# Application to obtain import permits should include the following information

1. Responsible person or persons involved
   1. Name, title, address, telephone number, and signature;
   2. Name, address, and telephone number of the person(s) who developed and/or supplied the regulated material;
2. Specify what Genetically Modified Organisms or products to be introduced;
   1. Country and locality where the Genetically Modified Organisms or products were, developed, and produced;
   2. Detail information of the Genetically Modified Organisms requested to be imported, or the Genetically Modified Organisms used to produced the products that to be imported.
      1. Nomenclature and characteristic of and history of safe use/adverse effects of the donor from which the genetic materials were obtained.
      2. Nomenclature, characteristic and history of safe use/adverse effects of the recipient in which the genome is altered.
      3. Nucleotide sequence and construction method of the recombinant molecule used as the transgene elements (Gene Cassettes) for transformation;
      4. Methods used to introduce transgenes into recipient cells.
      5. Specify the vectors if any, used in the transformation of recipient cells.
      6. Amino acid sequence of the proteins encoded by the inserted transgenes.
      7. Enzyme digestibility of the above proteins and susceptible sites react with respective enzymes.
      8. Heat and acid sensitivity of the proteins encoded by transgenes
      9. History of donor and recipient organisms as used in food production or eaten as food.
      10. Provide available data on toxicology, allerginicity, and other possible adverse effects of foods or any metabolites produced by Genetically Modified Organisms .
      11. Information about the products of Genetically Modified Organisms that can be concentrated in the food chain to levels which may become toxic.

2.2.12. Provide data on potential hazards or deleterious effects specifically being evaluated.

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 vaccine organisms 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.

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.
* 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).
  1. Specify the arrangement for the transport of imported Genetically Modified Organisms and products within the country.
  2. Indicate the Genetically Modified Organisms reproduction and survival rates under the natural environmental conditions.
  3. Indicate the capability of the organism to disperse under the natural environment. Indicate the dispersal mechanisms.
  4. Indicate if the inserted genetic trait could be transferred to other organisms in the release site and surrounding environment; if yes, specify with what organisms and at what frequencies.
  5. Indicate data available which show that the introduced genetic trait has no unforeseen deleterious effect in the long term.
  6. Indicate if the modified organism is intended to modify the characteristics or abundance of other species. If yes, specify these species and the intended changes.
  7. Indicate the experimental results or information available which show the probable consequences (positive and negative) of the release of the modified organism, including impacts on:

1. human and animal health;
2. agricultural production;
3. the target and non-target organisms in the area;
4. the general ecology, environmental quality in the area.
   1. Specify the range of consequences which has been considered (e.g., what range of species was examined for non-target effects).
   2. Give unlikely but possible impacts that have been postulated. Indicate if any of these would have substantial impacts if they actually occurred. Likewise, also

indicate if the release protocol minimizes or monitors these low probability risks. If so, indicate how.

* 1. Give the consequences of the organism remaining in the environment beyond the planned period.
  2. Indicate the methods that will be used to control or eliminate the organism from the site and the surrounding environment should such action be required.
  3. Provide data or any other information which the organization considers to be of assistance to the NFP’s assessment.