DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

EARLY FOOD SAFETY EVALUATION OF A NEW NON-PESTICIDAL PROTEIN PRODUCED BY A NEW PLANT VARIETY *(NEW PROTEIN CONSULTATION)*

Form Approved: OMB Control No. 0910-0583;
Expiration Date: 08/31/2024 *(See page 4 for OMB Statement)*

FDA USE ONLY

NPC NUMBER

DATE OF RECEIPT

Transmit completed form and attachments electronically via the COSM online submission system (see Instructions); OR Transmit completed form and attachments in paper format or in physical media to: Office of Food Chemical Safety, Dietary Supplements, and Innovation (HFS-200), Human Foods Program, Food and Drug Administration, 5001 Campus Drive, College Park, MD, 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☐ New ☐ Amendment to NPC No. _____ ☐ Supplement to NPC No. _____

2. ☐ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3a. For New Submissions Only: Most recent presubmission consultation *(if any)* with FDA on the subject new protein *(yyyy/mm/dd)*: _____

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes enter the date of communication *(yyyy/mm/dd)*: _____

PART II – INFORMATION ABOUT THE PERSON RESPONSIBLE FOR THE SUBMISSION

1a. Person Responsible for the Submission

Name of Contact Person	Position
Company *(if applicable)*	
Mailing Address *(number and street)*	

City	State or Province	Zip Code/Postal Code	Country

Telephone Number	Fax Number	E-Mail Address

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position
Company *(if applicable)*	
Mailing Address *(number and street)*	

City	State or Province	Zip Code/Postal Code	Country

Telephone Number	Fax Number	E-Mail Address

PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Title of Submission

2. Submission Format: *(Check appropriate box(es))*

☐ Electronic Submission (COSM) ☐ Electronic files on physical media with paper signature page

☐ Paper

If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

☐ Yes *(Proceed to Item 5)* ☐ No *(Proceed to Item 6)*

5. The submission incorporates by reference information from a previous submission to FDA as indicated below *(Check all that apply)*:

☐ a) BNF No. BNF .....

☐ b) NPC No. NPC .....

☐ c) GRAS Notice No. GRN .....

☐ d) GRAS Affirmation Petition No. GRP .....

☐ e) Food Additive Petition No. FAP .....

☐ f) Food Master File No. FMF .....

☐ g) Other or Additional *(describe or enter information as above)* _____

6. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes *(Proceed to Item 7)* ☐ No *(Proceed to Part IV)*

7. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information? *(Check all that apply)*

☐ Yes, see attached Designation of Confidential Information

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

8. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

PART IV – INFORMATION ABOUT THE NEW PROTEIN

1. Name of the new protein
(include both common name and systematic name as applicable)

Scientific Name Data

2. Registry No. of the new protein[1] *(optional)*

Registry Id

3. Describe the purpose or intended technical effect of the new protein

Description

[1] Common registries used include CAS *(Chemical Abstracts Service)* and EC *(Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology(IUBMB))*

PART V – INFORMATION ABOUT THE GENETIC MATERIAL

Provide the information about the genetic material that encodes your new protein.

Identity of Introduced Genetic Material	Source of Introduced Genetic Material
Scientific Name Data	Genetic Material Source
Scientific Name Data	Genetic Material Source
Scientific Name Data	Genetic Material Source
Scientific Name Data	Genetic Material Source
Scientific Name Data	Genetic Material Source

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PART VI – SCIENTIFIC EVALUATION OF THE FOOD SAFETY OF THE NEW PROTEIN

(check list to help ensure your submission is complete – check all that apply)

1. ☐ History of safe use in food or feed
2. ☐ Assessment of the amino acid similarity between the new protein and known allergens and toxins
3. ☐ Overall stability of the new protein and the resistance of the protein to enzymatic degradation using appropriate *in vitro* assays

4a. Did you include any other information that you want FDA to consider in evaluating your NPC?

☐ Yes ☐ No

4b. Did you include this other information in the list of attachments?

☐ Yes ☐ No

PART VII – SIGNATURE

Signature of Responsible Official, Agent, or Attorney	**Printed Name and Title**	**Date (mm/dd/yyyy)**

PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
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OMB Statement: Public reporting burden for this collection of information is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FDA PRA Staff Office of Operations, Food and Drug Administration email to PRAStaff@fda.hhs.gov. (Please do NOT return the form to this address). An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.