**Application to obtain permits for the production and introduction of Genetically Modified Organisms and products should include the following information**

1. Title of the project
2. Program/Project/Study Leader(s)
3. Name of Institution
4. Cooperating Institution(s)
5. Objectives of the Genetic modification
6. Materials and Methods
   1. Degree of Genetic Manipulation
   2. Methodology/Protocol (including timetable of activities)
   3. Location of Experiment
   4. Characteristics of the Organisms: (Plants, Animals, Microorganisms)

(Local strains; Collected within the region (mention exact location); Collected from other regions - origin of strains; Imported strains (indicate point of origin); Not present in the country; Present but of restricted distribution in the country; Widely distributed in the country; Genetically modified strains; Ecological context)

* 1. For Experiments Involving Genetically Modified Plants
     + Characteristics of the recipient organism

(nomenclature; the areas of cultivation or distribution in nature; reproductive cycle; possibility of natural crossing to related species; production of toxic substances, if any; weediness/effect on environment (soil, water, etc.)).

* + - Characteristics of donor organism

(taxonomy; the areas of cultivation, distribution in nature; reproductive cycle; possibility of natural crossing to related species; production of toxic substances, if any; weediness/effect on environment; functions of the target gene)

* + - Name, designation, origin and molecular characteristics of the vector
    - Construction method of the genetically modified organism
    - Structure and construction method of the recombinant molecule
    - Method to introduce target genes into recipient cells
    - Characteristics of genetically modified organism
    - Comparison with recipient organisms
    - Localization, copy number and stability of the target gene in recipient cell
    - Stability of the introduced gene expression
    - Any other important points obtained in the transformation experiment to develop the genetically modified plant
    - Specify if any member of the genus of the modified plant is known to be harboring pests or diseases
    - Indicate if the experimental plot is isolated from plants of the same species, with regard to the pollination characteristics of the plant
    - Provide data on any previous information on risk assessment of the organism
    - Provide data on any markers available to track the organism if it escapes.
  1. For Experiments Involving Genetically Microorganisms
     + Characteristics of the recipient organism

(Nomenclature (scientific name and strain); Genetic properties (Characteristics); History of prior genetic manipulation, if any; Factors which

might limit the reproduction, growth and survival of the recipient organisms; stability of genetic traits; Characteristics and stability of plasmids, phages, viruses, in the recipient organisms; Reproductive cycle (sexual or asexual); Pathogenicity (details and availability of appropriate prophylaxis and therapies, if any); Production of biological active compounds, if any; Adventitious agents; Previous reports of a history of industrial use, if any; Characteristics of the related strain of recipient organisms; Natural habitat and geographic distribution; Genetic traits; Characteristics and stability of plasmids, phages, viruses, in the recipient organisms)

* + - Characteristics of the donor organism

(Nomenclature (scientific name and strain); Pathogenicity, producibility of biological active compounds; Functions of the objective genes).

* + - Name, designation, origin, characteristics of the vector
    - Construction method of genetically modified organism

(Structure and construction method of the recombinant molecules; Method used to introduce target genes into recipient cells).

* + - Characteristics of the genetically modified organisms

(Comparison with recipient organisms; Characteristics with respect to survival, growth and reproduction; Crossing possibility; Inserted genes; Localization, copy number and stability of the inserted gene in recipient cells; Stability of the introduced gene expression; Any previous genetic manipulations applied to already modified genetically modified organisms; Method to restrict the multiplication ability in open environment; Any other important remarks obtained in the transformation experiment or during the preliminary application in the controlled model environment).

* + - Other Considerations in Assessing Characteristic of Genetically Modified Microorganisms:

Known potential of natural variants to cause epidemics (survival rates, reproduction, dispersal, etc.); Known potential to cause losses; Known potential hosts and their economic or social importance; Known natural ability to evolve; Known carriers of organism and abundance

* + - Known epidemiological factors

(Host range; Pathogenicity, infectivity; Production of biological active compounds, if any; Mode of spread including vectors and other transport hosts; Environmental conditions needed for epidemics; History of epidemic, if any)

* + - Laboratory testing

(Required containment facilities of laboratory; Required biosafety equipments; Sterilization procedures; Personnel awareness of biosafety procedures; Labeling/designation of "risk" areas; Decontamination facilities)

* + - Field testing (Microorganisms on Soil/Water Associated with Plants).

(Specify the survival and reproduction characteristics of the organism in the rhizosphere of the plant species in the test site and surrounding environment; Give the effects on organisms likely to be in the test area which are known to be beneficial to plants (e.g. Rhizobium, Frankia and mycorrhizal fungi))

* + - Field testing (Microorganisms to be used for biological control).

(State the effects that the unmodified and modified organisms have on the biological control target, the plant or animal being protected and non-target species (including humans) in the test area and surrounding environment.

State, in particular, if there are any growth or quality reductions in the protected organism)

* + - Live Vaccines

(Specify/give the identification characteristics or markers, the growth requirements, and the genetic modification of the vaccine strain of the organism; Specify the proposed dose rate(s); Give the period when the vaccine organism can be detected in the vaccinated animals and their excretions; Indicate if the vaccineorganisms spreads from vaccinated to in-contact, non- vaccinated animals of the same or other animal species. If so, state the mechanisms and frequency; Give the vaccine strain's frequency of reversion to wild type characteristics; For pen trials, specify arrangements proposed for disposal of waste containing any vaccine organisms and of the vaccinated animals at the conclusion of the trial; Give the clinical effects of the vaccine organism target and non-target species in the test area and surrounding environment; Specify the level and duration of immunity produced in the target species; State challenge or other tests using virulent field strains to be carried out on vaccinated animals; Indicate the probability of the host vaccine organism being used in other human or animal vaccines; Specify if the use of this vaccine precludes the future use of the host vaccine organism for immunization purposes)

* 1. For Experiments Involving Genetically Modified Animals
     + Domesticated or farmed animals (terrestrial, aquatic)

Indicate the desirable effects expected to result from the use of the modified animal (e.g. improved reproduction, weight gain, and disease resistance and production gains).

State the undesirable effects that may result from the release of the modified organism like alteration of nutritional quality (e.g. difficult birth, fertility reduction, and increased disease prevalence, tumorgenicity and production losses). Indicate if any of the likely gains are directly linked to losses in other characteristics of the species (e.g., an increased growth rate being accompanied by a decrease in wool or milk production).

* + - Indicate if the genetic trait can be transmitted other than through their normal reproduction (e.g., from animal to animal via virus or insect transmission).