FORM – III

APPLICATION FOR IMPORT OF FOOD AS LIVING MODIFIED ORGANISM (LMO) / PER SE AS FOOD/FEED/PROCESSING.

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Part A

(a) Not all the points included will apply to every case. It is to be 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 are 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 form together with the name of the body or bodies responsible for carrying out the studies.

(d) A 1-2 page summary of the proposal shall be appended with application.

Part B

1. Name and contact details of the Applicant
2. Name and contact details of the organization/firm
3. Approval required.
4. Quantity per year of the product to be imported/marketed.

Part C

1. Name of the product:

2. Intended use:

3. Purpose of import

4. Name and identity of the living modified organism(s).

5. Any unique identification of the living modified organism.

6. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, mode of propagation/ pollination point of collection or acquisition, and

characteristics of recipient organism or parental organisms related to biosafety.

7. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms; Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

8. Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

9. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

10. Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

11. Suggested detection and identification methods and their specificity, sensitivity and reliability;

12. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms;

13. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

14. Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

15. Safeguards required for field release, if any.

16. List of gene/events approved in the same crop species for commercial production in the country of export/ country of origin.

17. Whether the product has been approved for consumption (food/feed) in Countries other than producing countries. If so, details of the same.

18. Whether the gene/events from which the product has been derived is in commercial production and has been approved for marketing in the country of origin/export.

19. Approved uses of the living modified organism in the country of

origin/export.

20. Environmental and Food safety studies conducted in the country of origin/export.

21. Analytical / compositional report or LMO from the country of origin/export. Whether further processing is envisaged after import. If so details of the same.

22. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

23. Quality Control and Quality Assurance.

24. Stability and Shelf Life of product.

25. Regulatory status in India / abroad. In case the certificate is issued by the concerned authority of country of origin, the certificate should be endorsed/ authenticated by Indian Embassy/High Commission/Consulate in that country.

26. Every certificate shall be accompanied by other statutory information like manufacturing batch, no. date of manufacture, date of analysis, date of release of the certificate, signatory to the certificate etc.

27. A declaration that the above-mentioned information is factually correct.

Applicant's signature with seal.