APPRAISAL OF THE NATIONAL BIOSAFETY MANAGEMENT AGENCY (NBMA) ACT 2015*

Abstract
Since the advent and subsequent advancements in the field of biotechnology, there have been diverse reactions from stakeholders and experts in this rapidly growing field as to the advantages and adverse effects of products from biotechnology on the consumers, economy and the ecosystem as a whole. In the Nigerian context, this article examines the National Biosafety Management Agency Act 2015 in a bid to determine its adequacy or otherwise in regulating Genetically Modified Organisms (GMOs) and biotechnology generally, knowing fully well that technology keeps advancing and laws should be drafted in such a way as to accommodate scientific developments and advancements.

Keywords: *National Biosafety Management Agency Act 2015, Technology, Law, Nigeria*

1. Introduction

All over the world, the advocacy for the advantages of using biotechnologies pervade the agricultural, environmental, medical and industrial sectors. Advances in genomics and products of Genetically Modified Organisms (GMOs) necessitates the need for science to find solutions to the emerging issues which are the results of innovations in agriculture through plant biotechnology. Plant biotechnology has, over the time, achieved the production of superior plant varieties aimed at better and increased food and livestock production.[1] Alongside this positive feat are the concerns generating a quandary of questions for scientists involved in product development, risk assessment and other regulatory functions and those engaged in public policy.[2]

Applications of modern biotechnologies offer huge benefits in agricultural, medical, industrial and environmental sectors throughout the world. In agriculture, crops developed through genetic engineering have a considerable positive impact in the area of crop pest management in many countries. Notwithstanding the great potential benefits that this technology could bring to society, there is a common understanding within the international community that a balanced and comprehensive approach to biosafety is needed to evaluate the possible adverse effects of these products on the environment and human health. [3]

Developed countries have offered the technology to the developing countries as an avenue to secure access to the biodiversity of developing countries.[4] A country does not need to sacrifice harnessing the potential benefits of biotechnology on the altar of focusing on the need to avoid the perceived environmental and socioeconomic risks being attributed to it, such as, the perceived damage to biodiversity, including crop landraces and wild relatives; the assumption that GMOs are incompatible with local farming systems, particularly with poor smallholders; the perception that GMOs are a threat to the country's agricultural exports and concerns about farmers' dependence on multinational companies for patented seeds.[5] These assertions are strongly contested by supporters of the regulated use of GMOs who see them as potential

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[1] P. Macdonald, 'Genetically Modified Organisms Regulatory Challenges and Science: a Canadian perspective'. *Verbr. Lebensm.* 9 (Suppl 1): 2014, S59–S64
[2] P. Rzymski & A. Królczyk, 'Attitudes toward genetically modified organisms in Poland: to GMO or not to GMO?' *Food Sec*. 8:2016, 689–697
[3] Macdonald, *op.cit*
[4] A. Szgkely, 'Modified Organisms and International Law: An Ethical Perspective'. 14 *Transnat'l Law*. 2001, 129
[5] S. Ayele, 'Biotechnology and biodiversity debates and policies in Africa'. *IKD Working Paper No. 29*. The Open University; 2008, 19

sources of improved agricultural productivity and environmental sustainability resulting in reduced application of chemicals.[6]

This article appraises the National Biosafety Management Agency Act, 2015 which is the legislation in place in Nigeria aimed at 'establishing the National Biosafety Management Agency. This agency is charged with the responsibility of providing the regulatory framework as well as institutional and administrative mechanisms 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.'[7]
The Act is divided into ten parts with four schedules and this article analyses the provisions of the Act, considering the adequacy and relevance of the sections to the presented objectives of the Act. The paper makes a comparative analysis with other nations in relevant particulars and concludes with an appropriate call for action.

2. Critique of the Provisions of the National Biosafety Management Agency (NBMA) Act 2015

The Agency

The Act establishes the Agency as the national authority on biosafety in Nigeria charged with the responsibility of ensuring the effective management of all components of the Nation's biosafety. The Agency is a corporate body with perpetual succession and a common seal and may sue and be sued in its corporate name.[8] A comparative analysis of the Nigerian regulatory structure with that of the South African system shows that unlike the Nigerian system where an agency has been statutorily created to oversee issues on GMOs, the body in charge of GMOs in South Africa is a committee, an appendage of the Executive Council that is headed by the Minister of Agriculture.[9] It is hereby submitted that having an Agency in place will be a source of great stability than having a committee that will be headed by the Minister of Agriculture who may not share the same vision with the members of the committee. The agency has been charged with the responsibility of putting in place and controlling the institutional arrangement on biosafety matters; putting in place precautionary measures to protect food, human health, biodiversity and the environment from any potential adverse effects of genetically modified organisms; overseeing modern biotechnology to ensure safety and providing a holistic approach to the regulation of genetically modified organisms; providing measures for the case-by-case assessment of genetically modified organisms and management of risks involved; providing measures for effective public participation and education in the use and application of modern biotechnology and genetically modified organisms; and ensuring that the use of the genetically modified organisms does not have any adverse impact on socio-economic and cultural interests either at the community or national level.[10] The functions and powers of the Agency are directed towards the overall administration and control of GMOs and GM products in Nigeria in accordance with the nation's obligations under the conventions and protocols relating to the use of GMOs.[11]

Membership and Tenure of the Agency

The Agency is headed by a Director General who shall be appointed by the President upon the recommendation of the Minister of Agriculture.[12]The criteria stipulated for the appointment of the Director General under the Act depicts that he should be someone who is knowledgeable in the field of biosafety and his appointment is for a renewable term of 4 years. [13] However, the President reserves the power to remove

[6] A. Abraham, 'Agricultural Biotechnology Research and Development in Ethiopia. *Afr J Biotechnol*; 8:2009, 7196-204.
[7] National Biosafety Management Agency Act, 2015, Explanatory note.
[8] *Ibid*, section 1 (1) & (2)
[9] Genetically Modified Organisms Act 15 of 1997, Section 3 (South Africa)
[10] National Biosafety Management Act, 2015, section 2
[11] *Ibid*, section 3
[12] *Ibid*, section 5
[13] *Ibid*

the Director General on the grounds of inability to discharge his functions as a result of infirmity of the mind, misconduct, resignation, and where the President is convinced that it is not in the best interest of the Agency or the general public that the Director General remains in office.[14] It is submitted that the last ground mentioned above upon which the President can remove the Director General is too wide and vests a lot of discretionary powers on the President which is subject to abuse. This criterion therefore seems irrelevant and should be expunged. The criterion of removal based on acts amounting to misconduct by the Director General does not constitute one that promotes the best interest of the Agency and the society at large. Therefore, the ground of 'misconduct' is sufficient to accommodate instances where the Director General is not acting in the best interest of the Agency and the public rather than conferring the President with wide and unquestionable discretionary powers that can be influenced by several factors.

The Governing Board

The Governing board[15] comprises the following individuals: chairman, director general of the Agency, a representative not below the rank of director from the Federal Ministries[16], a representative each from the National Agency for Food and Drug Administration and Control (NAFDAC), National Biotechnology Development Agency (NABDA), Biotechnology Society of Nigeria and Non-governmental Organisations. All members of the board also serve for a renewable term of 4 years subject to the provisions of section 12 of the Act. The functions of the Board are administrative in nature[17] and they include advisory roles to the Agency, establishment of committees and appointment of employees for the Agency.

Financial Provisions

Section 14 of the Act allows the Agency to maintain its own personal account, and receive funds to carry out its statutory duties from: i. Annual budget allocations or other sums from the Federal government; ii. Grants-in-aid, endowments and donations; iii. Charges, due fees collected by the Agency. This can be classified as internally generated revenue; iv. Interests on money invested by the Agency. However, the Act also gives allows the Agency the privilege of borrowing funds from other sources, provided there is compliance with the Debt Management Act.[18] The Agency can also accept gifts of whatever form, provided that the conditions for such gifts are not inconsistent with the functions and objectives of the Agency under the Act[19] It becomes obvious from these provisions that the Act allows the Agency to be financially independent to a large extent so as to encourage effective and efficient discharge of its duties. For the sake of accountability and transparency, the Agency is also subjected to annual auditing.[20]

Request and Authorisation

The Act provides a framework regulating the application for, and the granting of permits to import, export or carry out trials on GMOs. Section 22 provides that, without the approval of the Agency, no person, body or institution can import, export or carry out trials on GMOs. Interested persons or institutions involved in importing, exporting or carrying out trials on GMOs must have applied for a permit in accordance with the provisions of section 23 of the Act. Such application must be accompanied by a detailed particularisation of: 'i. the purpose for which the GMO is developed; ii. place where such GMO product is 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.'[21] In determining whether or not to approve a

[14] *Ibid*, section 6
[15] *Ibid*, section 10
[16] The Ministries include Environment, Agriculture, Science and Technology, Trade and Investment, Health and Nigeria Customs Service.
[17] NBMA Act, 2015, Section 13
[18] *Ibid*, Section 16
[19] *Ibid*, Section 18
[20] *Ibid*, Section 20
[21] *Ibid*, Section 23(2)(h)

particular GMO for import, export or trials, the Agency adopts the risk or benefit test to evaluate the application. This means that the Agency weighs the risks of granting the application against its benefits. Also, applications must set out socio-economic considerations as provided in the Third Schedule of the Act.[22] Where a GMO product is intended for food or feed and has been assessed to be safe for human consumption, the NAFDAC shall further certify such assessment.[23] Importantly, the Act allows for public participation (through public display and public hearings) in the review of applications received by the Agency.[24] The purpose is to receive comments from interested members of the public, which may influence the decision of the Agency on the approval, or otherwise, of the application. It is submitted that the involvement of the public in the regulation of GMOs reflects a manifestation of transparency in the regulatory functions of the Agency and goes one step further to promote awareness and boost the confidence of the public in the Nigerian environmental regulatory institutions.[25] The incorporation of the provisions on public participation in the Act is a fulfilment of the obligation of the State under Article 23(2) of the Cartagena Protocol.[26] Furthermore, the provisions on request and authorisation form the bedrock of the regulatory framework for GMOs in Nigeria. The purport of the provisions is to allow the Agency monitor the influx and efflux of GMOs within the country and identify the bodies or institutions responsible for same. The creation of a database of approved and disapproved GMOs in the country enables the government to trace problems associated with particular GMOs to the source. Any applicant dissatisfied with the decision of the Agency may appeal to the Board or institute an action at the Federal High Court of Nigeria.[27] It is noteworthy to state at this point that the provisions of the Act on trans-boundary movements of GMOs by human agents and corporate bodies have not considered at all the possibility of trans-boundary movement of GMOs which may result from agents of pollination and other non-human biotic as well as abiotic agents. This I believe would defeat the whole purpose of the authorisation procedures.

Risk Assessment and Management

It is a mandatory requirement under the Act that any applicant bringing an application under section 22 must have carried out a risk assessment in accordance with the Third Schedule to ascertain the potential risks that the introduction of the GMO may have on human health, animals, plants or the environment.[28] The provision of section 32 is also pivotal to the risk assessment process as it aims to eliminate every tendency of partiality by prohibiting the involvement of anyone who has direct or indirect interest in the approval process which may lead to conflict of interest as a result of their participation in the process. It is also required that any institution or body that carries out activities relating to GMOs should develop and maintain a risk management plan as provided for under the Fourth Schedule.[29] The administrative requirements to be met which are provided for in the Act are stringent and would be expensive to satisfy. The Nuffield Report on the introduction of GM crops in developing countries has warned that 'an excessively conservative interpretation of the precautionary approach, demanding evidence of the absence of all risk before allowing the pursuit of a new technology is fundamentally at odds with any practical strategy of investigating new technologies.'[30] The report further states that: 'any highly restrictive interpretation of the precautionary approach is likely to ignore the possibility that, in some cases, the use of a GM crop variety may pose fewer

[22] *Ibid,* Section 24(3)
[23] *Ibid,* Section 24(5)
[24] *Ibid,* Section 25 and section 26
[25] M. A. Muzan, 'Institutional Mechanisms for Biosafety in Nigeria: An Appraisal of The Legal Regime under the National Biosafety Management Agency Act, 2015', *Law, Environment and Development Journal* vol.14, Issue1: 2018, 38
[26] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted in 2000
[27] NBMA Act, Section 30
[28] *Ibid,* Section 31
[29] *Ibid,* Section 33
[30] Nuffield Council on Bioethics, 'The Use of Genetically Modified Crops in Developing Countries: A Follow-up Discussion Paper'. London, 2004: Nuffield Council on Bioethics Accessed 27/11/2018 from http://nuffieldbioethics.org/project/gm-crops-developing-countries

risks than are implied by current practices or by plausible non-GM alternatives. In applying the precautionary approach, risks implied by the option of inaction (or by alternative actions) must also be considered.'[31] The provisions of the NBMA Act seem to enshrine the 'precautionary principle'[32] via risk assessment processes, risk management plans, involvement of Environmental agencies and the public in the activities involving GMOs within the country**.** The precautionary principle states that uncertainty about the potential for serious environmental harm is not a valid ground for refraining from preventative measures.[33] The precautionary principle is one of the approaches to biosafety legislation. Others are a spectrum of 'promotional, permissive and preventative' principles.[34] Some African countries such as Zambia however have decided to adopt the preventive principle. South Africa has taken the promotional approach. Burkina Faso is moving forward rapidly with field trials on GM cotton, while Egypt, Kenya, Morocco, Tanzania, Zambia and Zimbabwe are also conducting, or have conducted, confined field trials.[35] It is hereby submitted that the precautionary principle of the advancement informed the agreement procedure and the risk assessment provisions in this Act will be meaningless except the government puts in place adequate facilities for their achievement. This is particularly true if one considers the almost total lack of capacity, financial and human resources and technical know-how in the country to make the provisions workable.

Offences, Penalties and Enforcements

The Act outlines certain offences for which a person may be convicted or charged according to its provisions.[36] Some of these offences include importing, exporting or conducting trials without the approval of the Agency; contravention of the conditions for granting approval; awareness after the granting of approval that the GMO is dangerous to human health, plants, animals or the environment; and the disclosure of false information. There are some enforcement mechanisms provided under the Act such as withdrawal and revocation of permits/approvals,[37] right of entry into the laboratories or premises [of the applicant(s)?] and right of closure of facilities, confined field trial sites, farms and laboratories.[38]The South African law has no provision dealing with offences which supports the fact that the country is receptive of GMOs and GM products.

Interpretation Section: Meaning of 'Genetically Modified Organism'

The Act has only one interpretation section that is located towards the end of the Act before the Schedules. There are certain terms which the section defines within the context of the Act. According to the Act, a 'genetically modified organism' means 'any organism living or non-living that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. This position is somewhat contrary to what obtains under the Cartagena Protocol[39] that the Act is believed to be modelled after. Under the protocol, the term employed is 'living modified organism',[40] interpreted to mean, 'any living organism that possesses a novel combination of genetic material obtained through the use of modern

[31] *Ibid,* Summary and recommendations, p. xvi
[32] See Principle 15 of the Rio Declaration on Environment and Development
[33] R. Mackenzie, F. Burhenne-Guilmin, A. La Viña, & J. Werksman with A. Ascencio, J. Kinderlerer, K. Kummer, & R. Tapper, *An Explanatory Guide to the Cartagena Protocol on Biosafety*. Gland, Switzerland and Cambridge, UK: IUCN, 2003.
[34] R. L. Paarlberg,, 'Governing the GM Crop Revolution: Policy Choice for Developing Countries', 2000. 2020 Brief 68. Washington, DC: International Food Policy Research Institute Accessed 27/11/2018 from http://www.ifpri.org/2020/briefs/number68.htm.
[35]E. Jane Morris, 'The Cartagena Protocol: Implications for Regional Trade and Technology Development' *Africa Development Policy Review.* Vol. 26 (1): 2008, 29-57
[36] NBMA Act, Section 35
[37] *Ibid,* Section 38(2)
[38] *Ibid,* Section 39
[39]Cartagena Protocol on Biosafety To The Convention On Biological Diversity which entered into force on 29 December, 1993
[40]According to the Secretariat of the Convention on Biological Diversity (CBD Secretariat) 2013, 'the term living modified organism (LMO) is considered to be functionally the same as genetically modified organism (GMO)'

biotechnology'. When compared with the South African legislation on GMOs, a GMO is defined under the South African Act as 'an organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and 'genetic modification' shall have a corresponding meaning.' However, section 2(1) of the South African law excludes the application of the Act to certain processes. For instance, the term, genetically modified organisms, does not include processes such as human gene therapy, in-vitro fertilisation in humans and animals, conjugation, transduction, mutagenesis, etc. It is therefore evident, that from the perspective of the Nigerian biosafety and biotechnology jurisprudence, the term 'GMOs' as defined under the Act has a broader scope. In different jurisdictions all over the world, there are different factors contributing to the use of diverse terminologies to describe organisms that have not been traditionally bred. While some jurisdictions refer to such breeds of plants/animals as 'genetically modified organisms', 'living modified organisms', countries like Canada use the term 'plants with novel traits' (PNT). PNTs are defined as plants that contain traits which are foreign to the Canadian environment and have the tendency to affect the utilisation of such a plant considering environmental and health factors.[41] The need to focus on the products of biotechnology, and not the process, informed the decision of the Canadian Agricultural Research Council to advise that plants derived through artificial breeding techniques should be referred to as PNTs. The term, PNTs thus encompasses plants derived from genetic engineering and other breeding techniques such as mutagenesis, chromosome doubling, transposition and several others.[42]

3. Conclusion

This paper is an appraisal of the National Biosafety Management Agency Act, 2015. It has examined salient provisions of the Act and compared same with provisions of the Cartagena Protocol and laws on biosafety from other jurisdictions. The purpose of the Act is to set up an institutional framework to regulate the activities involving biotechnology within Nigeria, without losing sight of the health and environmental risks associated with such activities. It is hereby recommended that Nigeria should adopt the use of a more general and elaborate term such as PNTs to describe products of biotechnology rather than focusing on just one process of biotechnology used which is GMO. This approach will be in line with the title of the Act and accommodate emerging developments in biotechnology. Also, this will prevent a situation where there would be a constant need for enacting (new laws) or amending our laws to reflect the emerging trends in the constantly evolving field of biotechnology. It is recommended that a provision mandating the periodic publication of a gazette showing approved GMOs should be incorporated into the Act either by the way of amendment or through subsidiary legislations as provided for under section 41 of the Act to promote public awareness. From a perusal of the Act through this article, it can be deduced that Nigeria is quite receptive to the introduction of GMOs, provided that all conditions precedent stipulated under the Act are complied with. Although this article has not examined GMOs in the light bordering on international economic, environmental and health issues, it has provided a pathway to comprehending the purport, adequacy or otherwise of the National Biosafety Management Agency Act 2015. However, the implementation of the provisions in the Act has to be cautiously and efficiently carried out so as not to enhance the replacement of traditional agriculture and traditional varieties of staple crops through the use of genetically engineered crop varieties which exterminates seeds in the second generation leading to farmers having to purchase seeds for planting every year. This may eventually lead to loss of agricultural heritage as regards traditional systems of seed supply, soil fertilization and pest control.

[41]Canadian Food Inspection Agency, (2018): *Plants with Novel Traits*. Accessed 27/11/2018 from https://www.inspection.gc.ca/plants/plants-with-novel-traits/eng/1300137887237/1300137939635
[42]P. Macdonald, *op cit*, 60.