe that this is setting the stage for conflict of interest. Industry, Trade and Investments, Biotech Agency and Biotech Society people are not the best regulators here.

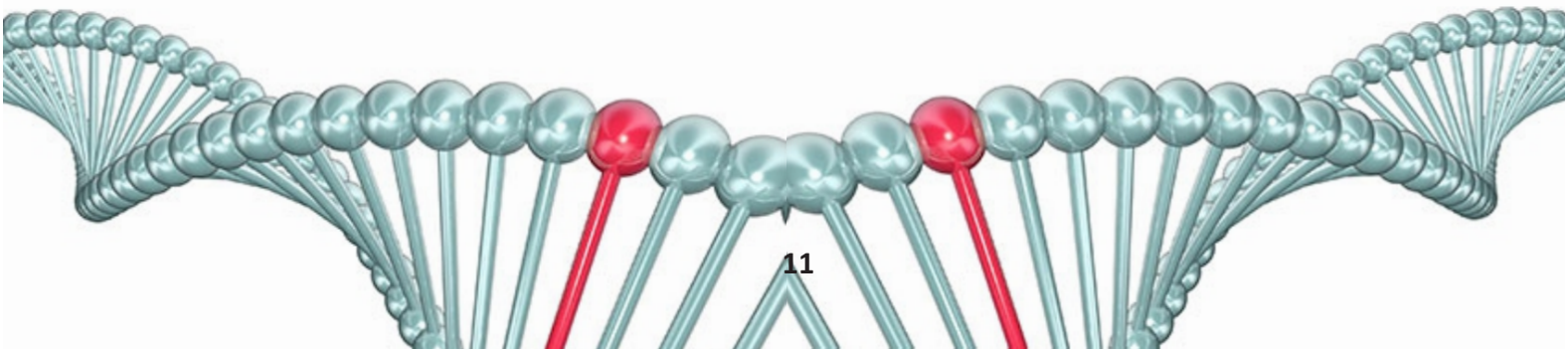
We also believe that having only ONE representation from the NGOs is not sufficient. There is also a proviso to the NGO representation, the only group given a clause. The Board is more political and cannot have only one NGO representative because it is against the public participation that the Act promotes in theory. We also object to the exclusion of representatives of farmers and consumers in the Governing Board. It is critical to ensure participation of farmers, because they will be the prime target, they should be "saved" according to the biotech industry.

Section 18 sounds weird.
Is there any example in another law in Nigeria where a Government Agency could receive gifts such as land without at least a direct linkage to avoid conflicts of interests etc?

Section 26(1): We are taken aback by the use of the verb “may” instead of “shall” in some sections of the Act, especially as it has to do with Public Participation. There is a big difference between what is legally binding for the authorities and what is not. It is of great concern to us that the Agency 'may ' decide to hold public hearings or consultations to obtain comments. We propose that the right word to use here is “shall" because holding public hearings should not be optional. Furthermore, the paragraph should state that this has to be taken into account.

Our proposed clearer language setting the obligation to consult the public is the following: “The Agency shall consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, the Agency shall lay down arrangements for this consultation.

We are worried with the discretion given to the Agency in section 25(2) to decide whether or not public notices will be published in national and local newspapers. These sorts of publications must be the basic minimum provisions in the context of public participation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion. '21 days' as stipulated under section 25(1) of the Act do not give enough time to the public and interested bodies to comment. More so, section 25 needs to state when the information needs to be made public, not only how much time is there for.



The provisions in section 24(1) give the impression that unless risk to human and animal health is 'substantial' it can be accepted. What is substantial risk in this context? This is at odds with the underpinnings of the precautionary principle and should be changed; otherwise this may open the floodgates to LMO-FFP approvals.

Section 31(2) could be a killer article because it seems to be sure that all risk assessments by foreign companies and institutions will be carried out outside of Nigeria.

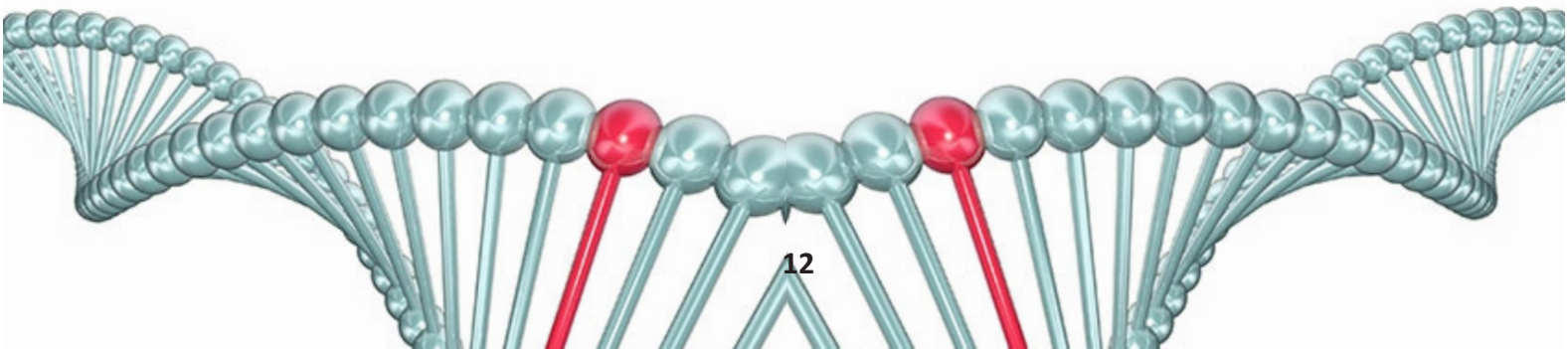
It is obvious from a cursory look at the Nigerian Biosafety Management Agency Act, the debate on whether or not GMOs are an appropriate development or intervention appears to be over. The general tone of the Act is clearly set for GMOs and products of GMOs imported for direct use as food, feed and industrial processing. This has been singled out for special consideration, as if Nigeria anticipates that this area will see the most activity in Nigeria. The starting point for us on this ACT should be to have a national discussion on the Big Question: Do Nigerians want GMOs or not?

The standard of liability and redress used in section 41(1) a) is fault-based. We would recommend a standard of strict liability, which is the standard in the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and in line with the Precautionary Approach. Fault-based liability requires a higher burden of proof, and could make it difficult for liability to be established. Note that this provision envisions that liability for GMOs will be dealt with by regulations, and through existing laws, not a specific liability and redress law

Liability and redress issues are very vital to any biosafety regime and this whole concept is omitted in this Act. There is no mention of liability in case damage arises from the release of GMOs into the environment even though they were considered safe and authorized at the time of the release. Who will be liable if damage arises from GMOs in the future from authorized products?

Another unacceptable provision under the Act is Section 30(1) only an aggrieved applicant is given the right to appeal against a decision of the Agency. No similar right is given to interested and affected parties who may be adversely affected by a decision. These provisions should be redrafted so as to enable interested and affected parties to appeal against approvals.

This ACT has to truly travel a Nigerian journey without any external interference. It must be a Law for Nigerians and by Nigerians. To this end we are asking that:
The Nigerian National Biosafety Management Agency Act has to be substantially reworked and amended to capture the concerns articulated in this Notes, otherwise it is patently unacceptable otherwise.



3.2 Specific Comments

PART I: ESTABLISHMENT OF BIOSAFETY MANAGEMENT AGENCY

Objectives of Agency

Objectives of Agency as set out in section 2, are couched in peremptory language: "shall."

Section 2(b) should refer also to animal health. Also the wording of this section is not consistent with the protection goals contained in other articles as for example at sections 28 (d), 29 (a), 31 (1), 34 (b) & (c). Biodiversity seems to be the better word because other texts such as 'plants and animals' do not include microorganisms

Section 2(d): It is interesting to note that one of the things the Agency must do is to provide measures for the case-by-case assessment of GMOs. Care should be taken that this does not imply that harmonised biosafety rules where a decision on the safety of a GMO in one country can be relied on by other member states to these rules such as Nigeria, will not be able to be applied. Moreover, it is one thing to provide for these measures and quite another that these measures are applied to GMOs.

In **section 2(e)** it should be clarified whether this provision will be broadly interpreted to include public participation in the processes involved in:

(i) Development of measures;
(ii) Criteria for risk assesment peer review;
(iii) Criteria for decision-making;
(iv) Risk assessment plans and strategies
(v) Monitoring protocols

We note the references made to "any potential adverse effect," "holistic approach" and "does not have adverse impacts on socio-economic and cultural interest either at the community or national level " in sections 2(b), (c) and (f) respectively. These are fair.

It is not at all clear how the Act intends to resource the plan to monitor human health and the environment to 'determine the effects of GMOs.' (section 2(i)). A lesson from South Africa is that despite growing GMOs commercially for around 17 years, the government has only carried out an assessment of the impact of GMOs on the environment in 2010/2011. This was done more than 10 years after GM crops were grown in that country commercially.[19]

19. ACBio. Sanbi Study Raises Environmental Concerns with GMOs. Jan 31, 2011. See http://www.acbio.org.za/index.php/media/64-media-releases/343-sanbi-study-raises-environmental-concerns-with-gmos

PART II FUNCTIONS AND POWERS OF THE AGENCY

Section 3(e) refers to 'public enlightenment programmes on biosafety' this phrase should be redrafted because it gives the impression that the public is misinformed about the risks posed by GMOs. This is clearly a line often touted argument by the pro-GMO machinery and should be eliminated from the Act. We propose a better wording thus: “to ensure mechanisms of public participation in decision making.”

Section 3(d) “develop measures, requirements and criteria for risk evaluation, peer review and decision-making;” The word "evaluation" should be replaced by "assessment" each time it appears in this document to ensure the consistency of the text.

Section 3(h) states (h) take samples and carry out laboratory analysis of crops, products or materials for purposes of determining if they contain genetically modified organisms and ensure compliance with this Act;

This should be reviewed to read:
(h) take samples and carry out laboratory analysis of genetically modified organisms, products or materials for purposes of determining if they consist of genetically modified materials or parts and ensure compliance with this Act;

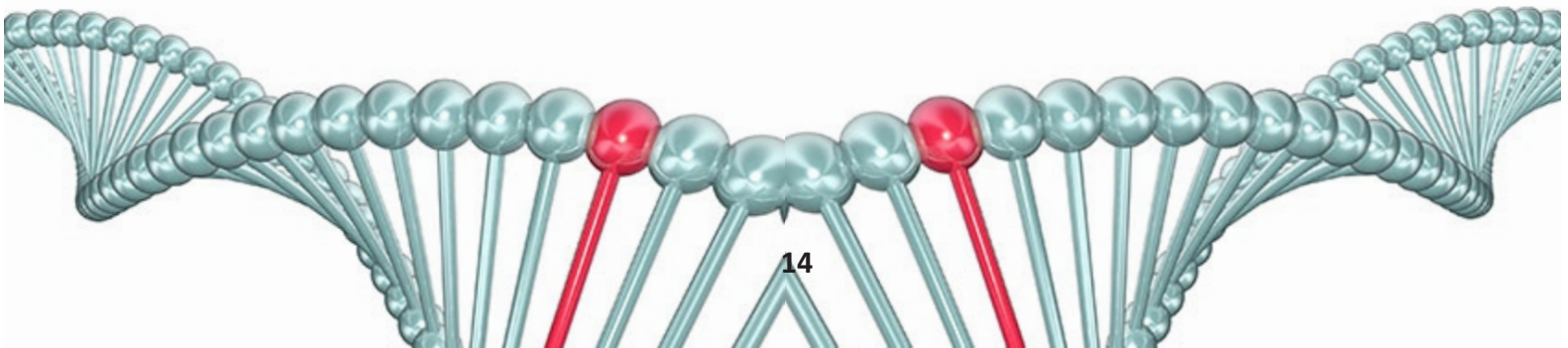
This revision is essential because the Act is concerned with all GMOs and not just crops. It will also help to clarify testing of genetically modified materials and products

Section 3(o) Should specify whose capacity is to be built. It is nebulous to merely state “carry out capacity building activities.”

PART V - ESTABLISHMENT OF THE GOVERNING BOARD

Section 10(1) (viii) 10 (d) 10 (e) includes a representative from the National Biotechnology Development Agency (NABDA), Biotechnology Society of Nigeria, the Private Sector. Meanwhile there is no place for a representative of farmers' organisations. We object to having **promoters of GMOs as part of the governing body as they cannot be both promoters and regulators at the same time.** Placing them in this Board prepares the grounds for conflict of interest. In addition, the private sector should not be represented on the Board, as the private sector is the entity being regulated by the Act for activities relating to GMOs.

We strongly recommend that the Board should include a representative from a small farmers' organisation instead.
In terms of NGO representation, we belie that specifying “conservation NGO” is not good enough. It would serve the interest of the Act better to have a slot for NGOs knowledgeable on biosafety issues or that represent consumers.



Section 11 deals with the cessation or removal from office of a member of the the Governing Board and needs to include a clause dealing with conflict of interest. In particular, it should exclude any member from participating in any GMO application where the person has a direct or indirect interest in the successful outcome of the application. Such a provision can ensure confidence in the regulatory system.

Section 12: There must be a paragraph requiring the declaring of conflict of interests. We propose the following:
"If a member of the Board is personally or institutionally involved in a specific application, this member cannot participate at the assessment process."

PART VI - FUNCTIONS AND POWERS OF THE BOARD

Section 13: There doesn't seem to be decision-making powers vested with the Board. Everything is vested with the Agency. This does not ensure an appropriate balance. We propose that key decisions of the Agency should require an endorsement by the Board.

PART VII- FINANCIAL PROVISIONS

Section 18(1): The Agency is setting itself to receive gifts and to be lobbied and thereby bow to the gift giver.

Section18 (2) sets out the conditions under which gifts may be accepted. Even if the terms and conditions are consistent with the Agency's functions under the Act, there are insidious ways by which such gifts may unduly influence decision-making.

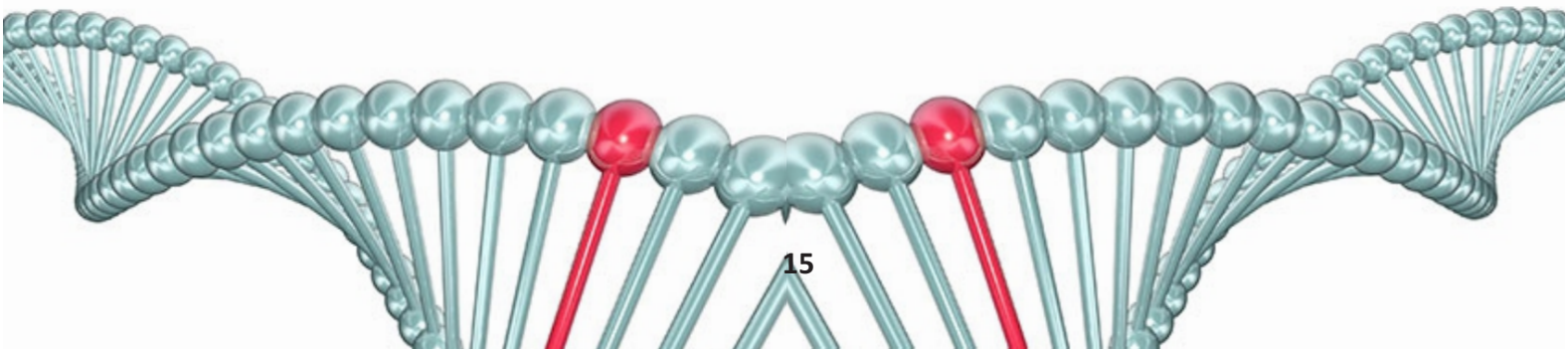
The entire Section 18 should be expunged from the Act.

PART VIII- REQUEST AND AUTHORISATION

Section 22 & 23: It is not known why the application for authorization is linked to the commencement of an activity. This is not relevant. What is relevant for the purposes of implementation of the Biosafety Protocol is the time frames within which a decision is to be made after an application is submitted.

Section 22: This section needs to be reviewed to cover every unauthorised imports, trails or commercial release of GMOs.

We agree that no legislation should operate retrospectively, but what legislation did the biotech promoters use to have authorised the field trials and multi-location trials underway in Nigeria? This section does not also contain a reference to “commercial release” and the sentence is not complete. It should refer to GMOs.



Section 23(1): This needs to read **confined** and not **contained** field trial.

Although Section 23(1) refers to commercial release and to GMO, the way it is formulated is rather convoluted because a host of activities are listed, 'including, import, export, transit, contained field trial, multi-locational trial or commercial release" of a GMO in respect of which authorisation is required. However, it then goes on to saying, "shall apply to the Director General of the Agency not less than 270 days to the date of the import, export, transit of the commencement of such activity." It is essential that the word "planned" be inserted before "date" in the above section. The Act should clearly refer to an application for a planned activity, not an already determined activity.

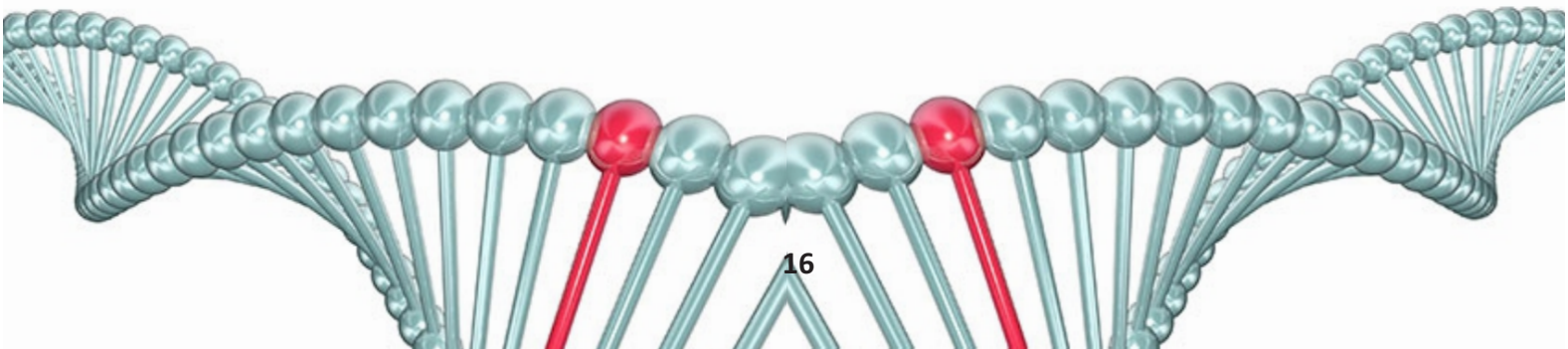
Section 23 (2) (g) an emergency response plan should also be included. Secondly, this management plan should include human health as indeed protection of human health is in the objectives. Section 23(g) read together with sub sections (a) and (b) these provisions are linked to the taking of remediation measures in the event of escape of GMOs from contained use and confined field trial facilities. Knowing that what will be required are emergency plans and not only remediation measures because the GMOs could also affect human and animal health, this clause should be amended accordingly..

Section 23(h): When GMOs are released or are marketed, these GMOs are then available for consumption and for planting. Thus, remediation measures are not sufficient to address what may occur as a result of adverse impacts on human and animal health. Again, we propose the replacement of **remediation** plans with **emergency plans**.

Section 23(2)(b): This section refers to risks that may be posed by genetically modified organisms. We do not see the need for referring to "organisms" in plural in this section because, in many cases the application would only cover one organism. Also the words "if any" is a pre-judgement and should be removed, as the purpose of each test is to find out if a GMO poses risks to human and animal health and the environment. Every activity has a level of risk and GMOs are not exempted.

The information needed for the activities to be conducted in terms of section 23(1) is set out in section 23(2). The information mentioned in section 23(2)(a)-(g) appears to still be provided for in guidelines and policy documents. **If this is the case, then the Act cannot be implemented until these are in place.** In any event, specific references are made to a risk assessment indicating the potential risk, if any, the GMO may pose to human health including food safety, biological diversity, or the environment including the consequence of an unintended release.

Section 23(3) contains an interesting provision to the effect that the Agency is required to set forth requirements for each activity with GMOs to determine the level of potential risk posed by such category of activity in accordance with the First Schedule. We are not entirely sure what the legal consequence of section 23(3) really is. It does appear to convey the notion that the Agency



is required to pass secondary legislation which sets out specific requirements for each and every activity required to be permitted (e.g. for import, export, transit, contained use, confined field trial and commercial release). If this interpretation is correct, then it appears as if such secondary legislation may first have to be promulgated before the permitting system established by the Act can come into force. Otherwise these may sabotage the Act itself.

Section 24(2): This section is very subjective, and without clear guidelines on what is a 'substantial risk.' The provisions here convey the notion that risk to human and animal health is acceptable unless the risk is substantial. What is substantial risk in this context? This is at odds with the underpinnings of the precautionary principle.

Also there is something wrong with the sentence 'Food and feed products are meant to be eaten.' This expression sounds awkward. The avoidance to be eaten is not the outcome of any established risk assessment methodology. The result of a risk assessment is usually characterised as "there is no / no significant / a small/ etc. risk of xxx to the environment / human health," etc.

Furthermore, on 'risk assessment,' we would recommend that this Act be compared with the recommendations of CODEX with regard to risk assessment of GE food. Nigeria should implement these recommendations although they are not legally binding.

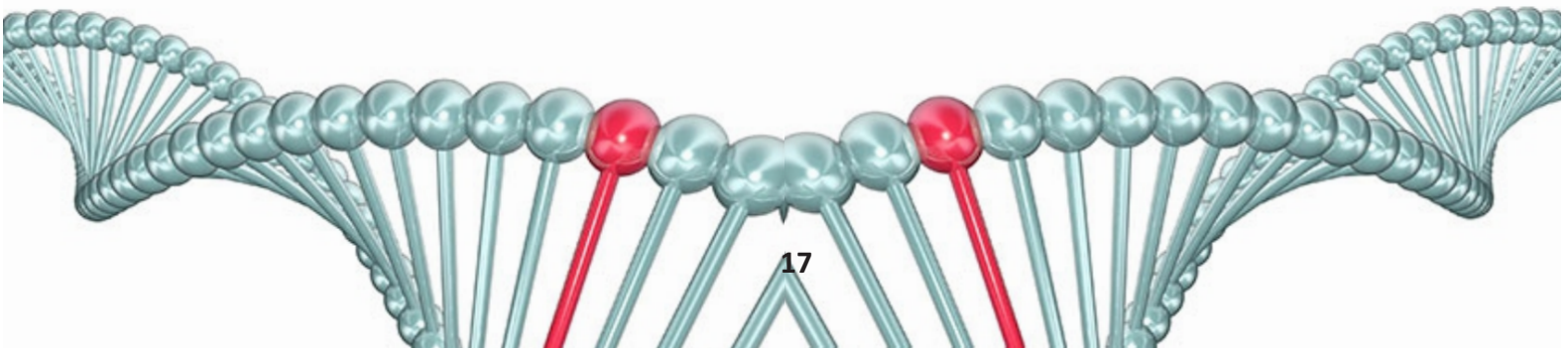
Section 24 (3): The inclusion of socio-economic considerations here is good. But there is no similar provision under Section 23, and should be included there especially as release of a GMO that is planted will have socio-economic impacts on farmers.

Section 24(4) It is not clear what analysis referred to here. 24(3) does not speak of 'analysis' . Also the Act for the first time talks of 'benefit assessment ' although the other article before covers risks but not benefits, see 2(f) of the Act for example

Section 24(5) this is a very important task, and is determined entirely by the food authority. More safeguards and detailed requirements etc. are necessary.

Section 24(1) deals with the need for approval from the Agency in respect to a GMO or the product of a GMO intended for direct use as food, or feed or for processing.

This relates to importation of live GMOs (GM grain, usually in bulk shipments) as well as products from such live GMOs. The information that the applicant has to provide has to be in accordance with the First Schedule, which deals with marketing information and labelling. Section 24(2) requires a safety risk assessment, and provides that authorisation may only be granted



if there is no substantial risk that the GMO ***could be eaten by humans or animals***. It is difficult to understand this provision read together with section 24(1). If it was a provision relating to experimental use of GMOs, it could then be understood. However, Section 24(3) appears to be referring back to a commercial release of a GMO and requires an applicant to address the socio-economic considerations set out in the Third Schedule.

PUBLIC DISPLAY OF APPLICATION

The provision on public information and consultation is very important, as it will be the main avenue for NGOs to ensure biosafety. However, the provisions in this Act are weak and has lots of 'may's. More detail about how the agency should do this, and stronger language would help. In the Cartagena Protocol public information and consultation are mandatory.

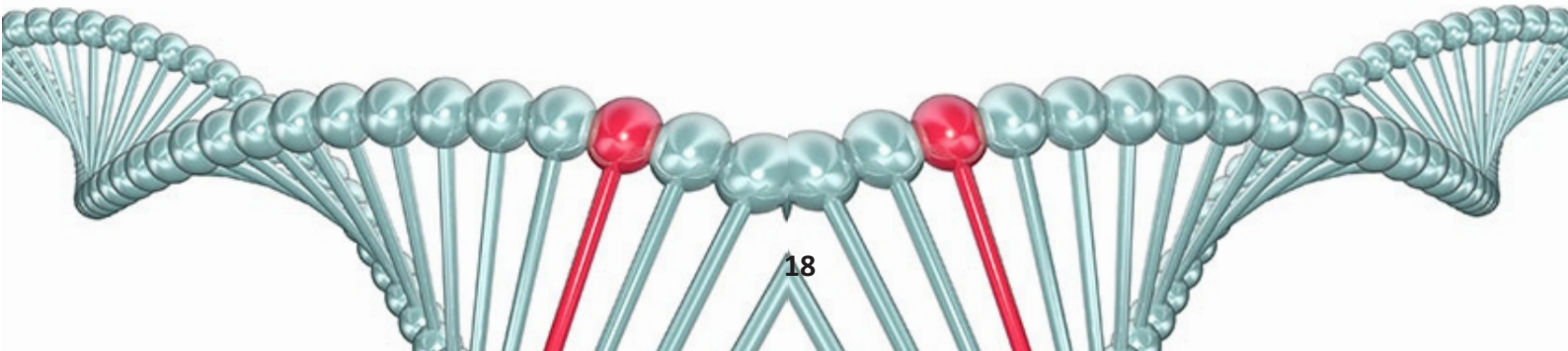
Section 25(1) deals with the duties on the Agency when it receives an application and the accompanying documents mentioned in section 23. The Agency shall display copies of the application and relevant information at such places and for such period of time as the Agency may from time to time determine, to enable the general public to make comments within 21 days.

While a clear, mandatory duty is placed in the Agency to make copies of the application and relevant information available to the public to enable the public to submit comments and inputs, the Agency still retains a discretion as to where it will place such information, what kind of information it will deem as “relevant” and for a period of time that it will place such information in the public domain in order to catch the attention of the public. We also consider the 21 days period of time allowed to the public to make such comments and inputs is very short, particularly where larger constituencies have to be consulted, such as farmer associations and organisations.

Legislation ought to create clear obligations on the part of the Agency to ensure that it facilitates access by the public to clearly define information to facilitate its involvement. This must include a clear obligation to place the information at the disposal of the public through local and national media in local languages and giving the public at the very least a 60 days period of time to react. To enable effective participation it should be taken intio account that the likelihood that some information may not available in Nigeria and may thus need to be collected from partners and experts outside of Nigeria. This requires more time.

More so, Section 25 needs to state when the information must be made public, not only how much time is allowed for comments.

There should be clear stipulations of range of publications that would support the basic minimum provisions in the context of public participation.



The holding of public hearings is also at the discretion of the Agency. This is both unhealthy and unacceptable.

Section 26(1): This clause should state that The Agency "shall" hold a public hearing, not "may." Furthermore the paragraph has to state that this information has to be taken into account. The African Model Law should be a guide here.

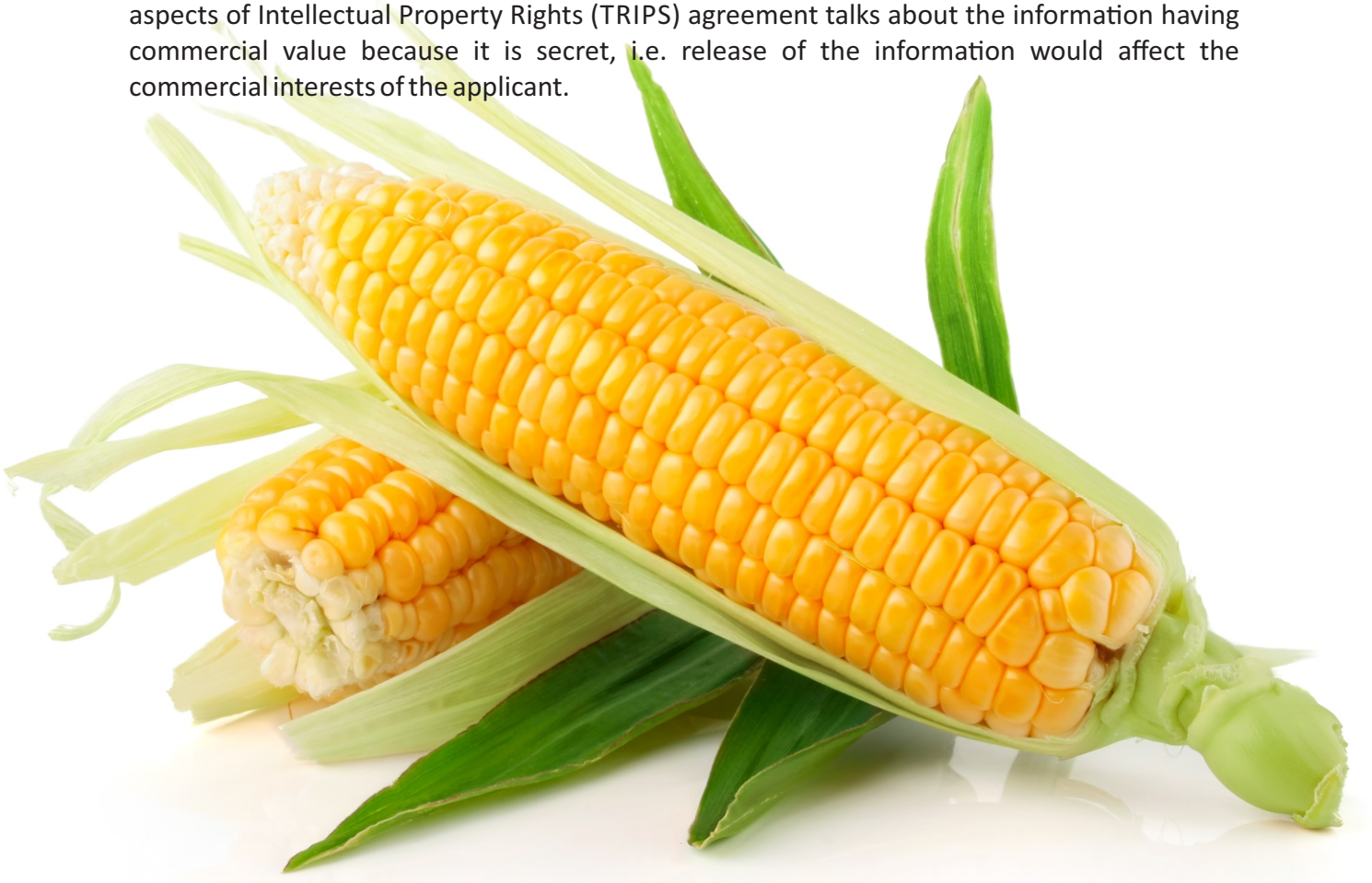
Section 26(2): States that the Agency shall not disclose any confidential business information submitted to it. This provision opens the door to abuse. The word "***submitted***" is a wrong word and should be replaced with the word "***determined.***" The Agency has a duty to protect the public and the applicant shall not determine what information should be withheld and what should be made public. The Agency should reserve the right to determine such.

Sections 26(1) and (2) here are unacceptable as they stand and require rectification.

Section 26(3)(a) It is important to know that in the EU the complete application dossiers including company studies and raw data must be made public by European Food Safety Authority (EFSA) to any person requesting for it (by email for example). This means that almost no data in any GMO application is qualified as confidential business information by EFSA. Only very few bits and pieces are blackened in EU GMO applications.

Section 26(3)(d) states that the information is not required to be released under section 23 of this Act. If a decision is passed such information should be released to the public.

Section 26 is too pro-business without due consideration for the people. The Trade-Related aspects of Intellectual Property Rights (TRIPS) agreement talks about the information having commercial value because it is secret, i.e. release of the information would affect the commercial interests of the applicant.



Section 27: We propose that the "location of the release" should also been listed as the information that cannot be considered confidential. The Protocol does not oblige, but other legislation like that of the EU does.

Decision Making

Section 28: Generally speaking, section 28 is very weak in terms of decision-making. It does in fact not discuss how decisions are to be made, what should be taken into account and certainly no reference is made to the precautionary principle at all. There is a great deal of attention paid to risk management though, conveying the overall impression that approvals will be readily granted and the emphasis will be on risk management measures to be taken on the part of the applicant.

It looks like the granting of approval is given to the Agency. This makes it very powerful, and they decide. In other countries, there are two layers – an agency or committee that makes recommendations based on the Risk Assessment, and a Board or inter-ministerial body that makes the decision. The Agency should also be required to constitute relevant committees of expertise for particular applications.

We recommend that the Agency should not be the approving body and its duty should be to recommend and the Board or an inter-ministerial body should be constituted to handle approvals.

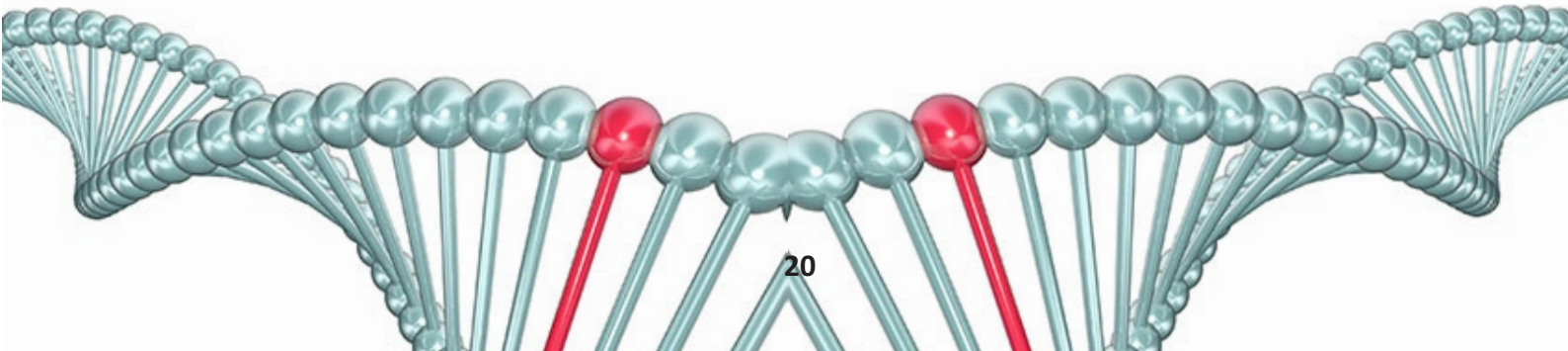
Section 28(a) An obligation has been created on the part of the Agency by this sub section to take the "relevant comments, inputs or concerns of the public received under the provisions of the Act. "This suggests that where the Agency deems comments, inputs and concerns to be irrelevant, it will then be discharged of its duty to take these into account.

Section 28(c) How and where the notification to the public provided for under this subsection will be communicated is not spelt out in the Act and the Regulations certainly should do so.

Section 28(g) does open the door for further regulations to be made with regard to decision making and every opportunity should be taken to ensure that these moderate the decision making of the Agency, taking into account the objectives of the Agency set out in section 2 of the Act.

Review of Decisions

Section 29 deals with revocation of the approval or permit granted and here it refers to a decision taken under section 23. But section 23 does not deal with decision making, section 28 does. Section 23 deals with the application process.



Section 29(a) otherwise is good and refers to "new information" and not necessarily to "new scientific evidence" and could permit other forms of evidence. The fact that GMO or its products is ***capable*** of having adverse effects on human health, animal, plant or the environment is also a good provision. We note that decision to refuse an application can be reviewed similarly on the grounds of new information, but that information has to be relevant. Relevancy will again depend on the discretion of the Agency.

Appeals

Section 30: There should be a time frame for appeals here and in 30(2). It appears that an open-ended appeals period could enable applicants to come back to the Authority at a later point in time when they, for example, have information that could convince the authority to allow a previously stalled release.

Section 30 appears only to give the Applicant a clear right to appeal against a decision to the Board. However, it is not clear if the right to administrative appeals by interested and affected parties may also be provided for by other legislation. If not then something should be provided for in the Regulations in this regard in the interests of administrative justice and procedural fairness.

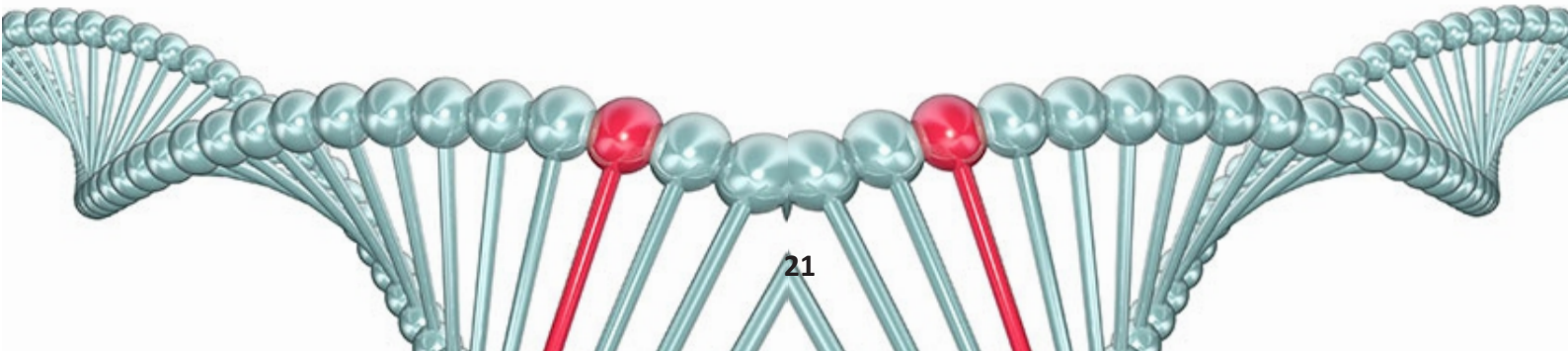
PART IX - RISK ASSESSMENT AND MANAGEMENT

Section 31:- For assessment of risks there should be field data from Nigeria to address the specific circumstances. But note should be taken that there are also many useful data from laboratory experiments that come from other countries than Nigeria

Section 31(1) It is not clear who would conduct the risk assessment. The article appears to suggest that the duty falls on the applicant. If it is the applicant who is applying for the permission this is risky and the results of the assessments could be compromised. **This section should be reviewed.**

Section 34(b) sets out the prohibition measures that the Agency may impose. Section 34(b) can only be operationalised at the discretion of the Agency and only if the specific traits or characteristics pose "***significant"*** risks to human health, animal, plant and the environment. This is very limited and does not take into account the risks that a GMO may pose in relation to the receiving environment and the interaction between the two or to the GMO in its totality.

Another question begging for an answer is why this section only allows the Agency to act if there are 'significant' risks while the title of the Act and objectives in Art 2 state that there shall be risk prevention, this discrepancy leaves a huge gap in the regulatory power of the Agency.



We suggest bringing in the wording of Cartagena Protocol **Art 10(g)** that directly applies to this situation: '... organisms if there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential risks to ... '

Section 34(c) A person, institution or body may also in terms of this section is required by the Agency at the Agency's discretion to take such measures as may be necessary, ***from time to time,*** to prevent or limit any [the word risk is missing] human health, animal, plant or the environment**.**

Section 34(d): Monitoring and evaluation are needed under Section 23 of the Act too. Environmental release needs to be monitored.

The issue of liability and redress is squeezed into one provision, in section 34(e). It provides that the Agency may take any measure as it may deem necessary to avert risk or danger to human health, animal, plant or the environment, where the person responsible shall bear the cost of any measure taken. However, no duty of care is created and obligations to first call upon the applicant to take measures to avert the risk or danger.

This section requires review as it appears that the provisions of an entire Protocol on Liability and Redress (Nagoya Kuala Lampur Protocol) have been condensed into one subsection!

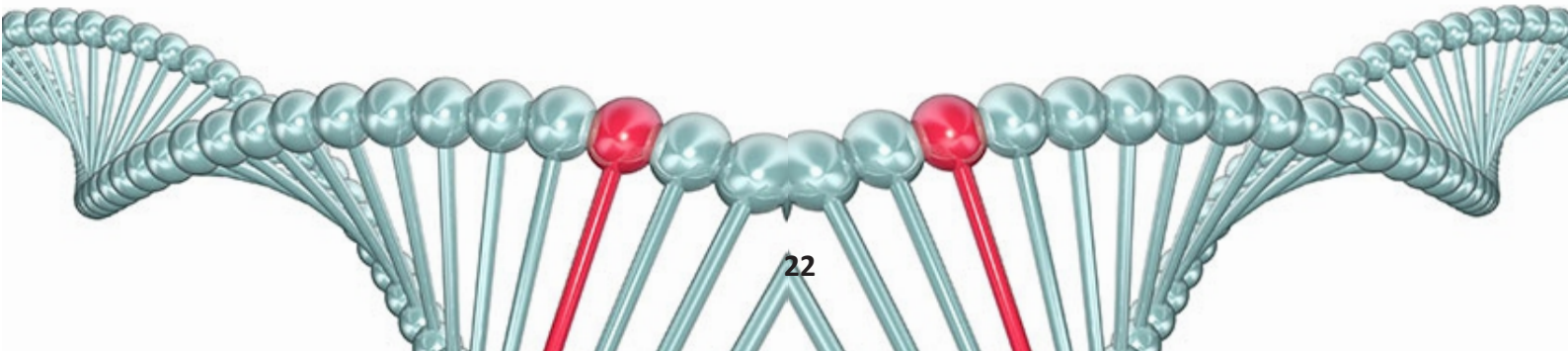
PART X - OFFENCES, PENALTIES AND ENFORCEMENT

Section 35: Fines and Penalties prescribed under Part X of this Act are just peanuts for corporations/applicants with multi million or billion dollars enterprises. The fine/penalty is not sufficient to deter them from committing the offence.

Section 35(a) Confined and multi-location field trials should be included here.

Section 35(b) In addition to imprisonment terms as specified in (i) and (ii), the fines for an individual should not be less than N5million (five million naira) while that of a corporate body should not be less than N10 million (ten million naira). The fines should be subject to upward review on a yearly basis. The fines for Directors of corporate bodies that are found wanting should also not be less than N5 million (five million naira), in addition to the stipulated prison terms.

We note the conspicuous absence of provisions on Liability and Redress as well as on Contamination in this section. These are very vital to any biosafety regime and the Act wholly overlooks these. This requires urgent rectification before any further step is taken on the implementation of the Act.



PART XI- MISCELLANEOUS PROVISIONS

Section 41(1): The standard of liability and redress used here is fault-based. We would recommend a standard of **Strict Liability**, which is the standard in the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and in line with the precautionary approach. Fault-based liability requires a higher burden of proof, and could make it difficult for liability to be established. We note that this provision envisions that liability for GMOs will be dealt with by regulations, and through existing laws, not a specific liability and redress law.

Section 43

Under 'Biosafety' replace the word ***minimizing*** with '***preventing'*** this would ensure consistency with the title and objectives. Refer also to our comments on the regulatory gap.

Under 'Contained use' we recommend the addition of the phrase 'that effectively prevents their contact with, and their impact on, the external environment' and also 'That effectively limits or prevent the emission of GMOs.' A qualifier of the characteristics of the structure is needed, otherwise any building or structure could qualify for acceptance as contained use.

Under 'Confined Field Trial' it is good that the Act meanwhile also mentioned multi-location field trials as step between the confined trials and commercial release. However, these should be defined.

FIRST SCHEDULE: Section 24 (2) (H)
ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING IN THE MARKET

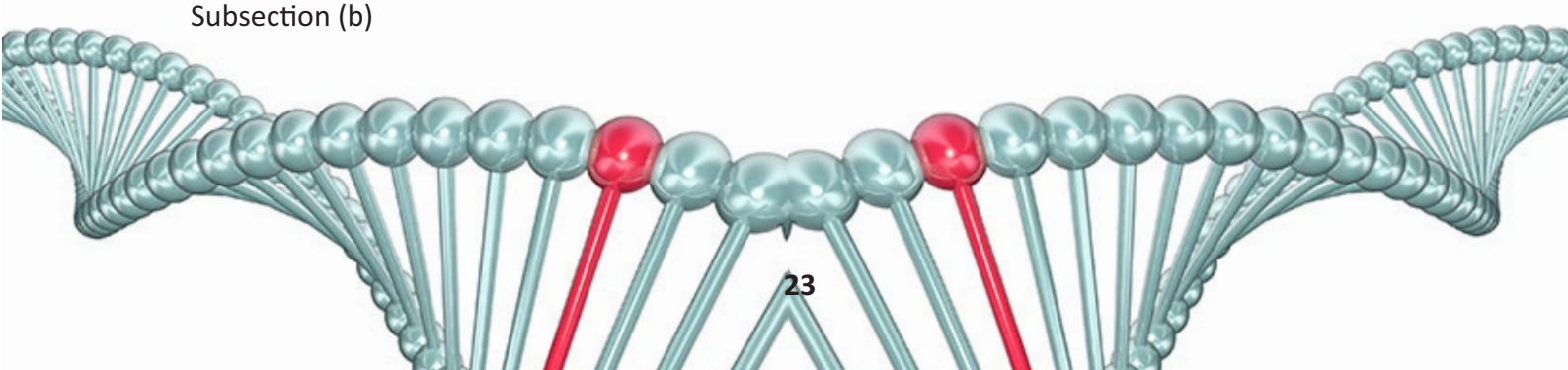
This First Schedule confuses the issues of documentation and labelling as well as labelling for information and warning purposes. These are two fundamentally different things.

Section 3(a): It is not clear what the “evidence” describes without the setting of thresholds. Some threshold has to be set for the detection of GM content. For instance, 0.1%. Otherwise, this provision will give rise to a great deal of problems in the future.

Section 3(c) the Act only allows consumer labelling when the GMO is dangerous; this is not a good concept. Nigeria has always been very strong in the Codex calling for GMO labels and this should be sustained in this Act.

Also the words “is known” should be removed and replaced by the words “there is a likelihood of”. The Act should ensure that the needed approval process is undertaken to enable the authorities to reject GMOs that pose such risks.

Section 3(d) seems not to be linked with subsection (c), but rather with Subsection (b)



4.00 CONCLUSION

The process that led to the passage of the Biosafety Bill and the eventual signing into law was one that was not public friendly. It was difficult for interested civil society groups and other parties to obtain copies of the several draft Bills thus making contributions to the debate difficult.

Although we now have a Biosafety Act it is not too early or too late to take a hard look on the legislation for the overall good of our environment, our peoples and our continent. We strongly propose that the National Assembly as well as the Executive arm of government take a close look at the dispassionate recommendations we have made in this submission and commence the process of rectifying the gaps and problematic areas of the Act in the best interest of our peoples and environment.

Appendix 1

NATIONAL BIOSAFETY MANAGEMENT AGENCY ACT, 2015

EXPLANATORY MEMORANDUM

This Act establishes the National Biosafety Management Agency charged with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern bio-technology in Nigeria with the view to preventing any adverse effect on human health, animals, plants and environment.

NATIONAL BIOSAFETY MANAGEMTNAGENCY ACT, 2015

ARRANGEMENT OF SECTIONS

SECTION:

A BILL FOR AN ACT TO ESTABLISH THE NATIONAL BIOSAFETY MANAGEMENT AGENCY CHARGED WITH THE RESPONSIBILITY FOR PROVIDING REGULATORY FRAMEWORK, INSTITUTIONAL AND ADMINISTRATIVE MECHANISM FOR SAFETY MEASURES IN THE APPLICATION OF MODERN BIOTECHNOLOGY IN NIGERIA WITH THE VIEW TO PREVENTING ANY ADVERSE EFFECT ON HUMAN HEALTH, ANIMALS, PLANTS AND ENVIRONMENT; AND FOR RELATED MATTERS 2015{ } Commencement.

ENACTED by the National Assembly of the Federal Republic of Nigeria as follows:

PART I - ESTABLISHMENT OF BIOSAFETY MANAGEMENT AGENCY

(1) There is established the National Biosafety Management Agency (in this Act referred to as the Agency) which:

(a) shall ensure the effective management of all component of the Nation's Biosafety;

(b) shall be a body corporate with perpetual succession and a common seal; and

(c) may sue and be sued in its corporate name.

(2) The Agency shall be the national authority on Biosafety in Nigeria. Establishment of National Biosafety Management Agency.

The objectives of the Agency shall be to:

(a) establish and strengthen the institutional arrangement on Biosafety matters in Nigeria;

(b) safeguard human health, biodiversity and the environment from any potential, adverse effect of genetically modified organism including food safety;

(c) ensure safety in the use of modern biotechnology and provide holistic approach to the regulation of genetically modified organisms;

(d) provide measures for the case by case assessment of genetically modified organisms and management of risk in order to ensure safety in the use of genetically modified organisms to human health and the environment;

(e) provide measures for effective public participation. Public awareness and access to information in the use and application of modern biotechnology and genetically modified organisms; and

(f) ensure that the use of the genetically modified organisms does not have adverse impact on socio-economic and cultural interest either at the community or national level.. Objectives of the Agency

PART II FUNCTIONS AND POWERS OF THE AGENCY

Functions and Powers of the Agency.

The Agency shall:

(a) propose, for the approval of the Board, the overall policy guidance on issues of Biosafety in Nigeria;

(b) implement the provisions of the Conventions and the Protocols on matters relating to genetically modified organisms;

(c) render reports to the secretariat of the Convention on the implementation of the Convention and Protocol on matters relating to the use of genetically modified organisms;

(d) develop measures and requirements and criteria for risk assessment peer review and decision making;

(e) develop measures and requirements for risk assessment;

(f) develop risk management plan and strategy for protecting human health, biological diversity and the environment from potential risks associated with genetically modified organisms;

(g) accept and verify applications in respect of genetically modified organisms and keep records of all approvals and unapproved applications as contained in Part VIII, subsection 24 (1);

(h) take samples and carry out laboratory analysis of crops, products or materials for purposes of determining if they contain genetically modified organisms and ensure compliance with this Act;

(i) carry out actions necessary to ensure compliance with the legal obligations set out in this Act, including, but not limited to, the inspection of facilities, conduct research activities with genetically modified organisms covered by this Act, the collection and analysis of samples of materials covered by the Act, the monitoring of human health and the environment to determine the effects of genetically modified organisms regulated by the Act;

(j) liaise with the secretariat of the convention and the Biosafety clearing house with respect to the administrative functions required under the Protocol;

(k) carry out and maintain inventory of laboratories with physical and human capacities to conduct research in modern biotechnology;

(l) monitor the activities of institutional committees and Biosafety officers;

(m) build, equip and maintain offices and premises for the performance of its action under the Act;

(n) pay remuneration, allowances, expenses and any other benefit to members of the Board and employees of the Agency or any other persons, in accordance with the National Salaries, Income and Wages Commission;

(o) carry out capacity building activities;

(p) perform other duties as may be necessary for the full discharge of its functions under this Act; and

(q) partner with other relevant local and international agencies for the speedy realization of the Agency's mandate.

PART III- STRUCTURE OF THE AGENCY

Structure of the Agency

4. The Agency shall have such Departments as it may deem appropriate..

PART IV - STAFF OF THE AGENCY

5. There shall be for the Agency a Director General who shall:

Appointment of Director General and staff of the Agency.

(a) be appointed by the President, Commander-in-Chief of the Armed Forces on the recommendation of the Minister;

(b) not be qualified for appointment as a Director-General unless he possesses outstanding qualifications and has at least 15 years cognate experience in the Management of Biodiversity, Biosafety or related field;

(c) be a holder of at least a Masters Degree in biological sciences or other related field;

(d) be the Chief Executive of the Agency and be responsible for:

(i) the day to day administration of the Agency;
(ii) the execution of the policies of the Agency; and
(iii) Performing other functions as the Board or Minister may from time to time assign to him.

(e) hold office in the first instance for a term of 4 years and may be reappointed for another term of 4 years and no more.

6. Notwithstanding the provisions of section 5 of this Act, the Director-General may be removed from office by the President, Commander-in-Chief of the Armed forces:

Cessation or removal from office.

(a) for inability to discharge the functions of his office (whether arising from infirmity of mind or body or any other cause) or for misconduct;

(b) if the President is satisfied that it is not in the interest of the Agency or the public for him to continue in the office;

(c) if the Director-General resigns his appointment by a notice in writing under his hand addressed to the President.

7. The Agency shall appoint a Secretary and Legal Adviser, who shall be:

Appointment of Secretary and Legal Adviser of the Agency.

(a) a legal practitioner of not less than 10 years post-call experience;

(b) subject to the control and supervision of the Board and Director- General; and

(c) keeping the books and records, conducting the correspondence of the Board and performing such other duties as the Board or the Director-General may from time to time direct and without prejudice to the generality of the foregoing, the Secretary shall be responsible for:

(i) making arrangements for meetings of the Board;
(ii) preparing the agenda and minutes of meetings of the Board; and
(iii) such other functions as may be assigned to him by the Board and the Director-General.

8. The terms and conditions of service and remuneration of employees of the Agency shall be determined in line with the appropriate authorities.

Terms and condition of service.

9. The removal and discipline of staff shall be in accordance with existing Public Service Rules and Regulations.

Removal and discipline of staff.

PART V - ESTABLISHMENT OF THE GOVERNING BOARD

10. (1) There is established for the Agency, a Board which shall consist of:

Establishment of the Governing Board and its composition.

(a) a Chairman who shall be appointed by the President, Commander-in-Chief of the Armed Forces;

(b) the Director-General of the Agency;

(c) a representative not below the rank of a Director, from each Federal Ministry responsible for:

(i) Environment;
(ii) Agriculture;
(iii) Science and Technology;
(iv) Trade and Investment;
(v) Health;
(vi) Nigeria Customs Service;
(vii) National Agency for Food and Drug Administration and Control (NAFDAC); and
(viii) National Biotechnology Development Agency (NABDA).

(d) one representative each of conservation Non-Governmental Organizations (NGOs) and organized private sector;

(e) one representative of the Biotechnology Society of Nigeria.

(2) All appointments in this section shall be made by the President, Commander-in- Chief of the Armed Forces.

(3) Membership of the Board is on part-time, except the office of the Director-General

Tenure.

11. A member of the Board appointed, other than the Director-General, shall hold office for a term of 4 years, and subject to the provisions of this Act.

Vacancy.

12. (1) The office of a member of the Board shall become vacant if:

(a) he resigns as a member of the Board by notice in writing under his hand addressed to the President; and

(b) if it appears to the Board that a member of the Board other than an ex-officio member or Director-General should be removed from office on the grounds of misconduct or inability to perform the functions of his office, the Board shall make a recommendation to the President.
(2) Notwithstanding the provisions of subsection (1) of this section, the President may remove any member of the Board if he is satisfied that it is in the public interest to do so.

PART VI - FUNCTIONS AND POWERS OF THE BOARD

Functions and Powers of the Board.

13. The Board shall:

(a) advise on the overall policy formulation of the Agency in particular with regard to financial, operational and administrative matters;

(b) establish committees as may be expedient and charged with specific functions;

(c) encourage and promote activities related to the functions of the Agency;

(d) carry out such other activities as may be directed by the President.

(2) The Board shall have power to appoint for the Agency either directly or on secondment from any public or civil service of the Federal such number of employees as may, in the opinion of the Board, be required to assist the Agency in the discharge of any of its functions under this Act.

PART VII- FINANCIAL PROVISIONS

Fund of the Agency.

14. The Agency shall establish and maintain a fund from which it shall defray all expenditures incurred.

(2) There shall be paid and credited to the fund:

(a) annual budget allocation from the Federal Government;

(b) such other sums as may be given to the Agency by the Federal government;

(c) all moneys accruing to the Agency, including grants-in-aid, endowments and donations;

(d) all charges, dues, fees or other amounts collected by the Agency; and

(e) all interests on moneys invested by the Agency.

15. The Agency shall, when necessary, apply the funds at its disposal for the purpose of the Agency. Expenditure of the Agency.

16. The Agency may borrow according to the provisions of the Debt management Act. Power to borrow Act No 18 2003.

17. (1) The Agency may, subject to the provisions of this Act and conditions of any trust created in respect of any property, invest all or any of its funds in accordance with section 15 (1) of this Act. Power to invest.

(2) The Agency may invest any of its surplus funds in such securities as may be permitted by law.

18. (1) The Agency may, accept gifts of land, money or other property or things from within and outside Nigeria, on such terms and conditions, if any as may be specified by person or organization offering the gift. Power to accept gift.

(2) The Agency shall not accept any gift if the terms and conditions attached by person or organization offering the gift are inconsistent with its functions under the Act.

19. The Agency shall submit to the President, in accordance with the prescription in the annual budget cycle each year, its programme of work and estimates of its income and expenditure for the following year. Annual Estimates.

20. (1) The Director-General shall keep proper accounts of the Agency and proper records in relation and to those accounts. Account and Audit.

(2) The accounts of the Agency shall be audited after the end of the year to which the audit relates, by auditors appointed by the Agency from among the list and in accordance with the guidelines supplied by the Auditor-General of the Federation.

21. The Agency shall prepare and submit to the President not later than 6 months after the end of the year a report, in such form as the President directs on the activities of the Agency during the immediate preceding year and shall include in the report a copy of the audited accounts of the Agency or that year and the auditor's report thereon. Annual Report.

PART VIII- REQUEST AND AUTHORISATION

Import and Export Permit.

22. As from the commencement of this Act, no person, institution or body shall import, export, transit, carry out the contained use, confined field trial, multi-locational trial without the approval or permit of the Agency.

Application of Import and Export Permit.

23. (1) Any person, institution or body who wishes to import, export, transit or otherwise carry out a contained field trial, multi-locational trial or commercial release of a genetically modified organism shall apply to the Director General of the Agency not less than 270 days to the date of import, export, transit or the commencement of such activity.

(2) Any application under subsection (1) of this section shall include:

(a) the information and data requirement that may be specified by the Agency in the regulations, guidelines, and policy documents;

(b) a risk assessment report indicating the potential risk, if any that the genetically modified organisms may pose to human health including food safety, biological diversity or the environment including the consequence of unintentional releases;

(c) the nature and identity of the genetically modified organisms involved in the activity being proposed to be carried out;

(d) information relating to any release of the genetically modified organisms in Nigeria or elsewhere;

(e) the nature and purpose of the activities including such activities as storage, transportation, production, culture and processing;

(f) destruction, disposal or usage of the genetically modified organisms in any way whatsoever;

(g) a management plan for remediation measures to be undertaken in the event of:

(i) any unintentional introduction into the environment of the genetically modified organisms from contained laboratory;
(ii) the escape or persistence in the environment of a genetically modified organisms from a confined field trial; and
(iii) any unintended consequence to the environment from the placing of genetically modified organisms in the market.

First Schedule

(h) the place where, and the purpose for which the genetically modified organisms or the product thereof is planned to be developed, used, kept, released or marketed including detailed instructions for use and a proposed labelling and packaging scheme in accordance with the First Schedule to this Act; and

(i) a declaration to the effect that the information provided to correct including where appropriate, the undertaking from the origination of such information affirming its accuracy and completeness.

(3) In all cases, the Agency shall set out requirements for each activity with genetically modified organisms to determine the level of potential risk posed by such category of activity in accordance with the second schedule to this Act. Second Schedule.

Import or transit of products to be approved.

24 (1) No person, institution or body shall import, export, transit or commercialize any genetically modified organism or a product thereof intended for direct use as food or feed or for processing unless with the approval of the Agency.

(2) Application under this section may only be granted upon completion of safety risk assessment to determine if there is not substantial risk that the genetically modified organism could be eaten by humans or animals

(3) Any person, institution or body that submits an application under this section for the commercial release of a genetically modified organism must ensure that the application addresses the socio-economic considerations set out in the Third Schedule to this Act. Third Schedule

(4) The Agency shall consider such analysis in the risk or benefit assessment to determine whether it is to be approved or denied.

(5) Review of the food safety assessment and the determination that the food is safe for human consumption shall be certified by the National Agency for Food, Drug Administration and Control.

Public display of application.

25. (1) The Agency shall upon the receipt of the application and the accompanying information under section 23 of this Act, display copies of such application and relevant information at such places and for such period as the Agency may, from time to time determine to enable the general public and relevant government ministries and agencies study and make comments on the application and relevant information within 21 days.

(2) The Agency may, prior to the display, make announcement in at least 2 national and one local newspapers, the national Biosafety clearing house or such other news media as the Agency may from time to time determine, giving summary of the application and brief information on the place, duration and time for the display.

Public Hearings

26. (1) The Agency may, in addition to the comment received pursuant to section 23 of this Act, hold public hearings or consultations to obtain further comments and inputs that will assist in the review or processing of the application.

(2) Notwithstanding any other provisions in this Act the Agency shall not disclose any confidential business information submitted by any person, institution or body to the Agency under this Act.

(3) To determine if any information identified by an applicant qualifies as confidential business information that cannot be disclosed to the public the Agency shall ascertain that:

(a) the information has not previously been released to the public anywhere in the world;

(b) the applicant has shown that it has taken steps to prevent the release of such information;

(c) release of the information would be detrimental to the applicant; and

(d) the information is not required to be released under section 23 of this Act..

Disclosable information.

27. The following information shall not be considered confidential business information and can be disclosed to the public:

(a) the name and address of the applicant;

(b) a general description of the genetically modified organism;

(c) a summary of the risks assessment for the genetically modified organisms;

(d) any scientific data that specifically addresses potential environmental or food risk from genetically modified organisms and any method; and

(e) plans for emergency response.

Procedure for grantingapproval.

28. With respect to any decision taken under section 23 of this Act, the Agency:

(a) shall take into consideration, the relevant comments, inputs or concerns of the public received under the provisions of this Act;

(b) shall notify the applicant in writing and the Biosafety clearing house of the decision and information, facts and analysis supporting the decision;

(c) shall notify the public of any genetically modified organism for which approval or permit has been granted for import , contained use, confined field trials, multi-locational trials or commercial release and provide the information, facts and analysis supporting the decision;

(d) may specify the steps to be taken in the implementation of the risk management plan where there are potential risk to human health, animal, plant and the environment.

(e) may in respect of any approval for import, transit, contained use, confined field trial, multi-locational trials or commercial release of any genetically modified organisms, direct the applicant to carry out monitoring and evaluation of risk for a specified period equivalent to the life cycle of the relevant species or for such period as the Director General may, from time to time, determine;

(f) impose any additional measure for risk management as provided in this Act;

(g) do such other things as take such other steps as he may consider necessary and expedient for carrying into effect this decision.

Revocation and review of application.

29. The Agency may:

(a) revoke or suspend the approval or permit or otherwise review any decision taken under section 23 of this Act if it is of the opinion that there is new information to the effect that the genetically modified organisms or its products thereof is capable of having adverse effect on human health, animal, plant or the environment; and

(b) review the refusal of an application if there is new and relevant information.

Appeal by the applicant.

30. (1) Any applicant who is aggrieved by any decision of the Agency under sections 24 and 25 of this Act may appeal to the Board to reconsider that decision, stating his grounds of appeal, including any additional information.

(2) Any applicant who is not satisfied with the decision of the Minister may apply to the Federal High Court for a review of the decision.

PART IX - RISK ASSESSMENT AND MANAGEMENT

MandatoryRiskAssesment.

31. (1) Every applicant seeking approval for any genetically modified organism under this Act shall, prior to the submission of the application, carry out a mandatory risk assessment of the potential risk the genetically modified organisms poses to human health, animal, plant or the environment in Nigeria.

(2) The risk assessment mentioned in subsection (1) of this section shall be carried out in Nigeria and in accordance with policies and guidelines set forth by the Agency and under the Third Schedule to this Act.

(3) Without prejudice to subsections (1) and (2) of this section, the Agency may constitute a National Biosafety Committee (NBC) to carry out risk assessment of any genetically modified organism under this Act.

(4) Where the National Biosafety Committee (NBC) carries out the risk assessment, the Agency may direct that such applicant bears the cost of carrying out the risk assessment notwithstanding that the applicant has previously carried out his own risk assessment.

Conflict of interest.

.32. No person, shall be involved in a risk assessment review by the Agency in respect of a subject matter in which:

(a) he has direct or indirect interest of any kind; or

(b) there is likely to be conflict of interest as a result of his participation in the risk assessment process.

Risk management plan and strategy.

33. Every person, institution or body that carries out any activity relating to genetically modified organisms shall develop and maintain a risk management plan and strategy in accordance with the provisions of the Forth Schedule to this Act.

Additional measure for risk management.

34. The Agency may impose additional measures for management of risks associated with any genetically modified organisms and without prejudice to the generality of the foregoing, may:

(a) direct that any genetically modified organisms undergo a period of observation commensurate with the life cycle or generation time, at the cost of the applicant before or after such genetically modified organism is certified for usage;

(b) prohibit the import transit, contained use, release or placing on the market of any genetically modified organism if it contains characteristics or specific traits which pose significant risk to human health, animal, plant and the environment;

(c) require any person, institution or body responsible for any activity relating to genetically modified organisms to take such measures as may be necessary, from time to time, to prevent or limit any human health animal, plant or the environment;

(d) direct any applicant under section 24 of this Act to submit periodic report of the monitoring and evaluation of risk carried out after the approval or permit granted under this Act; and

(e) undertake any measure, as may be reasonably necessary to avert risk or danger to human health, animal, plant and the environment where the person responsible for such action fails to act and the person so responsible shall bear the cost of any measure taken;

PART X - OFFENCES, PENALTIES AND ENFORCEMENT

Offences and Penalties.

35. (1) Any person, institution or body who:

(a) imports, export transit or otherwise carries out the activity of contained use or commercial release of any genetically modified organisms without a prior approval or permit of the Agency; or

(b) contravenes the conditions of the grant of an approval or permit under this Act, commits an offence and shall be liable on conviction:

(i) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment; or

(ii) in the case of a body corporate to a fine of not less than N5,000,000 and, in addition, the directors or officers of the body corporate shall each be liable to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment.

(2) For the purpose of section 24 (1) of this Act, any applicant who:

(a) becomes aware, after the grant of approval or permit to him, of any new information which indicates that the genetically modified organism poses possible risk to human health, animal, plant or the environment and fails to give such information to the Agency; and

(b) gives any false information purporting to be new information that suggest that the genetically modified organisms in respect of which approval or permit was refused has not adverse effect on human health, animal, plant or the environment, commits an offence under this Act and shall on conviction be liable to:

(i) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment; or

(ii) in the case of a body corporate to a fine of not less than N5,000,000.00 and in addition, the directors or officers of the body corporate shall each be liable to a fine of not less than N2,500.000.00 or imprisonment for a term of not less than 5 years or both fine and imprisonment.

False Information.

36. Any person, institution or body who submits or supplies false information in respect of any activity relating to genetically modified organism under this Act commits an offence and shall be liable on conviction:

(a) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 3 years or both such fine and imprisonment; or

(b) in the case of a body corporate, to a fine of not less than N5,000,000.00.

Obstruction of officer.

37. Any person who obstructs an authorized officer in the course of his duties under this Act, commits an offence and is liable on conviction to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 3 years or both such fine and imprisonment.

Penalty where it is not specified under the Act

38. (1) Any person who contravenes any provision of this Act for which no specific penalty is specified, commits and offence and is liable on conviction to a fine of not less than N2,500,000.00 or imprisonment for a term not exceeding 3 years or both such fine and imprisonment.

(2) Notwithstanding the punishments provided under section 36, 37 and 38 of this section, the Agency shall, in addition, revoke the permit granted to the individual or institution or body.

Powers of enforcement.

39. The Agency shall have powers to:

(a) in company of a Law Enforcement Officer, enter the premises, facility, laboratory, field, farm or other place, institutions or bodies covered by this Act to take action necessary to determine compliance with the Act;

(b) conduct, monitor and assess the impact of genetically modified organisms covered by the Act on human health, animal, plant or the environment;

(c) take other actions that include, but not limited to review and copy documents collecting samples, data interview individuals and seizing genetically modified organisms; and

(d) in addition to paragraphs (a), (b) and (c) of this section, seal or close down any facility, Confined Field Trials (CFT) sites, farms and laboratories..

Criminalproceedings.

40. (1) The Federal High Court shall have jurisdiction to try offences under this Act.

(2) The Court may, in addition to the penalties provided under this Act, order the forfeiture of any specimen, genetically modified organisms, or any genetic material, asset, other materials or anything in connection with commission of an offence under this Act.

(3) Without prejudice to subsection (2) of this section, the Court may order that:

(a) premises, laboratory, facility, field, farm or any place be sealed up for such period as be specified in such order; or

(b) remediation measures be undertaken by the offender.

PART XI- MISCELLANEOUS PROVISIONS

Regulations.

41. (1) The Board may, on the recommendation of the management of the Agency, make regulations generally for carrying into effect the provisions of this Act:

(a) handling, transporting, packaging; fault-based liability and redress for damages from the activities of modern biotechnology and genetically modified organisms. Liability and Redress for a damage that occurs as a result of an activity under this ACT is subject to applicable laws; and

(b) without prejudice to the generality of the provisions of subsection (1) of this section, the Agency may provide safety standards, guidelines and rules on:

(i) public participation processes and procedures;
(ii) risk assessment and risk management;

(iii) laboratories and relevant equipments relating to genetically modified organisms;
(iv) identification or labeling of genetically modified organisms; and
(v) fees and charges payable by applicants for any activities of the Agency under this Act.

Power to own property

42. The Agency shall:
(Ipurchase, hold, take on lease or dispose of any interest in land, building or probuild, equip and maintain offices and premises for the performance of its action under the Act;

.Interpretation.

43. In this Act:
"Agency" means National Biosafety Management Agency establishment under section 1 (1) of this Act;

"Appropriate authority" includes the National Salaries Incomes and Wages Commission";

"Biosafety Clearing House" means a pool of information mechanism established under Article 20 of the Protocol for exchange of scientific, technical, environment and legal information on and experience with genetically modified organisms, as part of the clearing house mechanism under Article 18 of the Convention;

"Biosafety" means the application of measures, policies, knowledge, techniques, equipment and procedures for minimizing potential risks that modern biotechnology may pose to the environment and human health;

"Board" means the National Biosafety Management Agency Governing Board established under Section 11 (1) of this Act;

"Committee" means the National Biosafety Committee referred to under Section 32 (3) of this Act;

"Contained use" means any operation using modern biotechnology undertaken within a facility, installation or other physical structure, such as a building, laboratory or greenhouse;

"confidential business information" consist of trade secrets and other proprietary information of commercial value;

"confined field trial" means a small scale experimental release into the environment of a genetically modified organism under physical and biological confinement conditions that limit the genetically modified organism's persistence in the environment after the experiment is completed;

“commercial release” means the release of genetically modified organism into the market as a product that can be purchased and use by any individual, such as a genetically engineered seed or animal;

“Conservation” means the protection of maintenance of nature while allowing for its ecologically sustainable use;

“convention” means the Convention on Biological Diversity;

“Court” means the Federal High Court;

“food and feed product” means a genetically modified organism or its product that is used for food, feed or processing and is primarily intended for consumption by humans or animals or for the consumption of both humans and animals;

“genetic material” means any part of a plant or animal or microbial containing functional units of the heredity;

“genetically modified organisms” means any organism living or non living that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

“modern biotechnology” means the application:

(a) in-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles; or

(b) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

“member” means a member of the committee and includes the Chairman;

'Minister” means Minister in charge of Environment;

“Director-General” means Chief Executive Officer of the Agency;
“Protocol” means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

“products thereof” means processed materials that are of genetically modified origin containing detectable novel combination of replicable genetic material obtained through the use of modern biotechnology;

“Institutional Biosafety Officer” means officer who is knowledgeable in Biosafety and has a degree in any of the biological science that is, Medical Science, Zoology, Genetic, Microbiology, Biochemistry, Veterinary Medicine, Animal Science, Soil Science, Agronomy or Plant Science (Botanist) and Ecology and appointed by the Institute dealing with Modern biotechnology for the purpose of ensuring compliance with the provisions of this Act.

44. This Act may be cited as the National Biosafety Management Agency Act, 2015. Citation.

FIRST SCHEDULE
Section 24 (2) (H)
ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING IN THE MARKET

1. The following information shall be provided in the notification for placing on the market of products, addition to that of the First Schedule:
(a) name of the product and names of genetically modified organisms from which they were made;
(b) name of the manufacturer or distributor and his address, including the address in the country;
(c) specificity of the product, exact conditions of use including; when appropriate, the type of environment or of the geographical areas of the country for which the product is suited; and
(d) proposed packaging which must be appropriate so as to avoid unintended release of the genetically modified products.

2. The following additional information shall be provided when required or relevant:
(a) measures to take in case of unintended release of misuse;
(b) specific instructions or recommendations for storage and handling;
(c) estimated production in or imports to the country;
(d) propose packaging when must be appropriate so as to avoid unintended release of the genetically modified organisms;
(e) proposed labeling which must include at least in summarized form, the information referred to in paragraphs 1, 2,3,4 and 5.

3. The following information concerning labelling of product shall be provided on a label or in accompanying documents:
(a) the words “This product contains genetically modified organisms” wherever there is evidence of the presence of genetically modified organisms;
(b) the words “This product may contain genetically modified organisms” where the presence of genetically modified organisms in a product cannot be excluded but there is no evidence of any presence of genetically modified organisms;
(c) the words “this product may cause reactions, allergies or other side-effects” where it is known that a particular reaction, allergy or other side effect may be caused by the product;
(d) where applicable, further or as a qualification to subparagraph (c) of this paragraph, the words “this product contains genetic material (nucleic acids); and
(e) genetically modified organisms or “this product is based on raw materials from genetically modified organisms.

SECOND SCHEDULE
Section 24 (3)

REQUIREMENT OF INFORMATION TO BE CONTAINED IN THE APPLICATION FOR APPROVAL OR PERMITPART A - GENERAL INFORMATION

(1)Name, address, telephone, fax, website or e-mail of applicant;

(2)Information on personnel and training which shall include qualifications and training of persons who shall be responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and evaluation of the safety measures.

PART B - INFORMATION RELATING TO GENETICALLY MODIFIED ORGANISMS OR THE PRODUCTS THEREOF

(1) Characteristics of the donor, the recipient or where appropriate, the parental organism Scientific name;

(2) Additional taxonomic information;

(3) Other names (usual name, strain name, cultivar name, transformation event, unique identification code (where applicable) etc);

(4) Phenotypic and genetic markers;

(5) Degree of relatedness between donor and recipient or between parental organisms;

(6) Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys parasites and competitors, symbionts and hosts;

(7) Potential for genetic transfer and exchange with other organisms;

(8) Verification of the genetic stability of the organism and factors affecting it taking into account the relevance of the laboratory experiments undertaken to the authentic ecological conditions under which the organism lives and used;

(9) Pathological, ecological and physiological traits which shall include:

(a) classification of hazard according to existing national rules concerning the protection of human health and the environment;

(b) generation time in natural ecosystems, sexual and asexual reproductive cycle;

(c) information on survival, including seasonality and ability to form survival structures (for example, seeds, spores or sclerotic);

(d) pathogenicity, infectivity, toxigenecity, virulence, allergenicity, ability to be a carrier (vector) of pathogen, possible vectors, host range including non-target organisms, possible activation of latent viruses (proviruses) and ability to colonise other organisms;

(e) antibiotic resistance and potential use of these antibiotics in humans and domestic animals for prophylaxis and therapy; and

(f) involvement in environmental processes, primary production nutrient turnover, decomposition of organic matter, respiration, etc.

Characteristics of the vector

(a) Nature and source of the vector;

(b) sequence of trasposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms or their products thereof and to make the introduced vector and insert function in the genetically modified

organisms or their products thereof;
(c) Frequency of mobilization of inserted vector and or genetic transfer capabilities and methods of determination;
(d) Information on the degree to which the vector is limited to the DNA required to perform the intended function;
(e) Factors (chemical biological, climatic, etc) influencing the functional level of the promoter or enhancer and how the functional level is changed.

Characteristics of Genetically Modified Organisms or Product thereof
Information relating to the genetic modification that is:
(a) Methods used for the modification;
(b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
(c) Description of the insert and vector construct; and
(d) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
Nature of the final genetically modified organisms:
(a) Description of genetic trait or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
(b) Structure and amount of any vector or donor nucleic acid remaining in the final construction of the genetically modified organisms or product thereof;
(c) Stability of the genetic traits of organisms in them is of both expression and structure;
(d) Rate and level of expression of the new genetic material" Method and sensitivity of measurements;
(e) Activity of the expressed protein;
(f) Expression levels for the recipient's genes situated as far as 100 kbp up and downstream from all DNA inserts;
(g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques; and
(h) Health consideration that has:
(i) toxic or allergenic affects of the non-viable genetically modified organism or products thereof and their metabolic products;
(ii) products hazards;
(iii) comparison of the genetically modified organisms or products thereof to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity;
(iv) capacity for colonization;
(v) its organisms as pathogenic to humans who are immune competent.
(i)Cases caused and mechanism of pathogenicity including invasiveness and virulence;
i. Communicability;
ii. Infective dose;
iii. Host range, possibility of alteration;
iv. Possibility of survival outside of human;
v. Presence of vectors or means of dissemination;
vi. Biological stability;
vii. Antibiotic resistance patterns;
viii. Allergenicity;
ix. Availability of appropriate therapies;
x. Allergenicity availability of appropriate therapies.

PART C -INFORMATION RELATING TO THE CONDITION FOR RELEASE AND THE RECEIVING ENVIRONMENT

Information on the Release

1. Description of the proposed deliberate release, including the purposes and foreseen products;
2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
3. Preparation of the site previous to the release;
4. Size of the site;
5. Methods to be used for the release;
6. Quantities of genetically modified organisms;
7. Disturbance on the site (type and method of cultivation, mining; litigation or other activities);
8. Worker protection measures to be taken during the release;
9. Post release treatment of the site;
10. Techniques foresee for climination or inactivation of the genetically modified organisms or products thereof, at the end of the experiments;
11. Information on and results of previous release of the genetically modified organisms or products thereof, especially at different scales and in different ecosystems including contained experiments.

Information on the environment

(The information shall be for both the site and the wider environment and in the case of genetically modified organisms destined to be used as food, feed or for processing, the environment includes the transposition routes and the market places as well as all the catchment areas of the market places):

1. Geographical location and grid reference of the site(s) in case of notification, the site(s) of release will be the foreseen areas of use of the product);
2. Physical or biological proximity to humans and other significant biota;
3. Proximity to significant biotopes or protected areas;
4. Size of local human population;
5. Economic activities of local populations which are based on the natural resources of the area;
6. Distance to closes areas protected for drinking water and environmental purposes;
7. Climatic characteristics of the region(s) likely to be affected;
8. Geographical, geological and pedological characteristics;
9. Flora and fauna, including crops, livestock and migratory species;
10. Description of target and non-target ecosystems likely to be affected;
11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART D - INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GENETICALLY MODIFIED ORGANISMS OR PRODUCTS THEREOF AND THE ENVIRONMENT

Characteristics and Factors affecting survival Multiplication, Gene Expression and Dissemination

1. Biological features which affect survival, multiplication and dispersal.
2. Known or predicted environmental conditions, which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals, etc).
3. Sensitivity to specific agents

Interactions with the environment

4. Predicted habitat of the genetically modified organisms;
5. Studies of the behaviour and characteristics of the genetically modified organisms or products thereof and their ecological impact carried out in simulated natural environments. Such as microcosms, growth rooms, greenhouses, animal houses and other containment facilities etc.
6. Genetic transfer capability, that is:

(a) post-release transfer of genetic material from genetically modified organisms or products thereof organisms;

(b) post-release transfer of genetic material from indigenous organisms of the genetically modified organisms or product thereof.

7. likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organisms or products thereof.
8. Measures employed to ensure and to verify genetic stability, Description of genetic traits which may prevent or minimize dispersal of genetic material. Methods to verify stability.
9. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent including inhalation, ingestion, surface contact, burrowing etc.

(a) Description of ecosystem to which the genetically modified organism or products thereof could be disseminated;

(b)for excessive population increase in the environment;

(c) Competitive advantage of the genetically modified organism or products thereof in relation to the unmodified recipient or parental organism;

(d) Identification and description of non-target organisms;

(e) Anticipation mechanisms and result of interaction between the released genetically modified organism or product thereof and the target organism;

(f) Identification and description of non-target organism which may be affected directly;

(g) Likelihood of post-release shifts in biological or host range;

(h) Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, host symbionts, predators, parasites and pathogens;

(i) Known or predicted involvement on bio-geochemical processes;

(j) Other potentially significant interactions with the environment.

PART E - INFORMATION ON MONITORING, CONTROL, WASTES TREATMENT AND EMERGENCY RESPONSE PLANS

Monitoring Techniques

10. Methods for tracing the genetically modified organisms or products thereof and of monitoring their effects;
11. Specificity (to identify the genetically modified organism or product thereof and to distinguish them from the donor, recipient or where appropriate, the parental organism), sensitivity and reliability of the monitoring techniques.
12. Techniques for detecting transfer of the donated genetic material to other organisms.
13. Methods to detect aberrant gene expression.

Control of the Release

14. Methods and procedures to avoid or minimize the spread of the genetically modified organisms or products thereof beyond the site of release or the designated area for use.
15. Methods and procedures to protect the site from intrusion by unauthorized individuals.
16. Methods and procedures to prevent other organisms from entering the site.

Wastes Treatment

17. Type of waste generated.
18. Expected amount of waste.
19. Possible risk.
20. Description of treatment envisaged.

Emergency Response Plan

21. Methods and procedures for controlling the genetically modified organisms or products thereof in case of unexpected spread.
22. Methods of decontamination of the areas affected (e.g. eradication of the genetically modified organisms or products thereof).
23. Methods for disposal or incineration of plants, animals, soil etc that were exposed during or after the spread.
24. Methods for the isolation of the area affected by the spread.
25. Plans for protecting human health, animals, plants and the environment in case of the occurrence of an undesirable effect.

THIRD SCHEDULE
Sections 25 (3) and 32 (2)RISK ASSESSMENT PARAMETERS

The user or applicant in respect of genetically modified organisms shall carry out an assessment prior to use or release of genetically modified organisms or products thereof as regards the risks to human, animal health, biological diversity, the environment and the socio-economic welfare of societies and its assessments shall take the following parameters into consideration including any other parameter seemed to be relevant in the circumstances).

1. Characteristics of donor and recipient organisms or parental organisms.
2. Scientific name and taxonomy.
3. Strain, cultivar or other name.
4. Species, it is related to and degree of relatedness.
5. The degree of relatedness between the donor and recipient organisms or between the parental organisms.
6. All sites from where the donor and recipient organisms or between the parental organisms were collected, if known.
7. Information on the type of reproduction (sexual or asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages.
8. History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified.
9. Phenotypic and genetic markers of interest.
10. Description of identification and detection techniques for the organisms and the sensitivities of these techniques.
11. Geographic distribution and natural habitat of the organism including information and natural predators, prey, parasites, competitors, symbionts and hosts.
12. Climatic characteristics of original habitat.
13. Ability of the organisms to survive and colonise the environment to which release is intended or otherwise.
14. Genetic stability of the organisms and factors affecting the stability.
15. The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability.
16. The potential of the organisms to transfer or exchange genes with other organisms either vertically or horizontally.
17. Pathogenicity to humans or animals, if any.
18. If pathogenic, their virulence, infectivity, toxicity and modes of transmission.
19. Known allergenicity or toxicity of biochemical and metabolic products.
20. Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

Characteristics of the vector(s)

21. Nature and source of the vectors.
22. Genetic map of the vectors, position of the genes inserted for the transfer, other coding and non-codling sequences affecting the expressing of introduced genes and marker genes.
23. Ability of the vector to mobilize and transfer genes by integration and methods of determining the presence of the vectors.
24. History of prior genetic manipulation where the donor or recipient organisms are already genetically modified.
25. Potential for pathogenecity and virulence.

26. Natural habitat and geographic distribution of natural and potential hosts.
27. Potential impacts on human and animal health and the environment.
28. Measures for counteracting adverse impacts.
29. Potential to survive and multiply in the environment or to form genetic recombinants.
30. Genetic stability of vectors such as hyper mutability.

Characteristics of Genetically Modified Organisms

31. The description of the modifications made using gene technology.
32. The function of the genetic modifications and the new insert including any marker Gene (s).
33. Purpose of the modification and intended use in relation to need and benefit.
34. Method of modification, and in case of transgeneric organism, the methods for constructing inserts and to introduce them into the recipient organism.
35. Whether introduced genes integrated or extra-chromosomal.
36. Number of inserts, position in the genome, and its or their structures (for example, the copy number whether in random or other types of repeats).
37. Products of the transferred genes, level of expression and methods for measuring expression.
38. Stability of the introduced genes in terms of expressions, structures and sites of integration.
39. Biochemical and metabolic differences of genetically modified organism compared with the unmodified organisms.
40. Probability of vertical or horizontal gene transfer to other species.
41. Probability of inserts or transferred genes to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria.
42. Allergencity, toxicities, pathogenicities and unintended effects.
43. Autecology of the genetically modified organism to diseases and pest compared with the unmodified organism.
44. Detailed information on past uses including results to diseases and pest leading to previous releases.

Characteristics of Resuscitated Organisms and Genes and Fossils DNA sequences, Resuscitated Organisms

45. Scientific name and taxonomy.
46. Identity of nearest species and their characteristics which are of relevance to the intended use.
47. Site which is found.
48. Method used for resuscitation.
49. Purpose of introducing the organism and benefits, if any,
50. Impacts on human and animal health and the environment.
51. Measures for counteracting adverse impacts.
52. Length of time the organism has been in use.
53. Genetic stability.
54. Likelihood of gene transfer to other organisms.
.55. Fossil and living organisms nearest relative species.
56. Biological and biochemical difference from related living species.
57. Information and previous uses since resuscitation.

DNA sequences from Fossils or from Resuscitated Organisms

58. Scientific name and taxonomy of the species whether resuscitated or a fossil.
59. Site of origin of the fossil.
60. Site of the gene in the resuscitated genome, if known.

61. Base sequence of the extracted gene.
62. Functions of gene, if known.
63. Purpose of use and benefits, if any.
64. Environment in which it lived before fossilization
65. Fossil species related to the species from which the gene was taken.
66. Living species related to the species from which the gene was taken.

Safety Consideration for Human and Animal Health

67. Capacity of colonization.
68. If the genetically modified organism is pathogenic to humans to animals, the following information is required, that is:
(a) diseases caused and mechanism of pathogenicity, including invasiveness and virulence and property of virulence;
(b) Communicability;
(c) Infective doses;
(d) host range and possibilities of alteration;
(e) ability to survive outside of the human or animal host;
(f) the existence of vectors and other means of transmission;
(g) Biological stability;
(h) Allergencity;
(i) Availability of appropriate therapies.

Environmental considerations

69. Factors affecting the survival reproduction and spread of the genetically modified organism in the environment.
70. Available techniques for detection, identification and monitoring of genes from the genetically modified organisms.
71. Available techniques for detecting transmission of genes from the genetically modified organism to other organisms.
72. Known and predicted habitats of the genetically modified organism.
73. Description of the ecosystems which could be affected by accidental release of the genetically modified organism.
74. Possible interactions between the genetically modified organism and other organisms in the ecosystem which might be affected by accidental release.
75. known or predicted effects on plants and animals such as pathogenicity infectivity, toxicity, virulence, being a vector of pathogens, allergenicity and colonization
76. Possible involvement in bio-geochemical processes.
77. Availability of methods for decontamination of the area in cases of accidental releases.
78. Effects on agricultural practices with possible undesirable impacts on the environment.

Socio-economic consideration

79. Anticipated changes in the existing social and economic patterns resulting from the introduction of the genetically modified organism or products thereof.
80. Possible treats to biological diversity, traditional crops or other products and in particular, farmers' varieties and sustainable agriculture.
81. impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agroclimatic zones.
82. anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and in general, means of livelihood of the communities likely to be affected by the introduction of the genetically modified organisms or products thereof.

83. Possible countries and communities to be affected in terms of disruptions to their social and economic welfare.
84. Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use of release of the genetically modified organism or the product thereof.

FOURTH SCHEDULE
Section 34 RISK MANAGEMENT PLANS
The user shall employ the following risk management plans and procedures from the development, through all stages of testing of the genetically modified organism or the product thereof, to its intended use or commercialization. Imported products of genetically modified organisms used for human or animal health (for example, antibiotics, drugs and hormones), that is:
(a) observation to ensure that changes in food habits, nutrition and other factors that could conceivably modify the expected impacts are insignificant; and
(b) such observation in subparagraph (a) of this paragraph can be limited in scope when it is shown that adequate trials on the specific products have been made on humans of animals, as appropriate, in areas other than the country of import.
Imported microbial genetically modified organisms for human health:
Besides the limited observation specified in paragraph 1 of this schedule, experiments shall be carried out to evaluate viability and risk of reacquiring virulence or lending virulence to other microorganisms when in the body and in the environment, since some spilling is inevitable.
Imported genetically modified organism for contained use:
(a) The products of genetically modified organisms and packaging will be tread as in paragraph 1 of this schedule;
(b) Experiments will be made in complete laboratory containment to determine:
(i) longevity of the genetically modified organism in cases of unintended releases should be specified;
(ii) methods for counteracting adverse impacts resulting from unintended releases should be specified; and
(c) methods for counteracting adverse impacts from the releases of genetically modified organisms resulting from unintended releases should be specified.
Where products of genetically modified organism are made:
(a) locally, trials on experimental animals shall be made when the product of the genetically modified organism is intended to be use on humans; and
(b) in all other cases, trials shall be made on species for which the product of the genetically modified organism has been designed.
Where genetically modified organism are made locally for use as vaccines for humans or animal there shall be:
(a) initial molecular, tissue culture, serological laboratory in complete containment;
(b) trails with experimental animals under strict containment;
© Experiments in complete containment to evaluate the extend of transfer of the genet of vector introduced or other genes through the agency of the vector to the genetically modified organism or to other species which will be found in association with the genetically modified organisms to ensure that virulence is not acquired by the genetically modified organism in question or by other micro-organisms;

(d) Trials on animals completely contained from their species and from related species and species known to be susceptible to the gene recipient micro-organism from which the genetically modified organisms has been made; and
(e) Statistically valid trials in conditions in which the vaccinated individuals live in their communities.

Where plants or microbial genetically modified organisms are imported for release:

(a) the reports from releases in areas other than the country of import shall be thoroughly evaluated by the National Biosafety Committee and particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;
(b) in the case of inadequacy of the regulations mentioned in sub-paragraph (a) of this paragraph, the National Biosafety Committee shall decide what step to take and which step of the observations should be applicable;
(c) and if it is found that the previous release mechanism have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but others kept at the same soil community, moisture, air, temperature and plant and animal community conditions as the intended area of release;
(d) the observation shall include the health of the genetically modified organism, the health of the organism within the area of limited release. And the biological diversity and the ecology of the area; and
(e) Nationally approved limited field release shall be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

Where genetically modified animal are imported for release:

(a) the reports from releases in areas other than the country of import shall be thoroughly evaluated by the national Biosafety Committee and particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate in ensuring safety;
(b) if the regulations mentioned in sub-paragraph (a) of this paragraph have not been adequate, the National Biosafety Committee may decide which step of the observations should commence;
(c) if it is decided that the regulations sued in the previous release have been rigorous enough, then the observation will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers; and
(d) when the results have met the stated requirements, then a trial release may be authorized with adequate emergency plants put in place to deal with cases of escape.

Where plant or microbial genetically modified organisms are for eventual release:

(a) laboratory bio-molecular experiments on transformation or resuscitation and other phenomena shall be carried out in complete containment;
(b) Tissue culture experiments to develop the genetically modified organisms. When required shall be carried out in complete containment;
(c) Observations aimed at understanding the nature of the genetically modified organism shall be carried out in complete containment;
(d) Experiments with the soil, soil micro-organisms, plant and animal species, under the environmental conditions of the areas of intended release shall be carried out in complete containment;

(e) Complete observation of the genetically modified organisms with the environment (soil including micro-organisms and terrestrial communities) shall be made in enclosed fields but not fully contained. At the end of the experiment, the products of the genetically modified organism may be used on an experimental basis, otherwise they shall be destroyed;
(f) the product from the genetically modified organisms shall be subjected to the procedure in paragraph 4 of this schedule;
(g) the monitoring of the spread and behaviors of any released genetically modified plant or micro-organism shall continue for at least 150 years in the case of trees, and for at least 30 years in the case of animals and micro-organisms. The duration for perennial, which live shorter than trees, may be between 30 - 50 years. The user who was responsible for releasing the genetically modified organism or its successor shall provide annual reports to the Minister through the National Biodiversity Management Agency.

Where animal genetically modified organism are produced locally for eventual release:
(a) laboratory bio-molecular experiments on transformation (or resuscitation if it is possible) and other phenomena will be carried out in complete contained;
(b) methods of incubating the transformed generative cell or the resuscitated animal shall be carried out under complete containment;
(c) the rearing of and observations on the genetically modified organisms shall be carried out under complete containment;
(d) the genetically modified organisms shall be observed under complete containment in an experimental environment which simulates the intended area of release in climatic microbial, animal and plant communities. The observations shall include the condition of the transgenic animal and those of its microorganisms especially in the context of gene transfer and those of the microbia" plant and animal communities in the experimental including gene transfer;
(e) a limited release shall be carried out in an area with appropriate enclosure and emergency measures shall be put in place to prevent escape. Observations shall include the condition of the genetically modified organisms, its micro-organisms focusing on gene transfer and the ecology of the microbial, plant and animal communities in the area including gene transfer;
(f) if the animal is intended to yield a product, the regulation of the product shall follow the procedure in paragraph 4 of this Schedule;
(g) the monitoring of the spread and behavior of any released animals genetically modified organism shall continue for at least 30 years.
General requirements with respect to risk management shall be as follows that is:
(a) all trials experiments or observations specified in this Schedule shall be put in their logical sequence and shall be subjected to the hierarchical procedures of approval by the institutional Biosafety Committees or the respective National Biosafety Technical Sub-Committee and the National Biosafety Committee;
(b) experiments starting from transformation of living organisms or resuscitation of fossil organisms carried out under completely contained laboratory conditions and continuing in the development of genetically modified organisms or products thereof shall be subjected to the approval by the respective Institutional Biosafety Committee or the International Biosafety Committee as the case may be;
© all experiments outside the strict laboratory isolations and initial experiments involving imported genetically modified organisms or products thereof shall be subject to approval of the national Biosafety Committee;

(d) all final approvals for the use of genetically modified organisms shall be made by the Agency upon the recommendation of the National Biosafety Committee;
(e) any disposal of the genetically modified organisms or the products thereof upon the completion of every trial or experiment, shall be made through complete incineration or other approved disposal by the National Biosafety Committee.

EXPLANATORY MEMORANDUM

The Act establishes the National Biosafety Management Agency charged with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern bio-technology in Nigeria with the view to preventing any adverse effect on human health, animals, plants and environment.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