

# NATIONAL GUIDELINES FOR THE RELEASE OF GENETICALLY MODIFIED ORGANISMS (GMOs) INTO THE ENVIRONMENT

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## I. INTRODUCTION

1. The development of techniques in genetic modification which include recombinant DNA technology and cellular techniques of introducing DNA into an organism has resulted in tremendous advances in agriculture, human health and the processing industry.
2. The emergence of genetically modified plants, animals and microorganisms with superior genetic traits and their subsequent release into the environment have currently raised concern among the public at large and highlighted issues regarding safety.
3. Biosafety procedures for genetic modification and release are well established in most industrialized countries, thus reflecting the level of biotechnology activities undertaken. In a developing country like Kenya, research in genetic modification is being performed on a smaller scale in government funded research institutions and universities. Nevertheless, release experiments of genetically modified organisms (GMOs) is envisaged in the future. Kenya also envisages that there will be release experiments performed by multi-national companies. Taking these into consideration, there is an urgent need for developing biosafety procedures at the national level and providing advice to the Government on biosafety policies. The establishment of biosafety regulations is to ensure monitoring and regulation of international projects pertaining to genetic modification and release, commercial activities and technologies, as well as development, release and large scale use of GMOs.
4. The proposed National Guidelines for release of GMOs into the environment have been developed from the existing principles derived from relevant regulations and guidelines at national, regional and international levels.
5. International documents taken into consideration in formulating the Guidelines are:
  - UNEP International Technical Guidelines for Safety in Biotechnology, 1996;
  - Biosafety Regulations: A Critique of Existing Documents (*Ingham et al.* 1994, an occasional paper of the Edmonds Institute, USA.);

- Risk Assessment on the Release of Genetically Modified Plants, (MAFF, UK, 1994);
  - Guidelines for Planned Release of Genetically Manipulated Organisms, (GMAC, Australia, 1993);
  - The UNIDO Voluntary Code of Conduct for Release of Organisms into the Environment, 1991;
  - Convention on Biological Diversity, 1992;
  - The FAO Code of Conduct on Distribution and Use of Pesticides.
6. The National Guidelines address the need for mechanisms of risk assessment and management, a need for international exchange of information in particular between neighboring countries with regards to release of GMOs and capacity building in order to adequately address safety in genetic modification research.
  7. The National Guidelines provide a more defined procedure for risk assessment on the release of GMOs into the environment.
  8. The National Guidelines also take into account factors for international harmonization of the existing biosafety guidelines.

## **II. NATIONAL GUIDELINES FOR RELEASE OF GMOs INTO THE ENVIRONMENT**

### **Objectives**

The objectives of the Guidelines are to:

9. outline the general principles governing standards of practice as outlined in Annexes 1 & 2 for all parties involved in the introduction of GMOs and products containing or consisting of GMOs to the environment. Some sections of the Guidelines may also be applicable to other phases of research and development;
10. encourage and assist the establishment of an appropriate national regulatory framework;
11. ensure that national authorities and institutions, distributors and users are informed or have access to information on safety and risk thereby facilitating the safe use and handling of GMOs and products containing, or consisting of GMOs;
12. discourage international governmental and non-governmental institutions, including funding organizations, from providing funds to researchers or producers who do not follow the principles set out in these Guidelines;
13. develop mechanisms for co-operation and consultation between governments to ensure safe research, development, use including environmental application dealing with transboundary movement and commercialization of GMOs and products containing or consisting of GMOs;
14. ensure the safety of all types of research, development and marketing of GMOs and products containing or consisting of GMOs by providing mechanisms to obtain consultation and advice on risk assessment and management as required;

15. stimulate the development of mechanisms for obtaining and disseminating information in a timely and efficient manner;
16. address the shared responsibilities in biosafety of many sectors of society, including government, regional, supranational and international organizations, scientific researchers, institutions and societies, trade associations, industry including manufacturers, formulators and distributors, users and non-governmental organizations, such as environmental groups, consumers and trade unions and funding institutions;
17. help industries, organizations and scientists seeking to facilitate, develop and apply biotechnology for social and economic improvement, to be aware that their judgments and actions involving GMOs, if taken with adequate review and notification, will ensure public health and environmental safety and thereby promote and not jeopardize, the long term development of the technology;
18. emphasize the need and responsibility of all national authorities and other parties involved to ensure that the public is well informed and when necessary, consulted.
19. provide a broad-based, sufficiently comprehensive and transparent framework so that they will be widely acceptable. They should be sufficiently flexible to allow evolution over time to accommodate new advances, expertise and requirements. Nevertheless, it should be emphasized that for complete safety in biotechnology, adoption of these Guidelines alone may not be adequate;
20. supplement the existing general regulations for agricultural, food and pharmaceutical products and assess requirement on amendments to the regulatory approach specifically aimed at GMOs and products containing, or consisting of GMOs.

### **III. SCOPE**

21. addresses all institutions and persons researching, developing, using, releasing and the marketing of GMOs and products containing or consisting of GMOs, including GMOs that are imported.
22. covers GMOs at all stages of research, development, use, release and placing on the market. It covers, but is not limited to, genetically modified plants, animals (including for example, insects, mollusks and fish) and microorganisms and products consisting of or containing GMOs.
23. covers safety issues regarding agriculture, public health, the environment and transboundary issues pertaining to release of GMOs and products containing, or consisting of GMOs.

### **IV. GENERAL PRINCIPLES OF THE GUIDELINES**

24. Regulatory oversight and risk assessments should focus on the characteristics of the modified organism rather than the molecular or cellular techniques used to produce it. Whilst knowledge of the techniques is useful as it relates to properties conferred to the GMO, it is the GMO or related

product to which humans, animals and the environment are exposed to that is the focus of the Guidelines.

25. The Guidelines also from time to time address the socioeconomic impact of any proposed release of GMOs, and products containing or consisting of GMOs.
26. Assessment and management of risk of the GMOs to agriculture, human health and the environment should be based upon of the following key parameters.
  - a. Focus on the organisms which should include:
    - i. characteristics of the parent organism and DNA donor organism which include taxonomy, life cycle, reproductive properties and physiological abilities;
    - ii. characteristics of the modified organism which include function of novel genes, vector and expression ability/stability, ability to dispense/integrate in other hosts, pathogenicity effects on other organisms potential for population increase;
    - iii. ecological traits of the donor and recipient; effects on other organisms in the environment, pathogenicity interactions;
    - iv. interaction of GMOs with biological systems (i.e. habitat, target ecosystem and other possible systems the GMOs can disseminate), stability of the engineered gene in GMOs, transfer capability, effects on target and non-target organisms, and where appropriate, effects on soil foodweb communities, plants and aquatic systems as well as sediments.
  - b. Application or intended use of GMOs: includes physical description of site, containment/decontamination, monitoring plans, mediation after completion.
  - c. The receiving environment:
    - i. assessment should be based on the organisms' traits and intended use. Risk must be evaluated at each step of research up to field release;
    - ii. the safety precautions and monitoring procedures specified should be appropriate to the level of assessed risk. Principal Investigators (PI) or Biosafety Officer (BSO) should be well versed with the Guidelines. Nevertheless responsibility for ensuring compliance with safety conditions set by risk assessment committees should fall within the ambit of the National Biosafety Committee (NBC)/Biosafety Authority;
    - iii. the type of risk management to be considered will depend on the GMOs and release activities. For example, in controlled releases, biological, chemical and physical barriers can be utilized to provide genetic isolation and limit dissemination of GMOs. Annexes 1 & 2 provide further details for assessment of release activities;
    - iv. a GMO will be allowed to be placed on the market if and only if it is considered to be safe.
  - d. National authorities, industry and researchers have a responsibility to disclose or make available safety information to the public. Acceptance of biotechnology products will be enhanced if the information is disclosed and

made available to the public, especially the community where the test will occur. There is a need for openness in this process.

- e. Unexpected or adverse public health, agricultural or environmental impacts resulting from the intentional and unintentional release of a GMO should be reported to NBC and relevant regulatory authorities immediately.
- f. Evaluations of risk should be conducted for local and imported GMOs/products at each step of development from the research laboratory to small-scale and large-scale release for production and testing, including commercial use. Evaluations at each stage should be built on those made at prior stages and need not always be conducted de novo. In evaluating release, information on similar releases elsewhere may be taken into account.
- g. The systems developed for review of proposal applications must remain flexible and capable of being adaptive in accordance with the latest scientific information. The systems should be constantly evolving to accommodate new findings.
- h. While the national authority has primary responsibility for ensuring review and making decisions concerning activities related to release of GMOs carried out within the country, regional cooperation will be desirable and sometimes essential.
- i. Information on anticipated consequences, which may extend beyond the country will need to be provided. In this case formal notification and relevant information should be provided to the country or countries which may be affected.

## **V. ORGANIZATIONAL FRAMEWORK**

- j. Safety Mechanisms at the National Level:
  - i. The National Biosafety Committee (NBC)/Biosafety Authority will monitor and implement the Guidelines;
  - ii. As a starting point in implementing these Guidelines, existing mechanisms already established, *such as the Standards Act, (Cap 496), Food, Drugs and Chemical Substances Act (Cap 254), Crop production and Livestock Act (Cap 321), Animal Diseases Act (Cap 364), Environmental Management and Coordination Act 1999 and the Plant Protection Act (Cap 324), etc.* be utilized.
- k. Roles and Responsibilities:
  - i. The NBC/Biosafety Authority shall be responsible for handling inquiries, proposals and approvals, i.e. all contacts concerning the use, release and introductions of GMOs. More than one subcommittee may be appropriate to cover specific areas of use; for example, pharmaceuticals, food, agriculture and pesticides.
  - ii. Case-by-case evaluation should be the rule unless sufficient experience and an adequate body of knowledge is gathered to allow classifications and generalizations based on experience and conclusions regarding the behavior of a GMO. Generalizations should be applied with caution as GMOs may behave differently in different environments.
  - iii. The NBC/Biosafety Authority should establish mechanisms to facilitate the collection, storage and dissemination of data on local conditions, such as agronomic, epidemiological, logistic and environmental data.

- iv. The NBC/Biosafety Authority should ensure that for each proposed use or release, there is compliance with the safety conditions set down as a result of the risk assessment. This should include any appropriate control or mitigation procedures as well as procedures for termination of the experiment and waste disposal.
- v. The NBC/Biosafety Authority should ensure that the principal investigator (PI)/ proposer has suitable monitoring procedure in place. In addition, the Committee may wish to/will undertake additional monitoring of the GMO, the site or the surrounding environment beyond that which is necessary, as part of the experimental protocol;
- vi. While ensuring maximum disclosure of information necessary for risk assessment and safety, the Committee should recognize and respect confidentiality if requested of business information submitted to the committee;
- vii. When an introduction of an organism is planned, the NBC/Biosafety Authority should ensure that the local community is informed prior to the release. In addition, the national body or authorities in collaboration with its (their) scientific advisory bodies and the principal researcher/proposer should provide appropriate information to the public;
- viii. Establish effective mechanisms for exchange of information with other interested countries, particularly those in her geographic region.

## **VI. SAFETY AT INSTITUTIONAL LEVEL**

- I. Establishment of the Institutional Biosafety Committee IBC:
  - i. Motivation and good judgment are key essentials to protection of health and the environment during a release project.
  - ii. IBC will ensure that experiments relating to genetic modification and release undertaken by the institution conform to the provisions of the Guidelines.
- m. Roles and Responsibilities
  - i. The committee should comprises members who collectively have experience and expertise in genetic modification techniques and the capability to assess risk associated with such experimentations and, also any potential risk to public health or the environment.
  - ii. Review for compliance with the Guidelines.
  - iii. Undertake risk assessment of the research proposal in order to identify all potential hazards to the research, the community and the environment.
  - iv. Inform the NBC/Biosafety Authority with regards to IBC assessment of the proposal for review and assessment of experiments.
  - v. Provide advice and risk management strategies to the principal investigator following NBC/Biosafety Authority assessment of the risk associated.
  - vi. Ensure that the institution complies with the correct containment levels, transgenic animal facilities, infectious animal holding facilities & glasshouses for use in genetic modification experimentation.
  - vii. Monitor ongoing work being conducted at the institution to ensure that the NBC/Biosafety Authority recommendations are being fulfilled.

- viii. Continual assessment of the facilities, procedures, and of the training and expertise of personnel involved.
  - ix. Provide an annual report of the institution's activities to the NBC/Biosafety Authority.
  - x. Adopt emergency plans covering accidental spills and decontaminating procedures.
- n. Conflict of Interests  
Members of an IBC should not be involved in the review or approval of their own project proposal(s) or commercial applications.
- o. Responsibilities of the Principal Investigator (PI)/Proposer
- i. The PI/proposer must notify and obtain approval through IBC from the NBC/Biosafety Authority prior to the conduct of an activity including the importation, testing and release of a GMO and products containing, or consisting of GMOs.
  - ii. The PI/proposer has the responsibility for conducting evaluations of potential risks at appropriate stages of research and development of an organism prior to its formal review or assessment.
  - iii. Records should be kept and securely maintained on all activities involving GMOs, products containing and consisting of GMOs, documentation should include the description and location of each activity, protocols involved, results, monitoring data and any other pertinent information.
  - iv. If an unexpected or adverse public health, agriculture or environmental impact occurs resulting from the intentional and unintentional release of a GMO, the PI/proposer must notify and provide relevant information to the IBC and the NBC/Biosafety Authority. The PI/ proposer must also be responsible in carrying out all the necessary mitigation measures for the clean-up.
  - v. The PI/proposer should disclose all relevant information to the NBC/Biosafety Authority. Details of specific approvals and refusals of all trials and applications, including those in other countries, granted or denied, should be included in any new application.
  - vi. The PI/proposer should adhere to IBC-approved emergency plans for dealing with accidental spills and personnel containment.
  - vii. The PI/proposer should remain in communication with the IBC throughout the conduct of the project.
  - viii. The PI/proposer is responsible in ensuring the safety performance of the staff and that proper safety practices and techniques are employed.

#### **ANNEX 1: PARAMETERS FOR ASSESSING RISK**

1. In assessing risk for a proposed release, a multidisciplinary approach is deemed necessary.
2. It also requires a team of experts specific to the type of release experiments i.e. a panel reviewing release of transgenic plants may differ in member composition to that reviewing release of organisms for biological control.
3. The different fields of expertise to be considered when selecting an expert panel should include, as appropriate:
  - Ecosystem health (soil/water); function of each ecosystem in which the organism will be released or to which it might spread

- Soil foodweb interactions
  - Nutrient cycling
  - Population genetics
  - Taxonomy
  - Agronomy/seed science
  - Entomology
  - Microbiology
  - Marine biology
  - Pathology
  - Veterinary
  - Process engineering
  - Food safety
  - Social science and economics
4. The objective of a risk assessment is to enable evaluation of possible harm or likelihood of it occurring during a release experiment. Wherever possible, information should cover expected probabilities of events occurring and the magnitude of their effects.
  5. Parameters for assessing risk with regards to the characteristics of the GMOs, host and recipient organism are already detailed in the Guidelines. This section only deals with characteristics of the intended use.
  6. For contained uses, parameters of assessment can include;
    - Number or volume of organisms to be used
    - Scale of the operation
    - Levels of containment
    - Procedure for waste management
    - Procedure for accidents and unexpected events
    - Information from previous relevant uses where appropriate
  7. Release Experiments of Transgenic Plants.

Apart from compliance with the general principles in the Guidelines, other specific factors that should be taken into consideration can include:

- i. size of release (start with small scale release prior to large scale field trials and production);
- ii. effects of transgenic products (primary and secondary) on pollinators and where possible non-target organisms. (Assessment of risk on pollinators should be considered for new crop traits on a case-by-case basis);
- iii. effect of secondary transfer of transgenes to wild relatives (assessment depends on the propensity of the transgenic plant or interfertile relative to become weeds in an agricultural system);
- iv. transfer by hybridization and introgression of transgenes from crops to wild-type species (assessment should include data on the probability of introgression into causal populations).

#### 8. Release Experiments of Transgenic Animals.

Apart from compliance with the general principles in the Guidelines, other specific factors that should be taken into consideration can include:

- i. effect of the modified trait on physiological behavior and reproduction of the transgenic animal;
  - ii. possibility of the inserted sequence to cross hybridize with feral population and subsequent effect on agriculture and the environment;
  - iii. if the organism is to be consumed as food or for animal feed, assessment should include production of new metabolites or toxins that may be hazardous to other organisms within the release ecological habitat at the site of release;
  - vi. potential transmission of genetic material from GMOs to other species by means other than reproduction;
  - vii. movement of GMOs into other ecological system.
9. Release of GMOs for Biological Control.
- Apart from compliance with the general principles in the Guidelines, other specific factors that should be taken into consideration can include:
- i. effect on species targeted for biological control, parent organism and probable effect on ecosystem;
  - ii. host range specificities as to whether there will be possibilities of GMOs affecting non-target species;
  - iii. secondary effect on predators and parasite of the target species;
  - iv. effect of secondary metabolites produced by GMOs on other organisms in the food chain.
10. Release Experiment of GMO for Bioremediation.
- Apart from compliance with the general principles in the Guidelines, other specific factors that should be taken into consideration can include:
- i. effect of the parent organism on its target substrate;
  - ii. effect of GMOs on target substrate;
  - iii. effect of secondary metabolites produced by a GMO on other organisms in the community/site of release;
  - iv. effect of GMO on water, air or soil quality;
  - v. possible toxicity effect to other organisms that ingest the GMO;
  - vi. possible dispersal of GMO from site of application and its consequences.

## **ANNEX 2: PROTOCOLS IN RISK ASSESSMENT**

In assessing risk for release of GMOs, paragraph 26 and Annex 1 has outlined the specific considerations for each release assessment. Information and flow charts indicating the protocols for assessing biosafety and the probable expectation of risk can be adopted from Guidelines for Planned Release of Genetically Manipulated Organisms (GMAC, Australia, 1993), The Planned Introduction of Genetically Engineered Organisms: ecological considerations and recommendation' (*Tiedje et al.*, 1989, Ecology, Vol. 70, pp. 298 315), and Biosafety Regulations: A Critique of Existing Documents (*Ingham et al.*, 1994; an occasional paper of the Edmonds Institute, Washington 98020).

## **GLOSSARY**

### **1. Biological control**

The introduction of organisms into a region where they are not normally found in order to eradicate or suppress the population of a selected target species.

### **2. Contained (work)**

Genetic modification work which is carried out in such a way that the spread of modified organisms outside the laboratory is prevented. Physical containment is accomplished by the use of special procedures and facilities. Biological containment is accomplished by the use of particular strains of the organism which have a reduced ability to survive or reproduce in the open environment.

### **3. Donor**

The organism or cell from which DNA inserted into an other organism (the host) is derived.

### **4. Exotic**

Introduced (i.e. non-native).

### **5. Expression**

Manifestation of a characteristic that is specified by a gene; often used to mean the production of a protein by a gene that has been inserted into a host organism.

### **6. Feral**

A domesticated animal which has escaped and established a population in the wild.

### **7. Genetic modification**

A technology used to alter genetic material of living cells or organisms in order to make them capable of producing new substance or perform new functions.

### **8. GMO**

Genetically modified organism.

### **9. Host range**

The range of species that can be infected by an agent.

### **10. Pathogen**

An organism that causes disease.

### **11. Recombinant**

Organisms, cells, viruses etc. which contain recombinant DNA i .e. DNA formed by Joining, in vitro, segments of DNA from different organisms.

### **12. Risk**

The combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences will occur.

**13. Risk assessment**

The measures to ensure that the production and handling of an organism are safe.

**14. Vector**

A self-replicating agent (e.g. plasmid or virus) used to transfer foreign DNA into a host cell.

**15. Wild type**

The form of an organism that occurs most frequently in nature.