**MINISTRY OF AGRICULTURE
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BIOSAFETY

Regulations and Guidelines

EGYPT

January 1994

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Applications of biotechnology are on the verge of great expansion in this decade. The production and release of the resulting Genetically Engineered organisms (GEOs) have raised concern about possible risks to human and to the environment, Accordingly, all biotechnology research has to be carried within a Regulatory Biosafety Framework.

This document recommends the establishment of a National Biosafety System in Egypt. The purpose is to provide a guide for policy makers to assist the establishment of an appropriate national biosafety framework, as no adequate structure currently exists. A national regulatory structure is proposed and biosafety guidelines developed by international organizations are attached. The establishment of such a system will ensure that Biotechnology continues to be safe and does not expose employees, the community and the environment to any possible hazards.

Introduction

Biotechnology refers to any technique that uses living organisms or substances from these organisms to modify or improve quality and product of crops and food, drugs and health care products, vaccines, industrial chemicals and its products. It consists of gradient of technologies ranging from the widely used techniques of traditional biotechnology through modern biotechnology which is based on the use of new techniques of Recombinant DNA (r- DNA) technology, known as Genetic Engineering.

Proposed uses of the resulting genetically altered microorganisms include controlling pests and weeds in agriculture, producing vaccines, cleaning up toxic chemicals at waste sites, microbial leaching of mineral ores, and enhancing oil recovery. Plants are being genetically engineered to enhance many traits: increasing pest and herbicide resistance, tolerating draught or other environmental stresses, decreasing loss of food during storage and transport and increasing nutritional value of food products.

Biosafety is one term that is used to describe the policies and procedures adopted to ensure the environmentally safe application of modem biotechnology. It is a term that is gaining wider currency as more countries seek to benefit from the application of modern science in agriculture, medicine, and the environment, without endangering public health or environmental safety.

Many industrialized countries have instituted mechanisms for the regulation of biotechnology. The R-DNA Advisory Committee of the National Institute of Health (NIH) has developed procedures for examining and assessing the safety of proposed experiments and has published extensive guidelines on the conditions under which various types of experiments should be done. The NIH guidelines were originally formulated exclusively for the laboratory use of R-DNA and do not extend to the

introduction of rDNA engineered organisms into the environment. The NIH Guidelines are attached as Appendix 1.

Since recombinant-DNA engineered organisms must be tested outside the laboratory, a procedure known as the "Deliberate Release" or "Planned Introduction" of these genetically engineered organisms (GEOs) into the environment, there may be risks associated with the release of these GEOs.

Questions and concerns related to identifying hazards posed by microorganisms when released into the environment, [1] include:

- Will the use of R-DNA techniques accidentally create new plant pests?

- Can R-DNA accidentally convert a nonpathogen to a pathogen?

- Can introduced gene spread in microbial population?

- Will r-DNA- engineered microorganisms alter soil microbial communities?

[1]Introduction of Recombinant DNA-engineered Organisms into the Environment. Key Issues: National Academy Press. D.C. 1987

The US National Academy of Science (NAS) made the following general conclusions regarding risks to the release of GMOs [2]:

- There is no evidence that unique hazards exist either from the use of r-DNA techniques or from the transfer of genes between unrelated organisms.

- The risk associated with the introduction of GEOs are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods.

[2] Risk Assessment in Genetic Engineering; M. Levin & H. Strauss

As a step further the United Nation Industrial Development Organization (UNIDO) has organized an expert group meeting in Vienna on March 1991 consisting of 20 experts representing academia, industry and governments from developing and developed countries and international organizations to prepare a draft code of conduct on the safe handling, use and the release of Genetically Modified Organisms (GMOs) into the environment. This code attempts to harmonize existing guidelines, capturing the minimum commonly accepted principles into an international frame-work in the form of a code of conduct for the release of GMOs. It aims to-set forth minimum acceptable components necessary for international cooperation. These guidelines expressed in the code are meant to be user friendly and aimed at promoting the process of biotechnology progress, which can be modified or extended to suit specific situations according to the desire of each country. [3] The code of conduct is attached as Appendix II.

[3] The code of conduct is available in the Genetic Engineering and Biotechnology Monitor Journal Issue No.39 Sept. 1992

Developing countries are also being increasingly faced with requests to conduct r-DNA research. Hence, there is an urgent need for the scientific community to provide guidance for both investigators and regulators in evaluating risks associated with biotechnology. A National Biosafety System should be established within the existing regulatory framework, drawn on existing institutions, personnel, and current legislation

to the greatest extent possible. This system should provide appropriate regulatory mechanisms for both contained and uncontained applications, to ensure that products produced by the use of new techniques are as safe as those produced by traditional biotechnology.

In order to prepare a national policy for the regulation of r-DNA research in a developing country, the following must be available:

1. National regulatory structure and finance to support it, The regulatory structure would consist of:

a. Biosafety Committees that form the regulatory authorities,

b. A set of Biosafety legislation, regulations and guidelines to be followed.

1.

2. Availability of funds and appropriate scientific & technical expertise for risk assessment analysis and modeling.

3. Coordination with international organizations,

4. Mechanism to gather information on local agronomic and environmental conditions

5. Systems to monitor developments in biotechnology that could affect worker health and safety,

6. Confidence in decision-making expertise.

7. Systems for the provision of information to, and education of the public.

This document provides specific suggestions for policies and procedures that national authorities may wish to consider in establishing a biosafety system. A national regulatory structure is suggested and examples of methods of risk assessment and biosafety guidelines tailored to the Egyptian environment are introduced. Internationally accepted standards (NIH Guides, UNIDO Code of Conduct) are attached and examples of research evaluated under the guidelines is presented.

It is important to remember that all these items will be presented and discussed as examples of a coordinated plan for biosafety regulations. It is furthermore important to remember that these presentations are only a small selection out of a large number of world wide used mechanisms for safety.

Finally, it is important to note that concern about risks to human health and to the environment is not peculiar to biotechnology. Rather, these questions have emerged as an important component in the development, regulation and promotion of the products of many new and older technologies such as chemicals and pharmaceuticals.

Definitions

Accessible environment : refers to the environment that can be reached by the organism and its progeny if introduced at the research site.

Biosafety : refers to the polices and procedures adapted to ensure the environmentally safe application of biotechnology.

Confinement : refers to that which restrains or limits the spread or survival of the organisms and their products in research involving planned introduction of organisms into the environment.

Contained facility : refers to a structure, (e.g., a laboratory or greenhouse) which surrounds and encloses the organism to effectively restrict its movement outside the structure.

Genetically Modified Organism : is operationally defined as an organism whose hereditary traits have been modified by human intervention using any method that results in the introduction, rearrangement or removal of genetic material from the genome of an organism.

Managed or natural ecosystem : refers to all plants, animals microorganisms, and their interactions, in domesticated and wild environment.

Organism : refers to any biological entity, cellular or noncellular with the capacity for self-perpetuation and response to evolutionary forces.

Parental organism : refers to the initial organism which is to be the recipient of introduced genetic material or whose genome is to be altered by removal or rearrangement of genetic material.

Research involving planned introduction into the environment : refers to research outside a contained facility at a designated site(s) with appropriate confinement.

Risk Assessment : refers to assessment of the risks of introducing R-DNA engineered organism into the environment, to human and natural or managed ecosystem.

Acronyms

ABRAC: Agricultural Biotechnology Research Advisory Committee

APHIS: Animal and Plant Health Inspection Service

BSO: Biological Safety Officer

EA: Environmental Assessment

FONSI: Finding Of No Significant Impact

GEOS: Genetically Engineered Organisms

GMOS: Genetically Modified Organisms

IBC: Institutional Biosafety Committee

LSC: Level of Safety Concern

NAS: National Academy of Science

NBC: National Biosafety Committee

NEIAP: National Biological Impact Assessment Program

NIH: National Institutes of Health

PI: Principal Investigator

UNIDO: United Nations Industrial Development Organization

USDA: United States Department of Agriculture

The establishment of a National Biosafety System has become a necessity due to the introduction and the rapid increase of biotechnology applications in Egypt.

Establishing a National Biosafety System and assuring compliance with biosafety regulations would :

1. Ensure that Biotechnology continues to be safe and does not expose employees, the community and the environment to any avoidable ill effects.

2. Facilitate access to modern biotechnology generated abroad, as many international institutions and companies will not test genetically engineered organisms unless the tests have been approved by a responsible governmental body.

3. Result in faster public acceptance and further development of modem biotechnology.

The key principles relevant to the preparation of national policy for the regulation of biotechnology are:

1. Regulatory review should focus on the characteristics and identified risks of the biotechnology products, not mainly on the process by which it was created.

2. For those biotechnology products that require review, the review process should be designed for efficiency and I effectiveness while assuring the protection of public health and environmental safety

3. Regulatory requirements for modern biotechnology should be integrated into the overall regulatory system which governs the release of new products in the agricultural sector.

4. The degree of familiarity with the behavior of similar organisms when released into the environment should determine the level of regulatory required, ranging from minimal to extensive depending on the degree of hazard identified.

5. Regulatory programs should be flexible and capable of adapting quickly to the new knowledge and rapid advances in biotechnology.

SECTION 1: BIOSAFETY COMMITTEES

The first step in developing appropriate policies and procedures for the regulation of biotechnology is to establish a national biosafety advisory committee. The national committee should then move quickly to establish policies and procedures to govern the use of modern biotechnology in the country.

1. National Biosafety Committee (NBC):

An Egyptian National Biosafety Committee is being established, comprising policy makers and designers, scientific experts in Agriculture, Health, Industry and Environment from government and academic research institutes.

1.1 Roles and Responsibilities of NBC:

The purpose of the national committee is to establish policies and procedures to govern the use of modem biotechnology in the country. This includes publishing the National Biosafety Committee guidelines (NBC Guidelines) to be followed at the national level. The committee would also provide technical advice to the regulatory authorities and the institutions responsible for the development of biotechnology in the country.

1.2. National Biosafety Committee Members

In order to ensure the competence necessary to set biosafety policies at the national level it is recommended that the NBC include:

- Representative/s from the Ministry of Agriculture

- Representative/s from the Ministry of Education

- Representative/s from the Ministry of Industry

- Representative/s from the Ministry of Health

- Representative/s from the sector of Environmental Affairs

- Representative/s from the private sector

- Policy makers and consultants knowledgeable in policies and applicable laws

- Non-technical members who represent the interest of the surrounding community with respect to health and protection of the environment

1.3 Activities of NBC

a) Formulate, implement and update safety codes
In order to establish safety research policies, NBC shall formulate guidelines for both contained and uncontained applications to cover laboratory practices, greenhouse facilities, small scale field trials, and finally commercial release. This will include guidelines for research with natural organisms that are exotic to the host country.

b) Risk assessment and license issuance
NBC shall review new initiatives to evaluate the benefits and potential risk of conducting research with modified organisms to the environment and to human community. If a license is issued after performing risk assessment analysis, NBC should periodically review containment measures and facilities to ensure that adequate safety guidelines are being followed.

c) Coordination with international and national organizations
NBC would establish contact and maintain communication with international and national organizations, taking into account new scientific and technical knowledge as they evolve. It would also monitor changes in intellectual property rights issues at the national and international level.

d) Provide training and technical advice
NBC is responsible that all personnel involved in biosafety issues receive adequate training on the most recent developments in safety procedures. It would also provide technical advice to the Institutional Biosafety Committees.

e) Report at least annually to governmental authorities
An annual progress report would be submitted to governmental authorities covering NBC activities throughout the year.

1.4 Principal Investigator (PI):

The National Biosafety Committee would designate one or more Principal Investigators whose duties include:

One) Inspect to determine whether institute facilities adhere to the local regulations and guidelines of the NBC.

Two) Upon receiving a permit request, the PI will visit the location to evaluate its facilities. Next, he will submit a report to the NBC upon which the permit will be issued or denied.

Three) Instruct and advise staff in practices and techniques to assure levels of safety concern.

2. The Institutional Biosafety Committee (IBC):

The National Biosafety Committee should request that all institutions conducting R-DNA research assemble an Institutional Biosafety Committee.

2.1 Roles and Responsibilities of IBC:

The IBC is responsible for ensuring that the r-DNA research is carried Out in full conformity with the Provisions of the NBC Guidelines. As part of its general responsibilities for implementing the NBC Guidelines, the IBC may establish additional Procedures as deemed necessary to govern the institution activities.

2.2 Institutional Biosafety Committee Members:

In order to ensure the competence necessary to review R-DNA research activities, it is recommended that:

a. the IBC include persons with expertise in R-DNA technology that cover the research directions in the institute

b. the IBC include persons with expertise in biological safety and physical containment

c. the IBC have available as consultants persons knowledgeable in institutional commitments, Policies and applicable law

d. IBC designate a Biologic I Safety Officer (BSO) that meets the a requirements set in section 1.4

2.3 Activities of IBC

One) Assemble a comprehensive set of research- and containment oriented guidelines that are tailored to the research activities of the institute and that comply with the NBC Guidelines.

Two) Establish a program for inspection to ensure that the physical containment facility

continues to meet with the requirements.

Three) Assessment of the facilities procedures . and practices. and of the training and expertise of R-DNA personnel.

Four) Review periodically R-DNA research being conducted at the institute to insure that the requirements of the NBC Guidelines are being fulfilled.

Five) Adopt emergency plans covering accidental spills and personnel contamination resulting from such research.

Six) Periodically review containment measures and facilities taking into account new scientific and technical knowledge relevant to treatments for disposals and spills of biohazardous wastes.

Seven) Monitoring changes in intellectual property rights issued at the national and international levels.

Eight) Reports annually to the National Biosafety Committee.

2.4 Biological Safety Officer (BSO):

The institute should appoint a Biological Safety Officer who should be familiar with the biosafety requirements for the R-DNA work and the facilities. His duties include the following:

One) Enforces policies and regulations approved ensuring that these regulations are not compromised by other considerations.

Two) Ensure through periodic inspections that laboratory standards are rigorously followed.

Three) Ensure safety of laboratory work and prevent the accidental escape of R-DNA modified organisms.

Four) Maintain a data base on all aspects of biosafety related to mandate crops.

Five) Checks and gives advice on biosafety issues on a day to-day basis.

Six) Monitor worldwide biosafety requirements for R-DNA, also act as a member of the biosafety committee, reporting all related issues.

SECTION II: BIOSAFETY GUIDELINES

1. Risk Assessment

Risk to the health of workers and others in the immediate vicinity of the work-place is one of the main concern in assessing the hazards associated with the contained use of GMOs. These risks are considered proportional to the scale of the operation and all regulatory systems distinguish small-scale use for research and development. As for large-scale use, the risk to health and possible risks to environment in the event of escape of organism from the production area must be evaluated and an appropriate level of containment applied. Containment may be physical, e.g. barriers limiting the escape of the organisms, or biological, e.g. physiological limitations to the survival and

replication of the organism outside the process environment. [1]

[1] Curtiss 1988

NAS posed the following three questions, used in making judgments of risk (1989):

- Are we familiar with the properties of the organism and the environment into which it may be introduced ?

- Can we confine or control the organism effectively ?

- What are the probable effects on the environment, should the introduced organism or a genetic trait persist longer than intended or spread to nontarget environment?

The development of new technology opens up a series of questions on risk for which there are few or no data to help in its evaluations [2]. A definition that was suggested is :-

Risk = Probability of hazard X Magnitude of hazard

[2]The second International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plnats and Microorganisms. May 11. 1992. Germany

As it was mentioned earlier biotechnology aims to produce crops with new properties presumably for the benefit of mankind. This means that if there is any increased in risk it has to be balanced against the benefits which would accure from using that transgene and we should consider redefining risk as "acceptable risk".

Acceptable risk = Probability of hazard X Magnitude of hazard
Benefits from product

In order to understand the circumstances under which a genetically engineered crop plant might become a persistent agricultural weed or become invasive of natural habitats, it is essential to know the value of the parameters in the following model:

The rate of increase
of the transgenic plant =   Plant development rate
in a given habitat.
+   Its seed production (timing and
duration)
+ Survival of vegetative parts (discounted by their mortality rate)
-          The effects of competition with other
plants of the same kind
-          The effects of competition with other
plant species.
-          The effects of herbivores (insect and
vertebrate)
- The effect of fungi and other plant diseases.
+ Immigration of transgenic seed from other sites.
+ Establishment of transgenic plants from dormant seed in the soil
(seed bank).

The conditions under which research with a genetically modified organism can be conducted safely should be assessed relative to the conditions that are normally accepted for conducting research with the parental organism. Therefore, the safety evaluation determining the level of safety concern is essential.

2. [Determination of the Level of Safety Concern (LSC):](#)

The Agricultural Biotechnology Research Advisory Committee (ABRAC) has recommended a step-wise process to the Assistant Secretary for Science and

Education for the evaluation of level of safety concern of the Genetically Modified Organism into three levels. [3]

[3] Available in the Federal Register of February1, 1991 (56 FR 4134)

Determining the level of safety concern is of great importance for analyzing the risks to human health and natural ecosystem for GMOs.

Step1 : Determine the level of safety concern of parental organism

Depending on two criteria:-

a. Whether the organism poses negligible risk to human health and no unreasonable risk to managed or natural ecosystem.

b. The ability to manage or control the organism during its planned introduction into the environment so that the research is conducted in a safe manner.

Level I of Safety Concern for parental Organisms

The organism poses negligible risk to human health and no unreasonable risk to managed or natural ecosystem. Those organisms whose ecological attributes in the specified accessible environment are understood. Some attributes in combination might indicate Level-1 organisms are:

One) No history of adverse effects in the accessible environment.

Two) Low evolutionary potential to become harmful organism in the accessible environment.

Three) Low probability of survival in the accessible environment. Level 2 of Safety Concern for parental Organisms :

Organisms whose ecological attributes in the accessible environment may pose a risk to human health that is not negligible or may pose an unreasonable risk to managed or natural ecosystem, which can and must be managed or controlled by appropriate confinement.

Level 3 of Safety Concern for parental Organisms

Organisms whose ecological attributes in the accessible environment may pose a risk to human health that is not negligible or may pose an unreasonable risk to -managed or natural. ecosystem, and no feasible confinement will ensure safe conduct of the research outside contained facilities.

Some attributes in combination might indicate Level-3 organisms are:

One) History of adverse effect in the specified environment.

Two) Ability to survive and proliferate in the environment.

Three) Non-indigenous status in the environment.

Four) High frequency of exchange of genetic information with adverse effect

Five) Lack of effective techniques to minimize the escape of the organisms from

Six) Lack of adequate techniques to recapture or kill escaped occurs.

Step 2 : Determine the effect of the Genetic Modification on level of Safety Concern

The genetic modification should be evaluated in terms of its effect on the attribute of the parental organism evaluated in step-1. Where the genetic modification may have no effect on safety or increase or decrease safety.

The effect of the genetic modification on safety must be evaluated with reference to :-

a. Direct effect of the organism on human health or the environment.

b. Indirect effect of the organism through the substances it produces.

c. Effects of genetic exchange with other organisms.

In step-2 investigators should examine the method of genetic modification; the molecular characterization and stability of the modified genes; the expression, function, and effects of the modified genes.

Type 1: Genetic Modification that Decrease Safety Concern for the Modified organism

Modifications that delete or disrupt the expression of a gene or genes, responsible for traits, such as, pathogenicity, fertility, survival, or fitness in a way that increase safety of the organism.

Type 2: Genetic Modification that Have No Effect on Safety Concern for the Modified organism

Sustainable understanding of the molecular biology and other information, including relevant experience, which shows that the modification is well characterized and that the gene functions and effects are adequately understood to predict safety.

Modifications include:

a. Insertions of nucleic acid, deletions, or rearrangement that have no phenotypic or genotypic consequences in the environment.

b. Insertions of nucleic acid, deletions, or rearrangement that have known or predictable phenotypic or genotypic consequences in the environment that unlikely may result in additional adverse effect to human health and the environment.

Type 3: Genetic Modification that Increase Safety Concern for the Modified organism

Modifications include:

a. Insertions of nucleic acid, deletions, or rearrangement that affect the expression of genes, But the functions or effects are not sufficiently understood to determine with certainty if the modified organism poses greater risk than the parental organism.

b. Insertions of nucleic acid, deletions, or rearrangement that have known or predictable phenotypic or genotypic consequences in the environment that likely result in additional adverse effect on human health and the environment.

Step 3 : Determination of the level of Safety Concern for Genetically Modified Organisms,

The genetically modified organisms should be assigned to one of three levels of safety concern by considering the effect of the genetic modification on safety, and if any affected attributes alter the level of safety concern for the modified organism compared to the parental organism.

The level of safety concern for the genetically modified organism is dependent on the same criteria applied to the determination of the level of Safety Concern for the parental organism.

Level-1 Parental Organism :-

A. Level-1 of Safety Concern for the Parental Organism with type-I modification is considered as LSC-1 for the genetically modified organism.

B. Level-1 of Safety Concern for the Parental Organism with type-2 modification is considered as LSC-1 for the genetically modified organism.

C. Level-I of Safety Concern for the Parental Organism with type-3 modification results in LSC-1, LSC-2, LSC-A genetically modified organism, depending on the degree of safety concern as follows:

a. If type-3 modification results in minimal increase in safety concern so that risk to human health remains negligible and risk to managed or natural ecosystem remains reasonable without the need for confinement measures, then the genetically modified organism remains LSC-1

b. If type-3 modification increases safety concern to the extent that risk to human health is no longer negligible or risk to the environment is no longer reasonable, but feasible confinement measures are available to conduct research with negligible risk to human health and the environment, then the genetically modified organism is LSC-2.

c. If type-3 modification increases safety concern to the extent that introduction into the environment cannot be adequately managed or controlled to achieve negligible risk to human health and no unreasonable risk to the environment, then the genetically modified organism is LSC-3

Level -2 Parental Organism

1) **Level-2** of Safety Concern for the Parental Organism with -1 modification results in **LSC-1** or **LSC-2** genetically modified organism, depending on the degree of safety concern as follows :-

a. If **type-1** modification decreases the safety concern to the extent that the organism poses negligible risk to human health and no unreasonable risk to managed or natural ecosystems without the need for confinement measures then the genetically modified organism is **LSC-1**.

b. If **type-1** modification decreases the safety concern and risk to human health is negligible and risk to managed or natural ecosystems is reasonable only when managed by use of confinement measures, then the genetically modified organism is **LSC-2**.

II) **Level-2** of Safety Concern for the Parental Organism with **type-2** modifications, remains LSC-2 genetically modified organism. Appropriate confinement measures are necessary for planned introduction into the environment.

III) **Level-2** of Safety Concern for the Parental Organism with **type-3** modification results in **LSC-2** or **LSC-3** genetically modified organism, depending on the degree of increase in safety concern as follows :-

a. If **type-3** modification increases safety concern, but planned introduction into the environment still can be managed or controlled by appropriate confinement measures, then the genetically modified organism is **LSC-2**,

b. If **type-3** modification increases safety concern to the extent that there is not reasonable certainty that planned introduction into the environment can be managed or controlled, then the genetically modified organism is **LSC-A**, Research must remain under confinement measures until there is a certainty that it could be controlled in a safe manner.

Level -3 Parental Organism

I) **Level-3** of Safety Concern for the Parental Organism with **type-1** modification results in **LSC-1**, **LSC-2**, **LSC-3** genetically modified organism, depending on the degree of decrease in safety concern as follows:

a. If **type-1** modification decreases safety concern to the extent that planned introduction into the environment poses negligible risk to human health and no unreasonable risk to managed or natural ecosystem without confinement measures, then the genetically modified organism is **LSC-1**.

b. If **type-I** modification decreases safety concern, but confinement measures are necessary for the planned introduction into the environment with negligible risk to human health and no unreasonable risk to managed or natural ecosystem, then the genetically modified organism is **LSC-2**.

iii- If **type-1** modification decreases safety concern, but not to the extent that planned introduction of the organism can be managed or controlled to achieve negligible risk to human health and no unreasonable risk to managed or natural ecosystem, then the genetically modified organism is **LSC-3**. Research must be conducted in a contained facility.

II) Level-3 of Safety Concern for the Parental Organism with type-2 or type-3 modification results in LSC-3 genetically modified organisms.

3. [Biosafety Guidelines](#).

Biosafety guidelines are designed to ensure that the products of biotechnology will not have adverse effect on the environment and agriculture, to prevent unintentional release of hazardous organisms, and to protect the surrounding communities as welt as employees and researchers involved . in the use of such. products from the research stage till commercialization.

3.1 [Biosafety Guidelines for Laboratories :](#)

- Food storage, eating, drinking and smoking are prohibited in lab.

- Mouth pipetting is prohibited

- Laboratory coats are obligatory and should be removed when exiting the lab.

- Working surfaces must be decontaminated using soap and alcohol after each working day.

- Waste products must be decontaminated by incineration or by autoclaving.

- Frequent hand wash is obligatory (at (east one hand wash sink should be available).

- Avoid contact with GMO's and other exotic biological agents, disposable .gloves should be worn when handling such items.

- Laboratory door should be closed at all times.

- Working with fume-producing chemicals must be under the laboratory hood.

- Biohazard warning signs should be always posted in labs.

3.2 Biosafety Guidelines for Containment Greenhouse

- Greenhouse should be locked at all times.

- Biosafety categories and safety codes should be posted at the greenhouse entrance.

- Air circulation system should not allow dispersal of pollen or GMOs from greenhouse.

- Non-living plant material, parts, or viable exotic biological agents should leave the greenhouse except for:

  - Disposal, were it has to be autoclaved before its disposal.

  - Storage in other facilities, in this case it should undergo adequate containment before transport.

- The outgoing water must be chemically treated before its drainage

- Coats should be worn at all times in the greenhouse, and autoclaved before removal from the greenhouse for any reason.

- Hand washing is required upon entering and exiting the greenhouse.

- A disinfecting pad embedded with a decontaminating substance must be located at the greenhouse entrance.

- Daily record all experiments carried out in the greenhouse.

3.3 Biosafety Guidelines for Field Trials (Small-Scale Field Testing)

- Field experiments with exotic plant pest and pathogens are prohibited.

- Plants must be prevented from spreading pollen by the removal of flowers.

- If flowers are needed for testing and further experimentation, the inflorescence flowers must be covered before maturation.

- Suitable plot isolation must be provided avoiding pollen transmission to other near plots.

- Entry of plots by unauthorized personnel is prohibited.

- Special protective measures should be taken to ensure complete isolation of harvested plant parts.

- Plots must be protected from the entry of animals or insects using boarder rows.

Appendices

Appendix I : NIH Guidelines

Appendix II: The Code Of Conduct

Appendix III: Permit Application System

Appendix IV: Permits & Time Line, Sample Applications

Appendix V : Examples Of Research Evaluated Under The Guidelines

Appendix VI :Environmental Assessment & Finding Of No Significant Impact

Appendix VII :Facility Inspection Checklists For Regulated Articles

Appendix I

NIH Guidelines
The following guidelines were developed by the Recombinant DNA Advisory Committee of the National Institutes of Health, The guidelines represent a comprehensive set of research- and containment-oriented guidelines, The original NIH guidelines were published in 1976 and were applied to NIH-funded research activities, Eventually these guidelines became binding on all institutions that received funding from any federal agency, Since their adoption, state and local governments, academic institutions, the industrial community, and foreign countries have adopted various versions of the guidelines

Not attached

Appendix II

The Code of Conduct
This code was prepared for the safe handling, use and release of Genetically Modified Organisms into the environment. It has captured the minimum commonly acceptable principles into an international framework to harmonize existing guidelines necessary for international cooperation.

Not attached

Appendix III

Permit Application System (PAS) for Preparation of Biotechnology Field Test Applications
PAS is a computer program developed by the National Biological Impact Assessment Program (NBIAP). It is designed to assist researchers in preparing an application to the appropriate federal agency for permission to conduct field tests of genetically altered organisms. PAS covers the following categories:

    Plants

    Animals

    Animal Vaccines

    Microorganisms

The program generates questions and prompts the user to enter an answer. Upon completion of the session, the program produces a full application form ready for submission to the regulatory agency.

The PAS is for release into the environment only. USDA/ APHIS requires additional permits for importation or movement of GEOS.

This program is distributed free of charge and may be copied. A copy is available at the Agricultural Genetic Engineering Research Institute (AGERI).

Not attached

Appendix IV

Permit & Time Line, APHIS FORM 2000 Sample Applications
These are sample applications for permit release for a genetically modified organism movement or release into the environment.

Several examples are provided to give an indication of the kind of information to include.

A suggested application form that can be submitted to the Egyptian regulatory authorities is included at the end.

Not attached

Appendix V

Examples of Research Evaluated Under the Guidelines

To assist users of the guidelines to analyze level of safety concern for their research organisms, four examples have been evaluated in a step-wise process. Theses examples are presented in the following order:
 	
   1. Bos taurus (domestic cattle)
 	
   2. Brassica napus (oil rapeseed)
 	
   3. Drosophila melanogaster (fruit fly)
 	
   4. Clavibacter xyli subsp. cynodontis

Not attached

Appendix VI

Environmental Assessment & Funding Of No Significant Impact
A clear example to the environmental assessment, evaluated by the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA) prior to issuing a permit for the release of genetically modified rice.

Not attached

Appendix VII

Facility Inspection Checklist For Regulated Articles
This is an example of a checklist that would be completed by the Principal Investigator during a facility inspection visit. According to this checklist the NBC will decide if a permit will be issued,

Not attached