Critical Areas of Policy Regulations for the Application of Biotechnology in Aquaculture Development in Nigeria


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Abstract
Biotechnology can be defined as the use of biological processes for the improvement of the characteristics of economically important plants and animals and is considered to be a means by which fish food supplies can be significantly enhanced. Although, biotechnological developments open for benefits, it also represents new challenges with regard to how they affect economic, social and environmental conditions. The successful commercialization of technologies is highly rewarding, as the innovative biotechnology products have immense potential to generate profits and returns on investments, thus impact the fortunes of aquaculture in a very short span of the production period. The role of government agencies in promoting this emergent area is very important for the promulgation of various proactive policies, incentives and support to the biotechnology sector. The various policy issues that were reviewed in this paper include Nomenclature and Description, Transboundary Movement of Genetically Modified Organisms and the issue of Intellectual Property Rights. Attention of various international Organisations such as the UN Convention on Biological Diversity is hereby necessary to coordinate the activities of different countries involved in the development and utilization of Genetically Modified Aquatic Organisms.

Key Words: Biotechnology, Aquaculture, Modification, Organism, and Policy.

Introduction
Biotechnology can be defined as the use of biological processes for the improvement of the characteristics of economically important plants and animals (Olufeagba and Yisa, 2011) and is considered to be a means by which fish food supplies can be significantly enhanced (De Silva, 2004).

Biotechnology has however been a tool for enhancing productivity in fish farming, bringing more profit to the farmer, and better food to the people, both poor and rich. These has been made possible through improvement in qualities such as growth rate, feed conversion efficiency, disease resistance, tolerance of low water quality, cold tolerance, body shape, dress-out percentage, carcass quality, fish quality, fertility and reproduction and harvestability.

Although, biotechnological developments open for benefits, it also represents new challenges with regard to how they affect economic, social and environmental conditions. The successful commercialization of technologies is highly rewarding, as
the innovative biotechnology products have immense potential to generate profits and returns on investments, and thus impact the fortunes of aquaculture in a very short span of the production period. The role of both government and non-government agencies in promoting this emergent area is very important for the promulgation and enforcement of various proactive policies, incentives and support to the biotechnology sector.

Worldwide, policies for the research and marketing of transgenic food organisms range from non-existent to rather strict, as in the European Union (EU) (Dunham et al., 2001; FAO, 2001). Government regulation of transgenic aquaculture species based on sound scientific data is needed; however, those data are lacking. Not surprisingly, global cooperation on issues of biotechnology is not unified.

**Nomenclature and Description**

One problem that hinders responsible development of legislation and government regulation is the lack of a common, understandable nomenclature for Genetically Modified Organisms (GMOs), (Dunham et al., 2001; FAO, 2001). Aquaculture geneticists at the Fourth Meeting of the International Association of Geneticists in Aquaculture refused to draft a technical definition, and the Convention on Biological Diversity (CBD) has yet to develop a definition of Living Modified Organisms (LMO) (Dunham, 2004).

Generally, international legal organizations and the industry restrict the definition of GMOs to transgenic, whereas some voluntary guidelines adopt a wider definition that includes additional genetic modifications, such as hybridization, chromosome manipulations, sex reversal and selective breeding.

International Council for the Exploration of the Sea (ICES) defines a GMO as: An organism in which the genetic material has been altered anthropogenically by means of gene or cell technologies. Such technologies include isolation, characterization, and modification of genes and their introduction into living cells or viruses of DNA as well as techniques for the production involving cells with new combinations of genetic material by the fusion of two or more cells. (Dunham et al., 2001; FAO, 2001).

However in Nigeria, the National Biosafety Policy defines biotechnology as the application of: a) Invitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into the cells or organelles: or b) Fusion of cells beyond the taxonomic family that overcomes natural physiological reproductive or combination barriers and that are not techniques used in traditional breeding and selection (Biosafety-Bill, 2010).
Transboundary Movement of Genetically Modified Organisms (GMOs)

This is the movement of a GMO from one country to another country. This could be through unintentional release, field trials, commercial release or export. Government regulation of transgenic aquacultured species based on sound scientific data is needed; however, those data are lacking. Not surprisingly, global cooperation on issues of biotechnology is not unified. Countries that are party to the Convention on Biological Diversity (CBD) and involved in the World Trade Organization (WTO) are divided on key issues, such as:

- a) transport of transgenic organisms between countries,
- b) precautionary principles driving biosafety decisions,
- c) liability in the case of negative effects on human health or biodiversity,
- d) possible social and economic impacts on rural cultures,
- e) regulation of transgenic products across borders,
- f) food safety and protection of transgenic trade goods.

The importation of a transgenic aquatic organism and its environmental release are addressed by European Community Directives, United Nations (UN) Recommendations on the Transport of Dangerous Goods (1995) (CBD), the Food and Agriculture Organization (FAO) Code of Conduct for Responsible Fisheries (CCRF), the International Council for the Exploration of the Sea (ICES) and the National Biosafety Policy in Nigeria. Common denominators of the legislation or guidelines are licensing for field trials and release of GMOs, notification that a GMO is being exported/imported and released and an environmental impact assessment. European Community Directive 94/15/EC of 15 April 1994 (Council Directive 90/220/EEC) requires notification that a GMO is to be deliberately released in the environment (Dunham et al., 2001). The directive includes requirements for impact assessment, control and risk assessment.

In 1992, the CBD (UNCED, 1994), which includes 175 countries, requested the establishment of means to regulate, manage or control the risks associated with the use and release of LMOs (living modified organisms) which are likely to have adverse environmental impacts. CBD also requests legislative, policy or administrative measures to support biotechnological research, especially in those countries that provide genetic resources. The Convention seeks to promote biosafety regimes to allow the conservation of biodiversity as well as the sustainable use of biotechnology (FAO, 2001). It also mandates each signatory to require environmental impact assessments of proposed projects that are likely to have adverse effects on biological diversity, with the goal of avoiding or minimizing such effects. A Working Group on Biosafety developed
a biosafety protocol, and each country was encouraged to develop central units capable of collecting and analysing data and to require industry to share their technical knowledge with governments.

Article 9.3 of the FAO CCRF addresses the ‘Use of aquatic genetic resources for the purposes of aquaculture including culture-based fisheries’ (Dunham et al., 2001; FAO, 2001). The key components of this article recommend the conservation of genetic diversity and ecosystem integrity, minimization of the risks from non-native species and genetically altered stocks, creation and implementation of relevant codes of practice and procedures and adoption of appropriate practices in the genetic improvement and selection of brood stock and their progeny. Article 9.2.3 instructs: ‘States should consult with their neighbouring states, as appropriate, before introducing non-indigenous species into transboundary aquatic ecosystems.’ The Technical Guidelines on Aquaculture Development indicate: ‘Consultation on the introduction of genetically modified organisms should also be pursued.’ The definition of non-indigenous in this case is not conventional and includes domesticated, selected breeding, chromosome-manipulated, hybridized, sex-reversed and transgenic organisms.

Aquatic GMOs will also eventually come under the purview of the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) (Dunham et al., 2001; FAO, 2001). This Commission is the only permanent UN intergovernmental agency working on the conservation and utilization of genetic resources and technologies for food and agriculture. The Commission established working groups for plant genetic resources and farm-animal genetic resources, but not for aquatic resources. ICES has guidelines for GMOs, and recognizes them as a form of non-native species, which again is scientifically questionable (Dunham et al., 2001; FAO, 2001). Like the CCRF of FAO, the ICES protocols are voluntary; however, they have been adopted by numerous regional fishery bodies, by the International Network for Genetics in Aquaculture (International Center for Living Aquatic Resources (ICLARM) secretariat (now the World Fish Centre)) and by national governments, including the Philippines.

Let us now turn to instruments that are more directly trying to tackle environmental concerns in aquaculture. Most central of these is the emerging Aquaculture Stewardship Council (ASC), which came into operation in 2011 as the world’s leading certification and labelling programme for responsibly farmed seafood. The ASC is the outcome of the Aquaculture Dialogues and it will be responsible for working with independent, third party entities to certify farms that are in compliance with the standards for responsible aquaculture, which is created by the Dialogues. These standards are designed to minimize the key negative environmental and social impacts related to 12
aquaculture species. Similar to those of the Forest Stewardship and Marine Stewardship Councils, these standards prescribe quantitative performance levels that farmers must reach to become certified. More than 2,000 aquaculture producers, conservationists, scientists and others are involved in the process, which is coordinated by World Wildlife Fund (WWF).

**Intellectual Property Rights (IPR)**
The ideological foundation of intellectual property law is that it promotes and encourages creativity, as well as research and or innovations. This can be achieved by allowing authors and inventors exclusive right or a sort of temporary monopoly to exploit their works and inventions for a period with the backing of legal enforcement mechanism and the subsequent disclosure to the public domain for the ‘common wheel.’ According to Charles L. Woodbury, “Only in this way can we protect intellectual property, the labors of the mind, production and interest as much a man’s own…as the wheat he cultivates or the flock he rears” (Akintola, 2012).

IPR concerning GM aquatic organisms are controversial (Dunham 2004). Some feel that it is not ethical to patent life-forms and that such systems restrict access or make access too expensive for farmers in developing countries. The other opinion is that the research investment will not be made unless protection of IPR is maintained and that this protection and commercialization ultimately lead to greater access to genetically enhanced stocks in developing countries. There is also some debate about ownership when biological or genetic resources are removed from one country to another and what the cost of access should be for countries where the genetic resource originated (Rosendal, 2006).

A conflict exists between those who want open access to the world’s indigenous genetic resources and those who want to restrict ownership so that benefits can return to the developing countries where useful genes commonly originate (Charles, 2001a,b; Doyle, 2003). Multinational agro-biotechnology firms and some international agricultural development agencies desire the open access, while national governments, environmentalists and native-rights groups want restrictions.

In Nigeria, the efforts of The National Office for Technology Acquisition and Promotion (NOTAP) in promoting patent and innovation culture has led to the establishment of Intellectual Property and Technology Transfer Offices (IPTTOs) in some Nigerian Universities, Polytechnics and Private Research Institutions (Abo, 2010). Legal systems routinely protect and reward inventors for their creativity and ingenuity through various instruments such as Patent, Copyright, Trademark and Co-Authorship.
Patents
A patent gives an inventor the exclusive right to make, use, and sell an invention for a limited period of time.
An invention is patentable in Nigeria if;
 a) It is new, results from inventive activity and is capable of industrial application; or
 b) It constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application. However, plants and animal varieties as well as the biological processes for producing them are not patentable (Abo, 2010).

An invention is capable of industrial application if that invention can be manufactured or used in any kind of industry, including agriculture.

The right to a patent in respect of an invention is vested in the person who, whether or not he is the true inventor, is the first to file an application, or the first to validly claim a foreign priority for an application, in respect of the invention. However, whether the true inventor is the applicant or not, he is entitled to be named as such in the patent and this right cannot be modified by contract.

An application must relate to only one invention but may cover claims for any number of products or processes.

Nullity of Patent
Since patents are granted at the risk of the patentee and without guarantee of their validity, they are liable to be attacked and set aside for invalidity at any time on the application of any person (Araba, 2010; Adediji, 2012). A patent may be declared null and void on any of the following grounds:
 a) That the subject-matter is not patentable; or
 b) That the description (specification) of the claim does not conform with the statutory requirements; or
 c) That a patent has been granted already in respect of the same invention.

Duration
A patent is granted for a period of twenty years from the date of filing of the patent application. During the life of the patent the patentee must pay a prescribed annual fee in order to maintain the patent and if this fee is not paid within six months of the anniversary date the patent will lapse. A lapsed patent cannot be restored (Araba, 2010).
**Convention applications**

Unlike in the case of trademarks, the necessary ministerial declaration has been made and the countries that are to be recognised as Convention countries have been listed. This declaration and list were made in 1971 and included the Paris Union members of the time. No subsequent declaration or list has been made. It is therefore not clear whether subsequent signatories to the Paris Convention qualify as Convention countries in Nigeria. In practice the Registrar of Patents has been accepting Convention applications from these later countries. The legality of this practice has, however, not been tested in court (Araba, 2010; Adediji, 2012).

**Rights Conferred by a Patent**

A patent confers upon the patentee the rights to preclude others from:

a) In respect of a product - making, importing, selling, using or stocking it for the purpose of sale or use; or

b) In respect of a process - applying the process or doing in respect of a product obtained directly from the process any of the acts mentioned above.

However, the rights are subject to two limitations, viz.:

i) They extend only to acts done for industrial or commercial purposes but do not extend to acts done in respect of a patented product after it has been lawfully sold. Thus, the rights do not cover private and domestic use of the product; and

ii) They do not touch a "concurrent user". A "concurrent user" has the same rights in respect of the product as a patentee.

Also, a patentee has the right of assignment and transmission of the patent or grant of a licence in respect of the patent (Abo, 2010; Araba, 2010; Adediji, 2012).

**Infringement**

An infringement is actionable at the suit of the patentee or his assignee. A licensee cannot sue in the first instance but must first of all require the licensor to sue to remedy the infringement. However, if the licensor (that is the patentee) unreasonably refuses or neglects to institute proceedings, the licensee may do so in his own name without prejudice to the right of the licensor to intervene in the proceedings.

In an action for infringement, all relief by way of damages, injunction, accounts or otherwise is available to the patentee as is available in any corresponding proceedings for infringement of other proprietary rights. Jurisdiction over legal proceedings is vested in the Federal High Court (Araba, 2010; Adediji, 2012).
International Conventions and Treaties
Nigeria is a member of the Paris Union since 1963, the Berne Union since 1993 and the World Intellectual Property Organisation [WIPO] since 1995.

Nigeria is, however, not a signatory to the Patent Cooperation Treaty. Nigeria is also not a member of the African Regional Industrial Property Organisation (ARIPO), the O.A.P.I. (African Union Territories), or any other body that provides for regional registration of intellectual property rights. Consequently, registration of intellectual property rights in Nigeria can be obtained only by making application in Nigeria (Rosendal, 2006).

Technology Transfer
The National Office for Technology Acquisition and Promotion (NOTAP) is the agency charged with protecting Nigerians entering into agreements for the transfer of foreign technology and with regulating the terms of such agreements. It is empowered to register and to monitor the implementation of such agreements including agreements for the use of trademarks or of patented inventions.

In deciding whether to register an agreement the NOTAP seeks, amongst other things, to satisfy itself that; the agreement obliges the foreign party to have a Management Succession Programme and a Comprehensive Training Programme for Nigerians; so far as possible plant and machinery are to be sourced locally; the prices at which a licensor supplies goods and services are competitive; the use of foreign consultants is kept to a minimum; rights to improvements in technology remain with the Nigerian licensee; disaggregation of technology is avoided; the Nigerian party is free to export its products to other countries; the duration of the agreement is limited to not more than ten years, except in special cases; royalties, license fees and other fees do not exceed 5% of net sales.

Conclusion
Although, there is a clear evidence of biotechnology applications in aquaculture development, the existing policy framework regulating its use is not strong enough. This has been as a result of conflicts of ideas and objectives across individual borders between which products of aquaculture are moved.

Responsibility now rest on the shoulders of various recognized international organizations such as the UN Convention on Biological Diversity to coordinate the activities of concerned territories.
References


