United Nations

UNEP

Environment Programme

Republic of Ghana

Global Environment Facility

GEF

GUIDELINES FOR RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS IN GHANA

The guideline on "Risk Assessment on Genetically Modified Organisms in Ghana" was prepared with financial support from the UNEP-GEF Project on "Development of National Biosafety Frameworks".

The guideline was prepared by the following:

Prof. Eric C. Quaye – University of Cape Coast, Cape Coast

Prof. George Y. P. Klu, Biotechnology & Nuclear Agric. Research Institute

Prof. Josephine Nketsia-Tabiri, Biotechnology & Nuclear Agric. Research Institute

Dr. Musheibu Mohammed-Alfa, Food & Drugs Board

Mr. E. K. Jack-Vesper Suglo, Plant Protection & Regulatory Services Directorate

Mr. Alex Owusu-Biney[1], Biotechnology & Nuclear Agric. Research Institute

Published by:

UNEP-GEF	United Nations Environment Program – Global Environment Facility
NBC	National Biosafety Committee
BNARI	Biotechnology & Nuclear Agriculture Research Institute

Copyright:

MES The Ministry for Environment & Science

Reproduction of this publication for educational or other non-commercial purposes is authorized without prior written permission form the copyright holder provided the source is fully acknowledged.

Editors: Alex Owusu-Biney, Eric C. Quaye & Josephine Nketsia-Tabiri

ISBN: 9988-8275-1-2

[1] *Contact Address for follow up and feedback – UNEP/GEF Project on "Development of National Biosafety Frameworks", BNARI, P. O. Box LG. 80, Legon, Accra, Ghana; Tel: 233-21-400310/402286/404963; Fax: 233-21-400807; Email: bineya@idngh.com*

ACKNOWLEDGEMENT

This guideline is a guidance document to assist scientists and reviewers in risk assessment involving Genetically Modified Organisms in Ghana. The document has evolved through consultation and review by several stakeholders. We would like to take this opportunity to acknowledge the support received from the National Biosafety Committee and several individuals and institutions in the development of this guideline. We however accept responsibility for any omissions in the drafting of this guidance document.

It is our fervent hope that this document will assist biotechnology activities in Ghana.

SCOPE

These guidelines shall apply to the contained use, deliberate release or placing in the market of all types of genetically modified organisms (micro-organisms, plants, animals), within the boundaries of Ghana.

A. INTRODUCTION

By using gene technology it is now possible to precisely identify the individual gene(s) that govern a desired trait, extract it and insert the copy into another organism, creating a genetically modified organism (GMO). This kind of genetic modification can provide us for example with a crop that is inherently resistant to pests, or a cow that produces more milk, or even microorganisms that produce useful drugs.

Modern biotechnology has wide applications in research and commerce however one of the applications, notably, recombinant deoxyribonucleic acid (rDNA) biotechnology continues to attract concerns which must be addressed to facilitate its responsible deployment and acceptability world-wide. The products of rDNA biotechnology are referred to as Genetically Modified Organisms (GMOs) or Living Modified Organisms (LMOs).

Genetic modifications that occur in traditional methods through cross breeding and induced mutations are naturally undefined or imprecise. Consequently, it takes years of unpredictable efforts with occasional offsprings, which have the desired genetic traits. In rDNA biotechnology, however, genetic modification is achieved with greater precision and speed. This is largely because the genes responsible for the desired trait are first identified and extracted from one or more organisms and their insertion into the receiving organisms. The transferred genes or transgenes do not have to come from related species in order to be functional; they can also be moved virtually at will among different living organisms. Therefore rDNA biotechnology can be applied to microorganisms, plants and animals in order to develop useful products and processes as diverse as drug development, fish farming, forestry, crop development, fermentation and oil-spill clean up.

GMOs can thus avail us with tremendous benefits. At the same time GMOs (*can pose serious*) have the potential to cause adverse effects to human health and the environment. These may include:

- Disease to humans, including allergenic or toxic effects
- Disease to animals and plants including toxic, and where appropriate, allergenic effects
- Effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations
- Altered susceptibility to pathogens facilitating the dissemination of infectious diseases.

- ❖ Compromising prophylactic or therapeutic medical, veterinary or plant protection treatment, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine.
- ❖ Effects on biogeochemistry, particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

All genetically modified organisms (GMOs), whether microorganisms, plants or animals[2], must therefore be carefully assessed prior to their use or release. Articles 2.2 of the Cartagena Protocol on Biosafety, to which Ghana is a Party, mandates all parties to among other things ensure that, use and release of any genetically modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking into account risks to human health. Article 15.2 of the same protocol particularly calls on parties of import to ensure that risk assessments are carried out before the decision to use or release of GMO is made. Risk Assessment can be defined as a formalized basis for the objective evaluation of risk in a manner in which assumptions and uncertainties are clearly considered and presented. Risk Assessment involves a number of objective considerations which include identification of potential adverse effects, an assessment of the likelihood that the potential adverse effects occur, and an evaluation of the consequences that may arise if adverse effects are realized.

This technical manual, containing guidelines for a step-by-step assessment of GMOs, has therefore been developed to enable Ghana derive the enormous benefits of GMOs, without compromising the health of the populace and the protection of its environment.

The guidelines have been made to harmonize to a large degree, with risk assessment criteria and standards that have achieved international acceptance in either practice or principle. This harmonization principle is clearly implicit in the Cartagena Protocol on Biosafety and is further necessitated by the fact that Ghana is a signatory to international agreements, conventions and treaties, such as trade agreements on plant, animal and food standards governed by the IPPC, WTO, WHO and FAO.

B. Objective of risk assessment (RA)

The objective of risk assessment is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health. Risk assessment should be conducted with a view to identifying if there is the need for risk management and if so, the most appropriate method to be used.

Adverse effects of GMOs can be direct, indirect, immediate or delayed, where:

[2] *Phytosanitary and Zoosanitary risks that may be associated with an LMO are within the scope of the International Plant Protection Convention (IPPC) and the Office Internationale des Epizooties (OIE) and should be considered using Pest Risk Analysis (PRA) to facilitate decisions regarding pest risk management.*

- ❖ ‘direct effects’ refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a casual chain of events;
- ❖ ‘indirect effects’ refers to effects on human health or the environment occurring through a casual chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Such effects are likely to be delayed;
- ❖ ‘Immediate effects’ refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;
- ❖ ‘delayed effects’ refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

Risk assessment underpins the decision making process for *granting* permits for the contained use, release and/or marketing of GMOs.

C. General Principles of RA[3]

In accordance with the precautionary principle, the under mentioned general principles should be followed when performing risk assessment of GMOs:

- The risk assessment should be carried out in a scientifically sound and transparent manner based on latest available scientific and technical data;
- Identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;
- The risk assessment should be carried out on a case-by-case basis. This implies that the required information may vary depending on the type of GMO concerned, their intended use and the potential receiving environment, taking into account, among other things, GMOs already in the environment;
- If new information on the GMO and its effects on human health and the environment becomes available, the risk assessment should be re-examined.
- The information required in the notification must include possible impacts of the specific techniques used for the management of the GMO where these are different from those used for Non-GMOs.
- Where the GMO is a crop, it is important to place the assessment in the context of existing agricultural practices and also evaluate the effect of the management of the GMO.
- The risk assessment should document the uncertainties, the assumptions made and the effect of these on the final risk estimate.
- Both qualitative and quantitative risk assessment methods are valid.

[3] *For guidance, refer to Annex III of the Cartagena Protocol on Biosafety*

D. Information required for a scientifically sound risk assessment

1. Characteristics of host organism

- name and identity
- pathogenicity, toxicity and allergenicity;
- natural habitat, geographic origin, distribution and role in the environment;
- mechanisms by which the organism survives, multiplies and disseminates in the environment;
- means for transfer of genetic material to other organisms.

2. Characteristics of the organism(s) from which nucleic acids are obtained (the donor)

- name and identity
- the relevant characteristics include, pathogenicity, toxicity and allergenicity;
- natural habitat, geographic origin, distribution and role in the environment;
- mechanisms by which the organism survives, multiplies and disseminates in the environment;
- means of transfer of genetic material to other organisms.

3. Characteristics of the vector

- identity, origin, natural habitat and the relevant safety characteristics
- the frequency at which the vector can transfer itself to other organisms
- factors which will affect the ability of the vector to become established in other hosts.

4. Characteristics of the inserted nucleic acid (the insert)

- functions coded by the inserted nucleic acid including any residual vector
- information on the expression of the inserted nucleic acid and the activity of the gene product.

5. Characteristics of the organisms with novel traits (GMO)

The GMO should be compared with the organism from which it is derived, examining where appropriate the following points:

- Pathogenicity, toxicity and allergenicity to humans and other organisms
- Survival, persistence, competitive abilities and dissemination in the environment
- Capacity to transfer genetic material and the way this might happen
- Methods for detecting the organisms in the environment and for detecting the transfer of the donated nucleic acid
- Functions which might affect its ecological range
- Characterization of the product(s) of the inserted gene(s) and, where appropriate, the stability of the modification.

6. Information relating to the intended use

The amount of information required will vary with the characteristics of the organisms and use, frequency and the scale of the intended use.

For contained uses, this can include:

- Number or volume of organisms to be used
- Scale of the operation
- Proposed containment measures, including verification of their functioning
- Training and supervision of personnel carrying out the operation
- Plans of waste management
- Plans for safety of the health of personnel
- Plans for handling accidents and unexpected events
- Relevant information from previous uses.

For deliberate use, this can include:

- Purpose and scale of the release
- Geographical description and location of the release
- Proximity to residences and human activities
- Method and frequency of release
- Time and duration of release
- Expected environmental conditions during the release
- Proposed risk management measures including verification of their functioning.
- Subsequent treatment of the site and plans for waste management
- Plans for handling accidents and unexpected events/disasters
- Relevant information from any previous releases.
- Likelihood of Transboundary Movements

7. Characteristics of the potential receiving environment

The potential of an organism to cause harm is related to the environments into which it may be released and its interaction with other organisms.

Relevant information can include:

- The geographical location of the site and any special features of the environments that expose them to damage
- The proximity of the site to human settlement and to other significant biota
- Any flora, fauna and ecosystems that could be affected by the release, including rare, endangered, potential competitive species and non-target organisms
- The potential of any organisms in the potential receiving environment to receive genes from the released organism

E. Methodology of risk assessment

To fulfill its objectives, RA should entail as appropriate the following steps:

1. **An identification of characteristics of GMO that may cause adverse effects on human health or the environment.**

   Comparing the characteristics of a GMO with those of the non modified organism will help the assessor identify any potential adverse effects that may arise due to the genetic modification,

2. **An evaluation of the potential consequence of each adverse effect should it occur.**

   The magnitude of the consequences of each potential adverse effect is evaluated on the assumption that such an adverse effect will occur bearing in mind that such magnitude is likely to be influenced by the environment into which the GMO is intended to be released at the manner of the release.

3. **Evaluation of the likely of the occurrence of identified potential adverse effects.**

   A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO is intended to be released and the manner of the release.

4. **Estimation of the risk posed by each identified characteristic of the GMO that can be a cause of adverse effect.**

   This is done by combining the likelihood of the adverse effect occurring and the magnitude of the consequence if it occurs.

5. **Identification of management strategies**

   Risks that require management are identified and appropriate strategies to manage them proposed.

6. **Determination of the overall risk of the GMO**

   This should be made taking into account any risk management strategies which are proposed.

F. Structure of Assessment Report

The assessment report should include in particular the following.

1. Identification of the Characteristics of the recipient organisms which are relevant to the assessment of the GMO(s) in question.
2. Identification of any known risks to human health and the environment resulting from the release in the environment of the recipient non – modified organism.
3. Description of the result of the genetic modification in the modified organism.
4. Assessment of whether the genetic modification has been characterized sufficiently for the purpose of evaluating any risks to human health and the environment.
5. Identification of any new risks to human health and the environment that may arise from the release of the GMO(s) in question, as compared to the release of the corresponding non-modified organism(s)
6. A conclusion as to whether the GMO(s)in question should
    I. be placed in the market and under which conditions
    II. not be placed in the market, in which case reasons should be given.
    III. be used under containment