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AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY
Mexico City, 25-29 July 2016

DRAFT OUTLINE OF GUIDANCE ON "RISK ASSESSMENT OF LIVING MODIFIED FISH"

1. The document herein attached is the outcome of the work of the Subgroup of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (AHTEG), in consultation with the Secretariat and taking into account input from the "Open-ended Online Forum" and AHTEG, in response to decision BS-VII/12.

2. The present document is being presented for the consideration of the AHTEG at its face-to-face meeting from 25 to 29 July 2016 in Mexico City.

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INTRODUCTION

Living modified (LM) fish are produced for a variety of purposes, including growth-enhancement, infection resistance or cold tolerance, human food production in aquaculture, biological control of nuisance species, recreational fishing, monitoring water quality to detect contaminants, as bio-factories to produce commercially valuable compounds such as human pharmaceuticals, cancer models (oncofish), xenotransplantation, identification of potential new drugs and ornamental aquarium market. Several species have been genetically modified, such as Atlantic salmon, channel catfish, goldfish, crayfish, tilapia, zebrafish, carp and medaka.

There are several issues that are unique or particularly relevant to fish and warrant further consideration during the risk assessment of LM fish. These issues include:

(a) Fish live in aquatic environments and are highly mobile;

(b) Potential to escape from containment facilities and spread to natural environments and across national borders;

(c) Potential inter-specific and inter-generic hybridization;

(d) Presence of venom toxins;

(e) Some species may be protected by national law, for example several countries protect species of wild salmon;

(f) Phenotypic plasticity;

(g) High number of species/varieties (around 30.000) and high intraspecific genetic variability.

As for the risk assessment of other LMOs, the case-by case approach must also be applied to the risk assessment of LM fish. It is suggested that any guidance to be developed on risk assessment of LM fish would be applicable to all types of LM fish and not focused on particular modification methods, receiving environments, intended uses or species. Therefore, the risk assessment criteria and requirements will not be equally relevant in all cases.

Gaps in information that are of possible relevance for the risk assessment of LM fish include:

(a) Lack of empirical evidence of LM fish behavior, invasiveness, fitness (survival and reproduction) and genetic stability in the wild

(b) Lack of data on Genotype-x-Environment (GxE) interactions

(c) Limited understanding of the whole genome of fish species

(d) Pleiotropic effects

(e) Potential impacts under climate change scenarios

(f) Migratory and mating behavior of LM fish

(g) Change in habitat range of LM fish

OBJECTIVE AND SCOPE

This outline was prepared to facilitate considerations of the COP-MOP concerning the need for developing guidance on risk assessment of LM fish to complement the Roadmap for Risk Assessment of Living Modified Organisms. The outline focuses on aspects that are unique or particularly relevant to LM fish, including freshwater, marine, catadromous and anadromous fish and shellfish, as well as aquarium species.

PLANNING PHASE OF THE RISK ASSESSMENT

Protection goals, assessment endpoints, theories or models on predicting the environmental fate of transgenes or the transgenic fish (purging, spread, Trojan gene, establishment, etc.) may be included in this section.

In addition to the considerations raised in the Roadmap, this section could also include considerations of the likely potential receiving environments, including unintentional transboundary movements to other countries.

The choice of comparators could also be discussed in the context of:

(a) Parental line and wild fish

(b) Experience and history of fish in cultivation, taking into account its ecological function

(c) Centers of origin and centers of genetic diversity

(d) Current distribution areas and habitats where wild type fish may persist or proliferate

CONDUCTING THE RISK ASSESSMENT

This section should provide information on issues of particular relevance for conducting risk assessment of LM fish, with reference to the steps in the Roadmap, as appropriate, such as:

(a) Testing the living modified fish in representative environments (see Roadmap step 1)

Regional variation and differences in the environment may influence the characteristics and the behavior of LM fish. Experimental trials should be performed in as representative conditions as possible.

(b) The likely potential receiving environment(s) (see Roadmap step 1, step 2 and step 3)

The identification and characterization of potential receiving environments may be dependent on several factors including whether natural or artificial barriers are present that could limit the dispersal.

(c) Vertical and horizontal gene transfer in the potential receiving environment (see Roadmap step 1, step 2 and 3)

Ecological, evolutionary, and stochastic factors that could affect the transgenes, survival of DNA/RNA from LM fish in water and spread of transgenes are relevant issues.

(d) Persistence and invasiveness (see Roadmap step 1, step 2 and step 4)

Of relevance could be to identify if metabolism and/or other biological parameters remain unchanged for LM fish. If they are different, identify how growth, fish health/welfare are affected.

The net fitness trait data on real transgenic individuals and their non-modified counterparts. Relevant fitness components (fecundity, fertility, juvenile viability, age at sexual maturity, mating success, and longevity) should be considered.

(e) Dispersal mechanisms (see Roadmap step 1 and step 2)

LM fish have a variety of ways to reproduce and disperse.

(f) Target/non-target organisms (see Roadmap step 2, 3 and 4)

Harm to species of special concern, such as endangered species or economically or culturally important species.

(g) Fish pathogens, infections and diseases (see Roadmap step 3)

Identify if LM fish that are resistant to fish pathogens, infections and diseases can be carriers of the same diseases and hence by escape spread the same diseases.

(h) Unintentional transboundary movements (article 17)

Fish have a broad geographical distribution, although that will vary depending on the species. Confinement will be dependent on the species and the strategy used to develop LM fish.

(i) Risk management strategies including containment strategies (see Roadmap steps 2 and 5)

In this section relevant strategies to reduce the identified risks could be included. A short overview of different containments strategies of relevance for risk assessment of LM fish could also be included. For example: physical containment, physicochemical containment, reproductive containment, and methods /of induction of sterility/to obtain sterility in fish and their efficacy. Potential consequences arising from escape and/or incidental exposure of humans and other animals to LM fish under containment conditions could be explored, for example, LM fish intended for biopharming.

BIBLIOGRAPHIC REFERENCES

References to relevant guidance and scientific papers on risk assessment of LM fish.