Form IB

(See sub-regulation (1) of regulation 4)

APPLICATION FOR THE APPROVAL OF FOODS DERIVED FROM GENETICALLY MODIFIED ORGANISMS (GMOs)

Note: Use Form IB for GM food as referred to in sub-regulation 2 (c) of regulation 1
(These include vitamins, amino acids, functional proteins (e.g., texturants), nutritional proteins, oligosaccharides, flavors, and sweeteners)

- Application form should be supported by documents.
- For any information not included, please provide a rationale as to why the information is not relevant or necessary or what information is being provided in its place, if applicable.
- The applicant shall, at the time of submission, clearly state which parts of the application are claimed to be confidential and provide verifiable justification.

SECTION 1: ADMINISTRATIVE REQUIREMENTS

1. Name and contact details of the Applicant:
2. Name and contact details of the organization/firm:
3. Approval required for import of (Name of ingredient/additive etc):
4. Quantity of the product to be imported/marketed per year:

SECTION 2: TECHNICAL INFORMATION

1. Name of the product/ingredient/additive:
2. Country of origin:
3. Purpose of import and intended use:
4. Name of Production strain (Identify genus, species, strain):
5. Is the production strain genetically modified?
6. If yes, is the production strain modified using rDNA techniques?
7. If yes, Name of Donor strain (Identify genus, species, strain):
8. Is the donor/host organism nonpathogenic? *
9. Does the donor strain have history of safe use in food (GRAS/QSP etc.) *?
10. Does the resistance gene(s) code for resistance to a drug substance used in treatment of disease agents in man or animal? *
11. Is the ingredient/additive approved by FSSA(I) for food use?
12. Is the ingredient/additive preparation free of transferable antibiotic resistance gene DNA? *
13. Does the resistance gene(s) code for resistance to a drug substance used in treatment of disease agents in man or animal? *
14. Is all other introduced DNA well characterized and free of attributes that would render it unsafe for constructing microorganisms to be used to produce food-grade products?
15. Is the ingredient/additive free of antibiotics? *
16. Is the ingredient/additive free of oral toxin so known to be produced by other members of the same species?[a] *
17. Is the NOAEL in short-term feeding studies sufficiently high to ensure safety?

*These statements must be substantiated with relevant documentation/Certificate of Analysis etc.
[a] For bacteria and yeasts: Is the test material free of toxins" known to be produced by other strains of the same species For molds, is the test material free of detectable levels of aflatoxin B1, ochratoxin A, sterigmatocystin, T-2 toxin, zearalenone, and any other toxins known to be produced by strains of the same species

SECTION 3 DETAILS OF PRODUCTION AND MANUFACTURE AND ANALYSIS

1. Details of manufacturing process:
2. List of countries where ingredient/additive derived from GMM is approved for food use:
3. Certificate of Analysis from an ISO/IEC 17025:2017 certified laboratory from the country of origin/export for compliance to ‘General Specifications detailed in Food Safety and Standards Rules and Regulations (FSSR) 2011 and amendments thereof. If not specified in FSSR (2011) then specifications of JECFA’s Combined Compendium of Food Additive

Specifications will appy:

4. Any other relevant information:

Signature of applicant Date

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief, and that this application includes all relevant data and information upon which to base a decision, including all data and information that are unfavorable to the application**.**

List of enclosures: