

FORM 17
FORMAT FOR SUBMISSION OF PRECLINICAL OR OTHER SAFETY STUDIES
OF rDNA PRODUCTS DEVELOPED USING GMOs/LMOs FOR
HEALTHCARE, INDUSTRIAL OR ANY OTHER USE

1. Name of the Applicant:
Designation:
Address:
Telephone No.:
Fax No.:
e-mail:
2. IBSC Code:
3. Objectives of the proposal:
4. Summary of the products characteristics and process of development:
5. List of preclinical study protocols approved by RCGM
(please attach a copy of the approval letter)
6. Preclinical study reports
 - 6.1 List of studies completed and deviations, if any from the approved protocols
 - 6.2 Dose calculation for conduct of safety studies
 - 6.3 Study reports *(Each study report would reflect all the issues approved in the protocols)*. In addition the following to be included:
 - RCGM approval of protocol
 - IBSC approval of report
 - IAEC approval for animal use and for the procedures
 - Quality assurance statement
 - Signatures of study director and all investigators who were involved in the study
 - All quality analytical reports on the test material and vehicle
 - Animal feed and animal health certifications
 - Protocol deviations if any
 - Discussion on the results
 - Individual animal data, summary data and any other data like computer analysis outputs etc
 - Conclusion
 - 6.4 Address and accreditation status of the labs where these studies were conducted.
7. Measures taken for containment

8. Decontamination and disposal mechanisms
9. Risk management (Emergency plan)
10. Any other relevant information
11. Declaration :
I declare that the information provided in the above format is correct and accurate to the best of my knowledge.

Date: Signature of the Applicant

Forwarded:

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

Date: Signature and name of the Chairman, IBSC

Note:

1. Please submit 20 copies of the application along with the enclosures to the Member Secretary, RCGM, Department of Biotechnology for consideration by RCGM.
2. Enclosures should include
 - RCGM approval
 - Copy of the minutes of IBSC meeting in which the proposal was approved
 - IBSC approval