Application to GEAC under Rules 1989 seeking approval for environmental release of transgenic crops, as per DBT Guidelines 1998

CERTIFICATION

(A certificate to the following effect be submitted by the applicant)

I/ We _____ Son(s)/ Daughter(s) of _____ certify that to the best of my knowledge and belief the information provided in the application includes all information and views on which a judgment can be made to decide about the status of the product under the Indian Environment (Protection) Act, 1986 and that it includes all relevant information and data known to me/ us.

Signature of the Applicant(s)

Name of the Applicant(s) _____

Representing _____

Full Address of the Applicant & the Representative Organization _____

Place :

Date :

EXPLANATORY NOTE APPENDED FOR THE REVIEW

(This should justify the design of the work, the citation of the past literature if any on the subject with proper referencing, the authentication of the gene/s and the gene product/s by method/s to be stated if unpublished, and any other relevant information published in the literature with proper citation. The idea is to enable the reviewers to appreciate the special features of the product/s being reviewed).

PARTICULARS OF THE APPLICATION SEEKING APPROVAL UNDER RULES 8,9,10 & 11 OF THE NOTIFICATION NO. GSR 1037(E) DATED 05.12.1989 ISSUED BY THE MINISTRY OF ENVIRONMENT &FORESTS UNDER THE ENVIRONMENT PROTECTION ACT, 1986, FOR TRANSGENIC PLANTS

Name of the Project	:	
Submitted by under Section/s of the EPA-1986	:	Name & Address of the Applicant indicating telephone No., Fax No., E-mail No. etc., and the Section/s under which application is submitted.
Document Prepared by and responsible for further responses	:	Name & Address of the person who is responsible for furnishing replies to subsequent queries.
Names & Addresses of the Contributor to the substantive parts of the document	:	1. _____ 2. _____ 3. _____ etc.

ABBREVIATIONS USED IN THE APPLICATION

Abbreviations/ symbols used	Expansion of the Abbreviations/ symbols with explanations if required

Content of the Chapters
(Data required for the appraisal of Environmental Risks and Safety from the use of Transgenic plants)

PART A

Chapter I : Introduction

1. Rationale for the development
2. Benefits - Economic Benefits, Agronomic benefits etc.
3. Regulatory approvals required for, and earlier approvals obtained if any for specific purposes in India with approval No. etc.
4. Other relevant information including status of regulation in the country of origin with documentation, and status of regulation in other countries.
5. Discussion and conclusions.
6. Referencing.

Chapter II : Biology of the Plant System

1. Relevance of the plant in India
2. Taxonomy, genetics, pollination pattern etc.
3. Description of the near relatives of the plant in the ecosystem
4. Methods of pollen dispersal in target plants & in near relatives
5. Others including documented references
6. Conclusions.
7. Referencing.

Chapter III : Molecular Biology of the Plant and Transformation Methods

1. Description of the plant materials to be transformed.
2. Source of the gene and the cloning strategy followed.
3. Characteristics of the plant expression vector
4. Characteristics of the inserted genes with sequence details
5. Characteristics of the vectors and the transformation system employed with description of sequences used.
6. Genetic analysis including insert No., Copy No., Insert Integrity, Segregation, Stability of the gene transfer, Description of the expressed gene, Biochemistry of the expressed gene products, authentication of the gene products by physical, chemical, immunological and biological methods etc.
7. Discussion and conclusions.
8. Referencing.

PART B

Chapter IV : Field Trial Plans

1. Field test permit, locations and design of trial
2. Plant growth and specific observations required to be made including the extent of gene escape, persistence of escape etc.,
3. Strategy adopted for determining efficacy of the transgenics in the field trials and plan for presentation of data
4. Summary and conclusions highlighting expectations from the trail.
5. References.

Chapter V : Results of Phenotype of the Transformed Plant & Fruits / Seeds

1. Germination and vigor results of the transgenic line in field & in the lab
2. Description of the Phenotype of the transformed plant
3. Composition and quality of the transformed plant and the seeds/ fruits of the plants and comparison with non-transgenic phenotypes.
4. Competitive Toxicant analysis of the transformed plant and potential for weediness in cases of uncontrolled release of transgenic plants
5. Risks during the processing / handling of the transformed plant/ fruits
6. Susceptibility of the plant products / fruits to diseases and pests
7. Long term influence of the plant pests to the transformed plants, fruits and seeds.
8. Gene transfer to non-transgenic lines including near relatives and percentage of transfer under specific field conditions.
9. Out-crossing potential including pollen transfer to cultivated genotypes, and wild species and its implications.
10. Implication of transfer of genetic information to species to which it can inter breed.
11. Possible impact on environment on over all assessment.
12. Summary and conclusions.

13. Referencing.

PART C

Chapter VI : Consequences to the Environment

1. Environmental consequence of introduction of transformed cultivars
2. Statement of unfavorable grounds
3. Effect on non-target organism including non-target insects, non-target birds and fish and non-target animals including mammals and wild life on extensive exposure of transgenics.
4. Impact on endangered species
5. Response plans for controlling unfavorable grounds in the environment.
6. Plans for protecting human and animal health from undesirable effects.
7. Summary and conclusions.
8. Referencing.

PART D

Chapter VII : Food Safety Evaluation

1. Evaluation of food safety assessment in approved protocol including nutritional studies (anti-nutritional factors if any and substantial equivalence studies etc.), sub acute and chronic toxicity studies & allergenicity status if any etc.
2. Classical animal feeding trials
3. Immuno-toxicological studies
4. Gut toxicological studies
5. Fundamental molecular biological studies including gene integration, gene regulation, gene expression and effects of transgenic proteins
6. *In vitro* hemolytic behavior of the transgenic proteins if any and its relevance to in-vivo studies in target animals
7. Summary and conclusions
8. Referencing.

PART E

Chapter VIII : Supportive Evidences for All The Chapters

1. Supporting evidences in statements of annexure cataloguing Chapter No. and Annexure No.
2. Supportive evidence providing lists of figures cataloguing Chapter No. and Figure No.
3. Supportive evidence providing lists of tables cataloguing Chapter No. and Table No.

PART F

Chapter IX : Summary and Conclusions

1. Executive summary and overall conclusions.

MINISTRY OF ENVIRONMENT AND FORESTS

Application for Environmental Approval of Transgenic Plants
(Genetically Modified Plants)

PART A

a) Not all the points included will apply to every case. It is expected, therefore, that individual applicant will address only the particular parameters that are appropriate to individual situations. In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated.

b) The details required in response to each parameter is also likely to vary according to the nature and scale of the proposed release.

c) The description of the methods used or the reference to the standardized or internationally recognized methods shall also be mentioned in the Proforma together with the name of the body or bodies responsible for carrying out the studies.

PART B

1 Name of the applicant

2 Name of the Organization

3 Approvals required

(i) Field Trials & Production:

(ii) Import/ Export

(iii) Release/Marketing

(a) Imported materials
(b) Indigenously developed.

Part C

1. Identification of Transgenic Plant

(i) Donor species

(ii) Recipient plant Species

2. Risk Assessment

(i) Are they harmful to man, animal, plant or environment?

3. Anticipated or actual expression of the incorporated genetic material in the Plant.

(i) Morphology

(ii) Physiology

(iii) Number of copies of the genes incorporated

(iv) Products

4. Purpose of Experimental Design

(i) Resistance to biotic stress

(ii) Any other

5. Details of Experimental System

(i) Nature of gene

(ii) Vector/Vector agent used for gene transfer

(iii) Testing procedure for trans-gene

6. Safeguard required for field release

(i) Biological

(ii) Physical

7. Sites for field trials

8. Mode of Propagation and Pollination

9. Regulatory status in India/Abroad

(i) India

(ii) Abroad

Place:
Date:

Applicant