FORM D4

PERMIT FOR CONDUCT OF SAFETY STUDIES OF GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR AGRICULTURAL AND ENVIRONMENTAL USE

PERMIT NUMBER: **DATE OF ISSUE:**

DATE OF EXPIRY:

Permittee:

Name of Organisation:

Address:

Phone, fax & e-mail:

Subject:

AUTHORISATION: This is in response to your letter No.
dated on the above mentioned subject.
It is informed that your application was considered by the Review Committee on Genetic Ma nipulation (RCGM) in its meeting held on
On the basis of the recommendations of the RCGM, you are permitted to conduct safety studies on
in the premises located at
subject to the acceptance of the following terms and conditions:

a) There would be no change in the protocols approved by RCGM which includes:

You would follow the guidelines issues by the Department of Biotechnology.

b) You would conduct laboratory studies with proper controls and reference materials.

c) You would be using the protocols in terms of dose fixation as was submitted to the RCGM Secretariat.

d) You would use the material of in these studies as far as equivalent to the final product to be used commercially at later stage and maintain sufficient stocks of the materials as reference inventory in proper storage conditions with the batch details of such stocks, which would be provided by you to the Competent Authority before starting the experiments as well as after completion of the studies. There would not be any subsequent major modifications or changes in material utilized in safety studies after finalization of studies. In case of any subsequent change, it is to be brought to the notice of the Competent Authority and no such altered materials be used by you for commercial purpose or other wise without prior approval from the Statutory and Competent Authority.

e) You would ascertain and maintain that only Organisation's authorized personnel would be allowed to visit the experimental lab and the details of personnel visiting the lab. with dates, purpose(s) etc. would be maintained in register, which may be available for inspection, whenever required by the Competent Authority.

f) You would inform the RCGM through your Institutional Biosafety Committee (IBSC) the progress of work from time to time. The IBSC will collect all the information on experiments and would submit the consolidated information/data/ results on experiments to the RCGM once in a year.

g) Accidents or accidental release, if any, arising out of the experiments would be brought to the notice of the Govt. immediately.

h) You are required to confirm the acceptance of the above conditions to the DBT at your earliest convenience before starting the safety studies. You are further informed that you may contact the Department of Biotechnology for any clarification in the matter, which you may require.

PERIOD: The permit letter shall be in force from to unless it is sooner suspended or cancelled under the said Rules.

Kindly acknowledge the receipt of the same

(Member Secretary, RCGM)

Copy for information to :

1. The Chairman, GEAC, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi-110 003
2. Office copy for file
3. Guard File