Form D3

APPLICATION TO RCGM FOR APPROVAL OF BIOSAFETY PROTOCOLS/ STUDIES FOR SAFETY ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR AGRICULTURAL AND ENVIRONMENTAL USE

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1. **Name of the Applicant:**

   Designation:

   Address:

   Telephone No.:

   Fax No.:

   e-mail:

2. **DBT Office Memorandum No.:**
3. **Application for :**

   3.1 Purpose

   3.2 New

   Yes ○ No ○

   3.3 Ongoing Project

   Yes ○ No ○

If yes, No. & Date of permission letter issued and also briefly state the purpose for which permission was granted.

3.4 Category (Biosafety level) of experiments as per the Guidelines of DBT.

4. Objectives of the proposal:

5. Description of the GMOs/LMOs (including plants and animals) in scientific terms:

5.1 Description of GMOs/LMOs

5.2 Anticipated new characters compared to non-transgenic counterparts.

5.3 Description of the target gene and mode of action.

5.4 Source of nucleic acid(s):

5.5 Copy number of gene(s):

5.6 Nucleic acid sequence (Please enclose the nucleic acid sequence map of the target gene) :

5.7 Vector(s) description (please enclose the Plasmid map) :

6. Work completed so far: (please check it from the following areas and provide the detailed work plan).

6.1 Transfer of target gene imported/ indigenously isolated in Indian germplasm and to assess the expression of the target gene in the transformed material.

6.2 Transfer of target gene from imported seed materials to indigenous species (by backcrossing) and to assess the expression of the target gene in the transformed material.

6.3 Lab/contained facilities/greenhouse/nethouse experiments conducted so far for testing/ assessing the efficacy of their new characters.

6.4 Confined field trials conducted so far and data recorded so far (please specify whether event selection trial/biosafety research trials/any other)

6.5 Proposed work plan for safety assessment

a) Description of the material to be used for testing (including type, quantity, dos age).

b) Biochemical characterization of the material in terms of near equivalence to its non-transgenic counterpart.

c) Information on quantity of target gene product (in different parts in case of large organisms such as plant or animals) and/or at different stages of development.

d) Toxicity and allergenicity protocols for food and feed safety assessment including choices of animals route of administration, Institutional Animal Ethics Approval Committee, in case of animals studies.

e) Addresses and their accreditation status of the lab where these studies are proposed to be conducted

f) Environmental safety assessment protocols

7. Decontamination and disposal mechanisms:

8. Risk management (Emergency plan):

9. Any other relevant information:

10. Declaration:

I declare that the information provided in the above format is correct and accurate to the best of my knowledge. The "Recombinant DNA Safety Guidelines 1990 and Revised Guide1ines for research in transgenic plants & Guidelines for Toxicity and Allergenicity Evaluation of transgenic seeds, plants and plant parts" 1998 brought out by the Department of Biotechnology, Ministry of Science & Technology, Govt. of India will be and is being strictly followed. The imported material will be and is being utilized for the said purpose only. In case any untoward incident occurs, the Chairman of the IBSC and the Member-Secretary of the RCGM will be immediately informed.

Date: **Signature of the Applicant**

Forwarded:

The proposal set out above has been considered and approved by the "Institutional Biosafety Committee" on and is forwarded to RCGM for further necessary action.

Date: **Signature of the Chairman, IBSC**

Note: Please submits 23 copies of the application to the Department of Biotechnology for placing the same in the meeting of RCGM)

Enclosed: (Kindly tick the enclosures)

- Copy of the permit, if issued earlier
- Copy of the minutes of IBSC meeting in which the proposal was approved