INSPECTION SERVICES

APPLICATION FORM FOR THE SAFETY ASSESSMENT OF FOODS DERIVED FROM GENETICALLY ENGINEERED PLANTS

- The application form will be supported by the full submission of a dossier, including supporting studies, that contain the complete set of data required for the safety assessment.
- For any information not included, please provide a rationale as to why the information is not relevant or necessary for the food safety assessment of the GE plant, or what information is being provided in its place, if applicable.

Section 1: Administrative Requirements

1.1 Applicant Details:

Name: Organization/Company: Address: Telephone: E-mail:

1.2 Authorized Signatory, if any

Name: Organization: Address: Telephone: E-mail:

1.3 General Information of the GE Plant

Name of the GE plant	
Description of the introduced trait (e.g., drought tolerance, insect resistance)	
OECD Unique Identifier (if applicable)	
Intended use (e.g., food, feed, cultivation)	
Status of authorization in other countries ● For cultivation ● For food and feed use	
Please mention countries and date of authorization and attach copies of relevant permits/authorization letters	

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Type of Authorization	Competent National Authority	Date of Authorization	Permit or Authorization No.	Official Authorization Documentation Attached (Yes/No)

Section 2: Technical Information

2.1 Description of Events in the GE plant

Name of the transformation event(s)	
Pedigree map for each transformation event	
Purpose of the modification	

2.2 Description of the Host/Recipient Plant

Common or usual name, scientific name, and taxonomic classification	
History of cultivation and development through breeding, in particular information on: ● Traits that may adversely impact human or animal health ● Any known toxicants or antinutrients ● Any known allergens	
History of safe use for consumption as food. Please provide a summary covering: ● How the plant is typically cultivated, transported, and stored ● Any special processing required to make the plant safe for consumption ● The plant's normal role in the diet	

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• Part of the plant that is used as a food source • If consumption of the plant is important in any vulnerable subgroups of the population • Important macro- or micro-nutrients it contributes to the diet	

2.3 Description of the Donor Organism

Common or usual name, scientific name, and taxonomic classification	
Information about: • the natural history of the organism as concerns to human or animal health • naturally occurring toxins, anti-nutrients, and allergens	
For donor microorganisms, additional information on human pathogenicity and the relationship to known human pathogens	
Information on the past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants).	

2.4 Description of the Genetic Modification

2.4.1 Method of Modification

Specific method used for the modification	
Description and characterization of all genetic material used to modify the plant, including the source (e.g., plant,	

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microbial, viral, or synthetic), identity, and expected function in the plant	
Details of modifications to introduced, intermediate and recipient genetic material (e.g., changes in amino acid sequence that may affect expression of the expressed protein)	

2.4.2 Potentially Introduced Genetic Material

Provide a detailed description of all genetic elements of the vector, including coding regions and non-coding sequences of known function. For each genetic element, include:				
A citation where these functional sequences are characterized	Indicate the portion and size of the sequence inserted	Indicate the location, order, and orientation in the vector	Indicate the function in the plant	Indicate the source (common and scientific and/or trade name, of the donor organism)
Provide a detailed map of the plasmid vector or transforming DNA with the location and orientation of all the sequences described above.				

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2.4.3 Molecular Characterization

Information about the DNA insertion(s) into the plant genome is required, including:				
Characterization and description of the inserted genetic material	Number of insertion sites	Copy number and sequence data to demonstrate if complete or partial copies were inserted, and if the arrangement of the genetic material was conserved or if significant rearrangements have occurred upon integration.	Sequence data of the inserted material and of the flanking regions bordering the site of insertion	Identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion proteins.

Describe how genetic stability of the introduced trait over multiple generations was demonstrated.

Describe how segregation of the introduced trait within a generation was demonstrated.

2.4.4 Expressed Substances in the GE Plant:

Information about each of the gene products (e.g., a protein or an untranslated RNA)

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The gene product(s)	Function	Level and site of expression of the expressed gene product(s) in the plant	Levels of its metabolites in the edible portions	Amount of the target gene product(s), where possible, if the function of the expressed s e q u e n c e (s)/gene(s)is to alter the accumulation of a specific endogenous mRNA or protein.

2.4.5 Any other information:

_____

_____

2.5 Potential Toxicity Assessment

Describe the safety studies undertaken to demonstrate lack of/no potential toxicity of any newly expressed proteins in the GE plant and that do not have a history of safe consumption

Protein*	Amino acid sequence similarity with known toxins? If yes, provide details	Rapidly digested via *in vitro* pepsin digestibility assay? If yes, provide details.	Activity is stable to heat or processing? If yes, provide details.	Acute oral toxicity testing? If yes, provide details.
				Dose tested:__

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				Toxicity observed, if any

**Where a host other than the transgenic plant is used to produce sufficient quantities of the newly expressed protein for toxicological analyses, demonstrate the structural, functional, and biochemical equivalence of the non-plant expressed protein with the plant expressed protein.*

Provide additional details as necessary:

_____

_____

2.6 Potential Allergenicity Assessment

Describe the safety studies undertaken to demonstrate that there is no potential allergenicity of any newly expressed proteins in the GE plant that do not have a history of safe consumption

Protein	Donor organism a known source of significant allergens? If yes, provide details	Amino acid sequence similarity with known allergens? If yes, provide details	Rapidly digested via *in vitro* pepsin digestibility assay? If yes, provide details.	Stable to heat or processing? If yes, provide details

Provide additional details as necessary:

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2.7 Compositional Analysis

Describe the results of compositional analyses. Data should be provided on the levels of key nutrients and antinutrients present in the edible portions of the plant (e.g., seed or grain), including other plant parts (e.g., forage) that may be used as animal feed

Plant part	Used as food or animal feed	Differences observed if any in the levels of key nutrients and antinutrients

Section 3: Procedural Information

3.1 Describe any specific instructions and/or recommendations for use, storage, and handling

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_____

3.2 Describe any proposed packaging and labelling requirements

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3.3 Briefly describe the event-specific detection method for the genetically engineered plant event

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3.4 Any other specific information

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Name and 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.