FEDERAL REPUBLIC OF NIGERIA

National Biosafety Management Agency

NBMA

NATIONAL BIOSAFETY GUIDELINES FOR GENETICALLY MODIFIED FISH

OCTOBER, 2022

ARRANGEMENT OF GUIDELINES

PART I - INTRODUCTION

Genetic modification is the process of altering the genes of an organism to express a desired trait which cannot occur under normal reproductive conditions. Genetically Modified Fish (GMF) are fish whose genes have been altered using genetic modification techniques.

Early activities on GMF date back to 1985 in China and emphasized the refinement of transgenic methodology and the development of novel strains of fish with commercially beneficial traits with an emphasis on growth enhancement. The production of transgenic fish has since expanded, focusing on general applications: to enhance traits of commercial importance.

GMF species produced so far express desirable traits, such as enhanced growth, faster growth, higher omega-3 fatty acids, disease (viral, bacterial) resistance, double muscles and cold tolerance etc. GMFs are mostly used for feed and food production as well as ornamentals among other uses.

Fish of commercial interest that have been genetically modified fall into two main groups:

1. Fish species used for food production.
2. Ornamental fish species used in aquaria.

The main food fish species modified include salmon, trout, carp, tilapia, bass, bream and catfish. These species have been modified with genes conferring a variety of desirable traits. Ornamental fishes such as zebrafish, tetra and barb fish have been modified to express features such as colour changes and fluorescence.

Notwithstanding the benefits of this technology, there are concerns over the potential adverse impacts of GM fish to human health, animals and to the environment as a whole. The commonly developed and economically valuable GM fish species are known for their fitness in nature (ability to survive and reproduce) resulting in:

- Potential ability to outcompete other aquatic organisms
- Alteration in community structure and the biodiversity of entire ecosystems

- Interaction with various ecosystem components (such as prey, predators, and pathogens)

The National Biosafety Management Agency (NBMA) therefore regulates GM Fish under the provisions of the NBMA Act, 2015 (as amended). Under these provisions, the NBMA specifies information requirements for applications in relation to Genetically Modified Organisms (GMOs) through its regulations, guidelines, and policy documents.

In exercise of the powers conferred on it by Sections 41(3) and 25A of the National Biosafety Management Agency Act, 2015 (as amended) and all other powers enabling it in that behalf, the National Biosafety Management Agency provides the following guidelines:

Commencement [ ]

PART 1 - OBJECTIVES

The objectives of these Guidelines are to:

i. guide the Agency on the regulatory processes of GM Fish and the expectations from applicants.

ii. provide guidance and information to any person, institution or body that intends to carry out genetic modification on fish and any dealings with GM fish products in Nigeria.

PART 2 - SCOPE

The scope of these Guidelines cover GM fish species (process and product) within Nigeria. These guidelines are without prejudice to other national extant laws and guidelines, taking into cognizance international treaties and agreements.

PART 3 - PROVISIONS FOR APPLICATION

Any person, institution or body that intends to carry out dealings with GM fish such as Containment; Confined Trials; Commercial Release; as well as Import or Export for Food, Feed and Processing (FFP) shall apply to the NBMA for a Biosafety Permit in line with the provisions of the National Biosafety (Implementation, etc) Regulations, 2017.

CONSIDERATIONS FOR RISK ASSESSMENT

1. Invasiveness
2. Pleiotropy
3. Toxicity
4. Allergenicity
5. Gene flow
6. Persistence

3.1 GM Fish for Use in Containment

Any person, institution or body that intends to use GM Fish in containment shall apply to the NBMA in line with the provisions of the NBMA Act, 2015 (as amended).

Considering potentials for disruption by a variety of natural and human activities in physical containment, biological containment may also be implemented. Biological containment is usually by sterilization to eliminate the potential for reproductive interaction. A variety of sterilization procedures include induction of triploid females and sterilization with high doses of androgens.

3.2 Confinement of GM Fish

The NBMA has identified the difficulty of remediation once the escape of GM Fish occurs and therefore requires persons, institutions or bodies wishing to use GM fish in confinement to provide information on confinement measures that would be adopted to significantly control the movement of GM fish into the wild (to prevent invasiveness and persistence).

Fish produce large quantities of eggs external to their body, making the escape of genes into the environment relatively easy. The escape of GM fish from fish farms could alter the delicate ecology of natural water bodies, causing ecological disruption or species extinction. Transgenes that increase cold, salt or heat tolerance could allow GM fish to expand into new territories. GM fish with higher disease resistance and better use of nutrients could out-compete wild relatives and change predator–prey relationships, and they could therefore occupy new ecological niches. In addition, by mating with wild fish, escaped GM fish could spread the transgene among the wild population, which could cause conflicting effects on mating success, viability in natural habitats and other fitness factors required for species survival.

Confinement can be achieved through methods that prevent or disrupt sexual reproduction (bio-confinement), physical confinement, or methods that prevent GM fish survival in the wild.

In the realization of the above, the following in addition to the provisions of the National Biosafety (Implementations, etc), Regulations, 2017 on confinement, shall apply:

3.2.1 GM Fish Bio-confinement

These may include but are not limited to:

a. Sterilization through induction of triploidy. This can be achieved by holding the transgenic brood stock needed to propagate the all-female progeny in one or a few facilities.
b. Combining triploid sterilization with all-female lines
c. Combining triploidization with interspecific hybrids
d. Gene Blocking and Gene Knockout
e. Reduced Viability

3.2.2 GM Fish Physical Confinement

a. The confinement facility should be located far away from permanent water bodies with an isolation distance of not less than 500m in order to prevent gene flow from any fertile GM Fish into wild fish populations. It should have an interior drainage system only.
b. Closed-loop recirculating aquaculture systems should be used
c. Appropriate tanks for fish, including fertilized eggs should be used
d. Presence of filters of sufficient mesh size in tanks is required to retain the smallest fish likely to be present. At the early stage of embryo development, the mesh size should be determined through knowledge of the variation in egg size
e. Secondary filters should be used to retain any eggs that may be detached from the hatching trays and also to prevent the escape of fish throughout the life cycle; the number of secondary filters required will depend on the potential risk of escape
f. A cleaning regime should be instituted to prevent filter clogging. Filters should be checked regularly within 7 days to prevent the build-up of algae or other materials. Consideration should be given to the (sand) filtration of supply if the build-up of algae is identified as a major problem
g. High water alarms may be required depending on the potential risks of overflow. It is likely that low water alarms may be used to protect stocks.

h. Consideration should be given to the use of high-water alarms at floor level so that flooding is detected early. The alarm system should be audible and visible throughout the site and operate 24 hours a day

i. A secondary containment may be required in case of overflow or rupture of vessels or tanks. Rupture or other damage may occur where people have to enter the tank to clean filters and as such should be avoided. The use of long-handled brushes may provide an alternative.

j. In the event of the discharge of water from the confinement facility, the use of an electrical kill system typical of the kind used in the aquaculture industry may provide a suitable final barrier before final discharge.

3.3 GM Fish for Commercial Release

Any person, institution or body that intends to commercially release GM Fish shall apply to the NBMA in accordance with the provisions of the NBMA Act 2015 (as amended) and the National Biosafety (Implementation, etc.) Regulations, 2017 on the commercial release of GMOs. The following terms and conditions for the commercial release of GM fish shall apply.

1. All GMF must only be released into confined water bodies (See 3.2.2 of these Guidelines) or farms approved by NBMA.
2. GMF for FFP from approved farms must be appropriately packaged as specified in the National Biosafety (Implementation, etc.) Regulations, 2017 to prevent unapproved or unintentional release.
3. GM fish for ornamentals and other aesthetic uses shall be under the approval of NBMA.
4. All processes involving the commercial release of GM Fish should be properly documented by the permit holder.

3.4 Import or Export of GM Fish

Any person, institution or body that intends to import or export GM fish for any purpose, including for Food, Feed or Processing (FFP), shall apply to the NBMA in accordance with the provisions of the NBMA Act, 2015 (as amended), the National

Biosafety (Implementation, etc.) Regulations, 2017, and Guidelines for the Importation of Genetically Modified Organisms for Food, Feed and/or Processing (FFP), 2020.

3.5. GM Fish Waste Management

Prior to disposal, the waste generated from dealings with GM Fish shall not be stored and must be immediately decontaminated at the same site. To decontaminate waste, any person, institution or body dealing with GM Fish shall refer to the provisions for waste decontamination in Part C (5) of the National Biosafety Guidelines on the Certification of Containment Facilities, 2017.

3.5.1. GM Fish Waste Management in Contained Use and Confinement

The following action should be carried out and documented in detail for inspection by NBMA:

a. Solid waste disposal: Solid waste should be decontaminated using heat or chemical methods prior to disposal in a landfill. Alternatively, the waste can be ground and tilled into agricultural land as fertilizer after treatment.
b. Liquid waste disposal: Liquid waste should be decontaminated before disposal via drainage exits, which must be fitted with liquid traps permanently filled with an appropriate decontaminant to ensure that any liquid waste is decontaminated prior to being released from the facility. All liquids from the facility entering the drains must be treated as waste.

3.5.2. GM Fish Waste Management in FFP and Domestic Use

Waste from GM Fish which has been commercialized should be decontaminated using any treatment method (heat method, incineration or pyrolysis) prior to disposal in a landfill or utilization as compost.

All waste from GM Fish which has been commercialised must not be disposed of near permanent water bodies (a distance of 500m should be maintained). The permit holder is responsible for all compliance to ensuring that all waste of GM Fish are decontaminated and are not disposed into permanent water bodies before.

3.6 Contingency Measures

In the event of predation by animals, poaching, force majeure, civil unrest, or any other forms of unintentional release, contingency measures should be put in place, which should include measures to recall. On the occurrence of any of the above potential risk incidences, NBMA should be contacted immediately in line with the National Biosafety Emergency Response Strategy.

PART 4: DEFINITION OF TERMS

In these Guidelines:

"Act" means the National Biosafety Management Agency (NBMA) Act, 2015 (as amended).

"Applicant" means a person, institution or body that applies to the NBMA to carry out dealings with GM fish.

"Confinement" means a small-scale experimental release into the environment of a Genetically Modified Organism under physical and/or biological confined conditions.

"Contained Use" means any operation using modern biotechnology undertaken within an enclosed facility, installation or other physical structure, such as a building, laboratory or greenhouse.

"Commercial Release" means the release of a Genetically Modified (GM) Fish into the market as a product that can be purchased and used by any individual.

"DNA" is deoxyribonucleic acid. It is a self-replicating material that is present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information.

"Gene" is the basic physical and functional unit of heredity and a sequence of nucleotides in DNA that encodes the synthesis of a gene product either RNA or protein

"Genetically Modified Organisms (GMOs) mean any organism living or non-living that possesses a novel combination of genetic materials obtained through the use of modern biotechnology.

"Modern Biotechnology" means the application of:

(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.

"Pleiotropy" – the expression of multiple traits by a single gene

"Product" means any material obtained from genetically modified organisms, in this context - fish.

"**Risk**" means the product of two probability distributions – the likelihood of exposure to a hazard and the likelihood the hazard will cause harm.

"Risk Assessment" means the process of identification, characterization and evaluation of risks that Genetically Modified (GM) Fish or its product(s) may pose to animal, human and plant health, biological diversity and the environment.

"Triploidy" Is a situation where a cell acquires an additional pair of chromosomes thus containing (3) three pairs of chromosomes.