GRAS Notice (GRN) No. 1132 with amendments
https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory

GRAS ASSOCIATES
Food Safety Regulatory Services, A Nutrasource Company
nutrasource

11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
T: 519.341.3667 | F: 888.531.3466

January 24, 2023

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Dr.
College Park, MD 20740

Attention: Dr. Susan Carlson
Re: GRAS Notification – Nor-HydroPep DM

Dear Dr. Carlson:

GRAS Associates, LLC, acting as the Agent for Norilia AS (Norway), is submitting for FDA review Form 3667 and the enclosed CD, free of viruses, containing a GRAS Notification for hydrolyzed poultry protein, tradename Nor-HydroPep DM. Along with Norilia AS's determination of safety, an Expert Panel of qualified persons was assembled to assess the composite safety information of the subject substance with the intended use as a source of protein in soups, snacks, tomato-based vegetable juices, gravies, condiments, nutrition bars, protein drinks, meal replacements and medical food applications. The attached documentation contains the specific information that addresses the safe human food uses for the subject notified substance as discussed in the GRAS guidance document.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me via telephone or email. I also authorize Amy Mozingo (amozingo@gras-associates.com), VP US Nutra Regulatory Sciences, GRAS Associates LLC to lead communications related to this submission.

We look forward to your feedback.

Sincerely,

William J. Rowe
Agent for Norilia AS
President, GRAS Associates, LLC
1810 Grand Park Ave, Suite 500
North Bethesda, MD 20852
wrowe@nutrasource.ca
Enclosure: GRAS Notification for Norilia AS – Nor-HydroPep DM

GRAS Conclusion

of

Nor-HydroPep DM

Food Usage Conditions for General Recognition of Safety

on behalf of

Norilia AS

Lørenveien 37
0585 Oslo, Norway

12/21/22

TABLE OF CONTENTS

FIGURES

TABLES

FOREWORD

Norilia based the Generally Recognized as Safe (GRAS) assessment of the Nor-HydroPep DM primarily on the composite safety information, i.e., scientific procedures with corroboration from history of use. The safety/toxicity of Nor-HydroPep DM, compositional details, specifications, and method of preparation of the subject ingredient were reviewed. In addition, a search of the scientific and regulatory literature was conducted through December 19, 2022, with particular attention paid to those that supported conclusions of safety of protein hydrolysates. Those references that were deemed pertinent to this review are listed in Part 7. The composite safety/toxicity studies, in concert with dietary exposure information, ultimately provide the specific scientific foundation for the GRAS conclusion.

At Norilia's request, GRAS Associates, LLC (GA) convened an Expert Panel to complete an independent safety evaluation of Norilia's Nor-HydroPep DM product. Norilia's Nor-HydroPep DM is manufactured by mixing poultry carcasses in water and physical separation of the water-soluble protein phase, which is evaporated and spray dried. The purpose of the evaluation is to ascertain whether Norilia's Nor-HydroPep DM is generally recognized as safe, i.e., GRAS, under the intended conditions of use. In addition, Norilia has asked GA to act as Agent for the submission of this GRAS notification.

PART 1. SIGNED STATEMENTS AND CERTIFICATION

A. Claim of Exclusion from the Requirement for Premarket Approval Pursuant to 21 CFR 170 Subpart E[1]

Norilia has concluded that Nor-HydroPep DM, referred to as "Nor-HydroPep" and which meets the specifications described below, is GRAS in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This determination was made in concert with an appropriately convened panel of experts who are qualified by scientific training and experience. The GRAS determination is based on scientific procedures as described in the following sections. The evaluation accurately reflects the intended conditions of food use for the designated Nor-HydroPep DM preparation.

This signed statement and certification has been prepared in accordance with the requirements of 21 CFR 170.225.

(a) This certification is signed by a responsible official of GRAS Associates, LLC acting as agent for Norilia.

(b) This Part 1 of the GRAS dossier does not include any confidential information.

(c) (1) This Independent GRAS Assessment was conducted in accordance with Subpart E of 21 CFR Part 170.

(c) (2) Names and addresses of organizations;

Sponsoring Party:

[1] See 81 FR 54960, 17 August 2016. Accessible at: https://www.gpo.gov/fdsys/pkg/FR-2016-08-17/pdf/2016-19164.pdf (Accessed 12/21/2022)

Norilia AS
Lørenveien 37
0585 Oslo, Norway

As the Responsible Party, Norilia accepts responsibility for the GRAS conclusion that has been made for Nor-HydroPep DM, preparation, as described in the subject safety evaluation.

Agent:
GRAS Associates, LLC
11810 Grand Park Avenue
Suite 500
North Bethesda, MD 20852

(c) (3) The common name of the ingredient to be used on food labels is “hydrolyzed poultry protein” as per 21 CFR § 102.22. Norilia also plans to market our hydrolyzed poultry protein isolate preparation under the trade name Nor-HydroPep DM.

(c) (4) Norilia’s Nor-HydroPep DM is intended for use in processed food products to increase the level of protein in a product as a replacement for other animal or vegetable protein. The intended food categories, include soups, snacks, tomato-based vegetable juices, gravies, condiments, nutrition bars, protein drinks, meal replacements and medical food applications. Nor-HydroPep DM will not be used in infant formulas. The proposed use levels will be determined by current good manufacturing practices (CGMP).

(c) (5) The statutory basis for our conclusion of GRAS status is through scientific procedures in accordance with § 170.30(a) and (b).

(c) (6) It is our view that the ingredient is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on our conclusion that the notified substance is GRAS under the conditions of its intended use.

(c) (7) If FDA were to ask to see the data and information that are the basis for our conclusion of GRAS status, either during or after FDA evaluation of this notice, we agree to:

(i) make the data and information available to FDA; and

(ii) agree to both of the following procedures for making the data and information available to FDA:

(A) Upon FDA’s request, we will allow FDA to review and copy the data and information during customary business hours at our address specified where these data and information will be available; and

(B) Upon request by FDA, we will provide FDA with a complete copy of the data and information either in an electronic format that is accessible for their evaluation or on paper.

(c) (8) None of the data and information in Parts 2 through 7 of this GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552 (e.g., as trade secret or as commercial or financial information that is privileged or confidential).

(c) (9) We certify that, to the best of our knowledge, this GRAS Assessment is a complete, representative, and balanced review that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

(c) (10) Norilia does intend to add Nor-HydroPep DM to meat and/or poultry products that come under FSIS/USDA jurisdiction. Therefore, 21 CFR 170.270 does apply.

(c) (11) Signature

[redacted]

Agent for Norilia

William J. Rowe
President
GRAS Associates, LLC
11810 Grand Park Ave
Suite 500

Date: 12/23/2022

PART 2. IDENTITY, METHOD OF MANUFACTURE, SPECIFICATIONS, AND PHYSICAL OR TECHNICAL EFFECT

A. Chemical Identity of Ingredient

Hydrolyzed poultry protein is the common or usual name of the Nor-HydroPep DM. The compositional features of the Nor-HydroPep DM are described in more detail in this section. Nor-HydroPep is the abbreviated term used for Nor-HydroPep DM in referring to the notified substance.

1. Chemistry of Protein Hydrolysates

Chicken and turkey products are widely consumed as they are rich in protein and amino acids and low in fat. Proteins have an important role in human nutrition and are also utilized by food manufacturers for their functional properties, such as gelatin, water bonding ability, fat binding ability, thickeners/viscosity builders, and foaming agents.

The basic backbone of proteins are amino acids joined together by peptide bonds, between the amino-terminus (N-terminus) and carboxy-terminus (C-terminus) (Figure 1). While the amino acid sequence makes up the primary structure of the protein, the chemical/biological properties of the protein are dependent on the tertiary structure. The bonding of different amino acids in varying sequences is what determines the final structure of the protein.

Protein hydrolysates are a complex mixture of peptides of different chain length together with free amino acids. Protein hydrolysates are derived from purified protein sources by heating with acid or, preferably, addition of proteolytic enzymes, followed by purification procedures (Manninen, 2009).

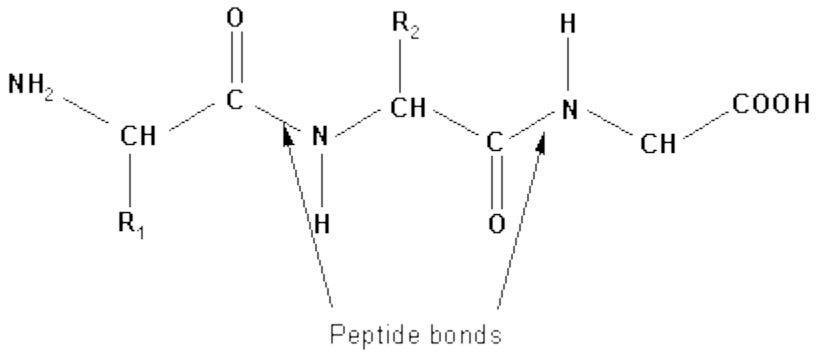


Figure 1. Structure of Basic Primary Protein

2. Chemistry of Nor-HydroPep

The chemical composition of Nor-HydroPep hydrolyzed poultry protein primarily consists of protein-derived peptides with lesser constituents being fat, moisture and ash (Table 1). The typical molecular weight distributions of the peptides in Nor-HydroPep are provided in Table 2.

Table 1. Chemical Components of Nor-HydroPep

COMPONENT	TYPICAL VALUE (%)
Dry Matter	60
Crude Protein	55
Water Soluble Protein	53
Crude Fat	1-3
Ash	5

Table 2. Typical Molecular Weight Distribution of Peptides in Nor-HydroPep

MOLECULAR WEIGHT (DALTONS)	AMINO ACID UNITS	TYPICAL VALUE (%)
> 20,000	N/A	1
20,000-15,000	N/A	2
15,000-10,000	N/A	5
10,000-8,000	71-88	5
8,000-6,000	53-70	7
6,000-4,000	36-52	10
4,000-2,000	18-35	15
2,000-1,000	10-17	12
1,000-500	5-9	8
500-200	2-4	11
< 200	≤ 2	25

3. Nutritional Profile of Nor-HydroPep

The typical nutritional data for Nor-HydroPep is summarized in Table 3.

Table 3. Nutritional Profile of Nor-HydroPep

NUTRIENT (PER 100 G)	TYPICAL VALUE
Calories	238
Protein (g)	55
Total Fat (g)	2.0
Saturated Fat (g)	0.6
Trans Fat (g)	0
Total Carbohydrates (g)	0
Dietary Fiber (g)	0
Total Sugars (g)	0
Vitamin D (mcg)	< 0.25
Calcium (mg)	45
Iron (mg)	1.9
Potassium (mg)	1700

g – gram; mg – milligram; mcg – microgram

4. Amino Acid Profile of Nor-HydroPep

Due to its high protein content, Nor-HydroPep is rich in amino acids. Nor-HydroPep typically contains the eight essential amino acids needed in a healthy diet. These are phenylalanine, valine, leucine, isoleucine, lysine, threonine, methionine, and histidine, in addition to non-essential amino acids. The typical amino acid content of Nor-HydroPep is compared amino acid profile of a previously FDA-notified poultry protein GRN168 (manufactured by Proteus Industries (2005)) shown in Table 4.

Table 4. Typical Amino Acid Profile of Nor-HydroPep

Amino Acid	Nor-HydroPep Typical Amino Acid Profile (g/100 g Protein)	Proteus Industries Poultry Protein (GRN 168) Amino Acid Profile[1] (g/100 g Protein)
Alanine	7.6	7.07
Arginine	6.3	6.0
Aspartic Acid	9.4	12.63
Cysteine	0.5	NR
Glutamic Acid	14.3	18.63
Glycine	9.3	4.07
Histidine	2.5	3.21
Isoleucine	4.2	4.07
Leucine	8.0	8.35
Lysine	7.7	8.78
Methionine	2.0	2.78
Phenylalanine	3.8	3.64
Proline	5.5	3.85
Serine	4.3	4.93
Threonine	4.6	5.14
Tryptophan	1.0	NR
Tyrosine	2.4	2.36
Valine	4.1	4.50

1.Proteus Industries Inc. (2005)
g – gram

B. Manufacturing Process

1. Incoming Raw Material Quality

The incoming raw turkey and chicken carcasses used to produce Nor-HydroPep are tested for quality. Table 5 outlines these quality specifications.

Table 5. Chemical/Physical Properties of Raw Poultry

PARAMETER	SPECIFICATION
Chemical Content	
Dry Matter (g/100g)	> 30
Crude Protein (g/100g)	> 12
Crude Fat (g/100g)	> 14
Ash (g/100g)	> 3
Microbiology	
Total Plate Count (CFU/g)	< 5,000,000
***E. Coli* (CFU/g)**	< 50,000
***S. aureus* (CFU/g)**	< 5,000
Heavy Metals	
Lead (ppm)	< 0.1
Arsenic (ppm)	< 0.1
Cadmium (ppm)	< 0.1
Mercury (ppm)	< 0.1

g – gram; CFU – Colony Forming Unit; ppm – parts per million

2. Manufacturing Process for Nor-HydroPep

Nor-HydroPep is produced consistent with standard procedures used in the production of protein hydrolysates produced using enzyme hydrolysis. The manufacturing process for Nor-HydroPep begins with raw poultry carcasses that are homogenized in water, hydrolyzed with proteolytic enzymes, followed by physical separation of water-soluble proteins, water insoluble proteins/minerals and fat/oil phases. The manufacturing process in described below in more detail.

Hydrolysis

Poultry meat and bones (chicken and turkey) are ground in a Seydelmann 2055 automatic meat grinder in a room with a maintained temperature of 4º C.

Water is then added and ground poultry mixture and heated to 55º-66º C . Food-grade protease enzymes are added to the mixture and the temperature is maintained a 55º-66º C for 30-120 minutes. The hydrolysis is terminated by inactivating the enzymes by increasing the temperature to 80º- 95º C.

Separation, Packing, Storing, and Shipment

The ground poultry mixture is then mechanically separated into three phases by centrifugal force using a tricanter centrifuge separator: a water-soluble protein phase, a non-water-soluble protein phase and a fat/oil phase. The product of the GRAS conclusion, Nor-HydroPep DM Protein Hydrolysate, is derived from the water-soluble phase, which is an aqueous solution containing 5-10% proteins. This solution is then filled into a vacuum evaporator which evaporates to 60% dry matter.

The product is spray-dried (without a carrier) at 187º C, producing the final product, Nor-HydroPep DM.

The proteolytic enzymes used to manufacture Nor-HydroPep are food-grade permitted by U.S. regulations (21CFR184.1150). Documentation for the food grade status of enzyme, Promod™ 950 L Protease, is found in Appendix 1. Nor-HydroPep is produced in accordance with FDA current Good Manufacturing Practices (CGMP). A Certificate of Conformity for Food Safety Audit for Bioco AS (the manufacturer of Nor-HydroPep) is found in Appendix 2.

The manufacturing process for the production is illustrated in a flow chart provided in Figure 2.

[Remainder of page is blank]

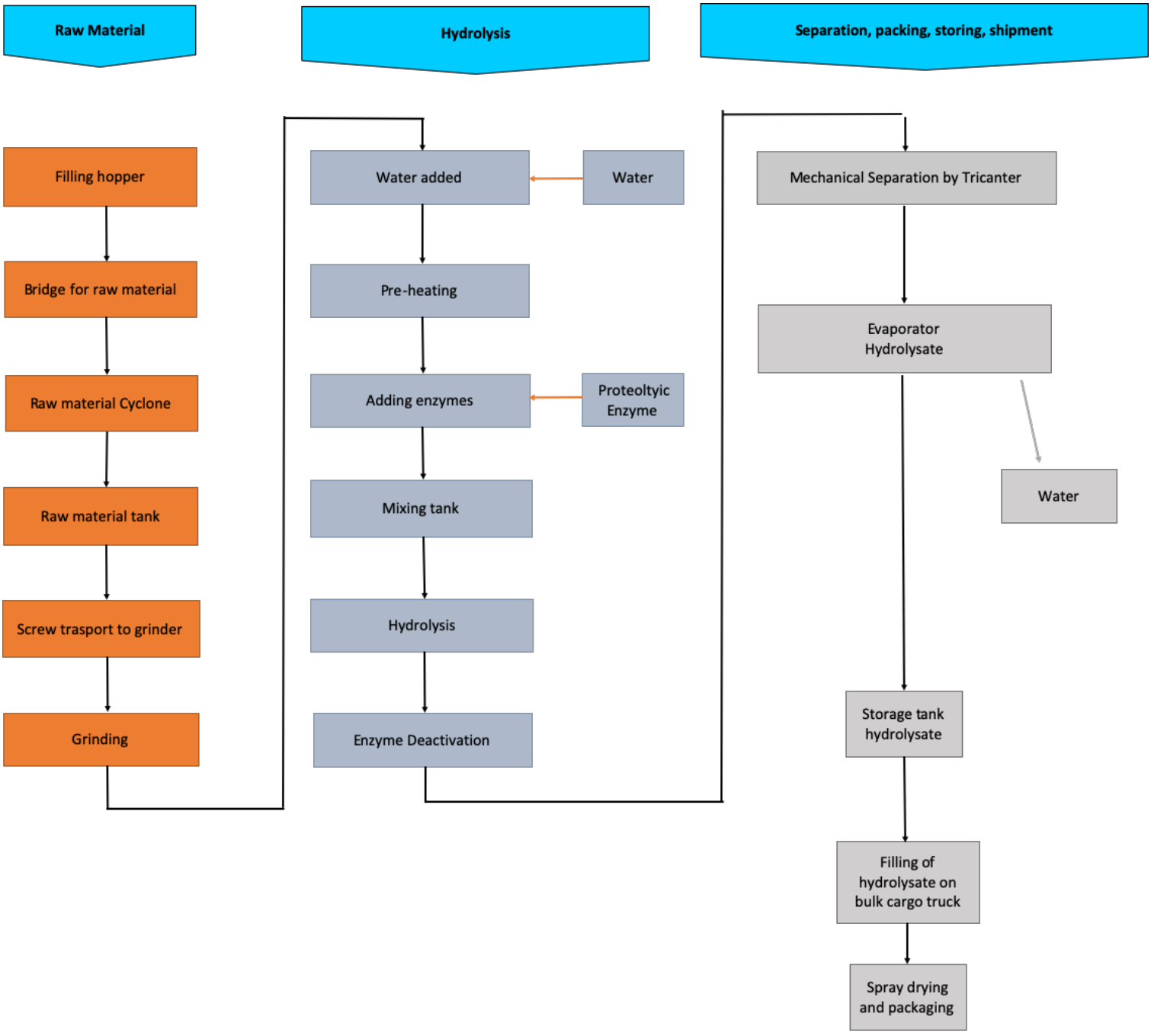


Figure 2. Manufacturing Process for Nor-HydroPep DM

C. Product Specifications

1. Specifications for Norilia's Nor-HydroPep

Norilia has adopted product specifications for its Nor-HydroPep, which are outlined in Table 6. The compositions of five non-consecutive lots of Norilia's Nor-HydroPep are also outlined in Table 6. Specifications for Norilia's Nor-HydroPep and provide evidence that Norilia's Nor-HydroPep meet these adopted specifications. Specifications/product data sheet and Certificates of Analysis (COAs) for 5 lots of Nor-HydroPep DM are found in Appendix 3.

Table 6. Specifications for Norilia's Nor-HydroPep

Physical & Chemical Parameters	Norilia's Specifications for Nor-HydroPep DM	Testing Method	Nor-HydroPep DM Representative Lots				
			Batch 1002863440	Batch 10021251616	Batch 1003076382	Batch 1002981948	Batch 1002903572
Appearance	Brownish paste which may vary slightly	Visual	Complies	Complies	Complies	Complies	Complies
Odor and Taste	Chicken and umami flavor	Sensory	Complies	Complies	Complies	Complies	Complies
Dry Matter (g/100g)	>59	NMKL 23	62	60.0	61.4	59.7	60.7
Crude Protein (g/100g)	>50	NMKL 6	52.6	51.8	52.1	52.3	53.2
Crude Fat (g/100g)	<3	NMKL 160 mod	2.24	1.99	2.83	1.79	2.55
Ash (g/100g)	<6	NMKL 173	2.24	3.98	3.84	4.09	3.67
Lead (ppm)	<0.1	EN ISO 17294-2:2016/EN 13805:2014	<0.020	<0.020	<0.020	<0.020	<0.020
Arsenic (ppm)	<0.1	EN ISO 17294-2:2016/EN 13805:2014	<0.069	<0.070	<0.050	<0.061	<0.069
Cadmium (ppm)	<0.1	EN ISO 17294-2:2016/EN 13805:2014	<0.010	<0.010	<0.010	<0.010	<0.010
Mercury (ppm)	<0.1	EN 16277:2012	<0.020	<0.020	<0.020	<0.020	<0.020
Total Plate Count (CFU/g)	<1000	AFNOR 3M 01/01-09/89-UMQFG	<1000	<1000	<1000	<1000	<1000
Yeast (CFU/g)	<100	NMKL 98	<100	<100	<100	<100	<100
Mold (CFU/g)	<100	NMKL 98	<100	<100	<100	<100	<100

Physical & Chemical Parameters	Norilia's Specifications for Nor-HydroPep DM	Testing Method	Nor-HydroPep DM Representative Lots				
			Batch 1002863440	Batch 10021251616	Batch 1003076382	Batch 1002981948	Batch 1002903572
***E. coli* (CFU/g)**	<10	AFNOR 3M 01/08-06/01 - UMQIM	<10	<10	<10	<10	<10
***Salmonella spp.* (per 25 g)**	Negative	AFNOR EGS 38/01-03/15 - UMQEK	Negative	Negative	Negative	Negative	Negative
Aerobic Spores (CFU/g)	<3000	NMKL 189 - UMQKU	<100	<100	<100	<100	<100
Anaerobic Spores (CFU/g)	<3000	NMKL 189 – UM3K8	<100	<100	<100	2300	<100
Enterobacteriaceae 37ºC (CFU/g)	<10	AFNOR 3M 01/06-09/97 - UMQI0	<10	<10	<10	<10	<10
***Clostridium perfringens* (CFU/g)**	<10	NMKL 95 – UMQGL	<10	<10	<10	<10	<10

AFNOR – French Standardization Association; C – Celsius; CFU – Colony forming units; EN – European Standard; g – grams; NMLK – Nordic Committee on Food Analysis; ppm – parts per million

D. Physical or Technical Effect

Nor-HydroPep DM is be added for flavoring and as an ingredient to increase the level of protein in a product, as a replacement for other animal or vegetable protein.

E. Stability Data for Nor-HydroPep DM

Norilia conducted a stability study of Nor-HydroPep for several parameters at various temperatures ranging from 4°C to 50°C for a period of 12 months (the product specification for Nor-HydroPep DM lists shelf life of 6 months). During the shelf-life test, samples has been collected for analysis of dry matter, vitamin content, antioxidant level, free and total amino acids, fat and fatty acid content, mineral and ash content bioactive content, biogenic amines formation, molecular weight distribution, oxidation product formation, and microbiology. The full report can be found in Appendix 4.

1. Microbiology

No microbiological activity in any of the samples measured were observed during the shelf-life study.

2. Biogenic Amines

Biogenic amines (BA) are considered food hazards – their presence is related to spoilage and fermentation processes. Biogenic amines are formed by the enzymes of raw material and generated by microbial decarboxylation of amino acids. The most significant biogenic amines occurring in foods are histamine, tyramine, putrescine, cadaverine, tryptamine, and β-phenethylamine. Toxicological characteristics of food poisoning are generally associated with histamine and tyramine. Putrescine, cadaverine, and phenylethylamine, may intensify the undesirable effects of histamine. The freshness

of meat products can be measured by the biological amines index (BAI = histamine + putrescine + cadaverine + tyramine) and quality index = (histamine + putrescine + cadaverine)/(1 + spermidine + spermine) (Ozogul and Ozugul, 2019).

BA formation after 12 months at 4º C is shown in Table 7 below.

The only biogenic amine with FDA limitation is histamine. FDA limits histamine in seafood at 50 ppm (Biji et al., 2016). The maximum daily intake of histamine from one serving of fish containing 50 ppm of histamine (assuming a serving of fish is between 100-200 g) is 10 mg at the high end. Using the highest 90th percentile daily estimated intake of Nor-HydroPep of 31.3 g (as calculated in Part 3), the amount of histamine per day from 12-month-old Nor-HydroPep is 0.4 mg.

The no-observed-adverse-effect-level (NOAEL) for tyramine for individuals with no susceptibility to tyramine, has been reported as 200 mg tyramine per meal (Ozogul and Ozugul, 2019). Tyramine content of Nor-HydroPep DM after 12 months at 4º C is 43.7 mg/kg.

In a review of biogenic amine formation and potential toxicity, Ozogul and Ozugul (2019) state “the toxicological level of biogenic amines is very difficult to set as it depends on individual characteristics and the presence of other amines. However, a maximum total BAs level of 750–900 mg/kg has been proposed.” The total biogenic amine content after 12 months at 4º C is 367 mg/kg, which is below this proposed limit.

Although Ozogul and Ozugul (2019) state that high levels of spermine and spermidine are associated with these potential health risks, FDA has not set limits of spermine and spermidine in foods. In a study in which the cytotoxicity of spermine and spermidine was evaluated using an *in vitro* human intestinal cell model reported that spermine was more cytotoxic than spermidine. However, the authors state the concentrations found to be toxic were above the maximum at which spermine and spermidine have been found in food. The authors concluded that that spermine or spermidine in food are not harmful to healthy people. However, patients with cancer are not advised to consume spermine/spermidine-rich foods (Del Rio et al., 2018). The highest level of spermine found in foods is 19.7 mg/portion in cow liver (Atiya Ali et al., 2011). Using the highest 90th percentile daily estimated intake of Nor-HydroPep of 31.3 g (as calculated in Part 3), the amount of spermine is 3 mg from product that is 12 months old.

In a spermidine supplementation trial in adults by Schwarz et al. (2018), it was concluded that spermidine supplementation using a spermidine-rich plant extract is safe and well-tolerated in mice and older adults. The authors set the expected upper safety limit for treatment with spermidine-rich extract at 3.4 mg spermidine/day for the average person weighing 70 kg (4.9 mg/kg per day). Using the highest 90th percentile estimated intake of 31.3 g/day Nor-HydroPep (as calculated in Part 3), the amount of spermidine is 2.8 mg (0.04 mg/kg for a 70 kg person) from product that is 12 months old.

[Remainder of page is blank]

Table 7. Biogenic Amines Formation in Nor-HydroPep After 12 Months at 4º C

Biogenic Amine	After 12 Months (mg/kg)
Phenylethylamine	5.99
Histamine	12.65
Cadaverine	54.325
Putrescine	63.85
Spermadine	90.85
Spermine	95.7
Tryptamine	<5.0 (LOQ)
Tyramine	43.7
Total Biogenic Amines	367.1

kg – kilogram; LOQ – Limit of Quantitation; mg - milligram

Norilia's stability testing results of Nor-HydroPep DM support the position that this ingredient is well-suited for the intended food uses.

PART 3. DIETARY EXPOSURE

A. Intended Use

Norilia's NorHydro-Pep DM poultry protein hydrolysate is intended to be used in processed food products (with the exception of infant formulas) to increase the level of protein in a product, as a replacement for other animal or vegetable protein. The intended use levels vary by food category as shown in Table 8, but range between 5 to 10 g per serving for processed foods and up to 20 g/serving when used as a protein source in nutrition bars, meal replacements, and medical food applications. However, the amounts of Norilia's Nor-HydroPep DM to be added to foods will not exceed the amounts reasonably required to accomplish the intended technical effect in foods.

Intended use includes use in soups containing meat and soup mixes. A sensory analysis was completed by Norilia to determine the effect of Nor-HydroPep on flavor in tomato soup, chicken soup and vegetable soup at levels that provided 3-10 grams of protein (approximately 6-20 grams of Nor-HydroPep-DM based on 50% crude protein). The sensory analysis reported that the addition of Nor-HydroPep-DM as a spray-dried hydrolysate is mainly described as bitter and burnt. These flavors are attributed to the spray-drying process. The more Nor-HydroPep added, the more the products are perceived as burnt and bitter. A brief translation (from Norwegian) of the Sensory Test Results is included in Appendix 5.

The proposed levels of Nor-HydroPep DM per product category is outlined in Table 8 below.

Table 8. Proposed Intended Uses for Nor-HydroPep DM

FOOD CATEGORY (PER 21CFR170.3)	PROPOSED FOOD USES	MAXIMUM USE LEVELS (G) PER SERVING	RACC[1]
Condiments and Relishes	Mayonnaise and other condiments	5	15-17 g
Processed Vegetables, Vegetable Juices	Tomato-based juices	5	240 mL
Gravies & Sauces	Gravies	2	60 g
Herbs, Seeds, Spices, Seasonings, Blends, Extracts, and Flavorings	Seasonings for meat coatings/rubs and in seasoning pastes	2[2]	Not applicable
Soups & Soup Mixes	Soups	10	245 g
Snack Foods	Popcorn, pretzels, chips, & crackers	5	30 g
Not Specified	Nutrition Bars	20	40 g
Not Specified	Protein drinks & protein powder mixes	20	240 mL
Not Specified	Ready-to-drink meal replacements & nutritional beverages	20	240 mL
Not Specified	Medical Foods (protein component only)	20[3]	Not Specified

g – gram; mL – milliliter; RACC – Reference Amounts Customarily Consumed
1. RACC based on values established in 21 CFR §101.12. When a range of values is reported for a proposed food-use, particular foods within that food-use may differ with respect to their RACC. RACCs reported with household measure were converted to g based on USDA Food Central Database (https://fdc.nal.usda.gov/).
2. Maximum use rate of 2g/100 g in seasoning blend. Blended seasonings used in meat products are used at low levels, usually around 3% and rarely exceed 10% (Brown, 2009). Therefore, the consumption of Nor-HydroPep used in seasoning blends for processed meat products will be negligible.
3. Medical foods are not included in the intake analysis because these are not consumed by the general population and are prescribed under supervision of a physician.

B. Estimate of Dietary Exposure to Nor-HydroPep DM

1. Methodology

The daily intake of Nor-HydroPep is estimated using the proposed intended in all food categories shown in Table 8 (with the exception of seasoning blends and medical foods) and the mean and 90th percentile (consumers only) consumption estimates of these intended food categories as reported by the National Health and Nutrition Examination Survey (NHANES) 2017 – 2018 survey. Calculations for the mean and 90th percentile consumer-only intakes were performed for all proposed food uses, and summaries of the estimated dietary intake (EDI) for individual food categories as well as the food codes used in the calculation can be found in the intake report in Appendix 6.

"*Per capita*" intake refers to the estimated intake averaged over all individuals surveyed, regardless of whether they consumed food products to which Nor-HydroPep is intended to be added. Individuals were considered "consumers" if they reported consumption of one or more food products on either Day 1 or Day 2 of the survey. As the consumer-only estimates present the exposures in the target population which has the highest exposures, discussion will be limited to this population.

2. Estimated Daily Intake of Nor-HydroPep DM from All Proposed Food Uses in the U.S.

a. Estimates of Nor-HydroPep Daily Intake

A summary of the consumer-only intake for all the proposed conventional food categories combined, with respect to the intended use levels, is provided in Table 9.

Table 9. Summary of Estimated Daily Mean and 90th Percentile Intake for Nor-HydroPep DM from All Intended Food Uses Based on Consumer-Only Population (Based on NHANES 2017–2018 Survey)

Population Group		Ingredient Intake (g/day)		Ingredient Intake (g/kg bw/day)	
	N	Mean	90th Percentile	Mean	90th Percentile
Children (1-5 years) Male/Female Combined	541	6.7	13.5	0.41	0.81
Children (6-11 years) Male/Female Combined	613	10.3	21.4	0.32	0.69
Teenage (12-18 years) Female	350	10.8	19.9	0.19	0.34
Teenage (12-18 years) Male	329	11.5	22.9	0.19	0.42
Adults (19+ years) Female	1882	10.9	23.6	0.15	0.33
Adults (19+ years) Male	1713	14.5	31.3	0.17	0.39
All Ages	5483	11.9	26.2	0.19	0.42

bw – body weight; kg – kilograms; g – grams; yr. – year

The estimated mean and 90th percentile intake of Nor-HydroPep among all ages of consumers is 11.9 g/day and 26.2 g/day (0.19 and 0.42 g/kg bw/day), respectively. The population with the highest mean and 90th percentile estimated dietary intake is adult males, with an estimated intake of Nor-HydroPep of 14.5 and 31.3 g/day, respectively. On a body weight basis, the highest estimated intake of Nor-HydroPep from fortified conventional foods at the intended use levels is in children (1-5 years of age) with a mean and 90th percentile intake of 0.41 g/kg bw/day and 0.81 g/kg bw/day, respectively. All of these estimated intakes assume the highest estimated consumption in that these estimates assume populations will consume all fortified foods at the maximum consumption level each day.

b. Intake Considerations

Despite the fact that there is the wish to use Nor-HydroPep DM in a broad range of applications, it is extremely unlikely that any consumer ever will be exposed to maximum amounts as described above due to production limitations. Norilia estimates the maximum production capacity of their manufacturing plant is 2500 MT per year. Using this value and the total population of the US (approximately 332 million as of 2021), per capita consumption would be 7.5 g/yr.

Assuming the major consumption would be in preparations sold to consumers as a protein source in meal replacements and protein drinks/powders, the number of 20 g-servings available on a daily basis —and assuming a supply of 2500 MT— would provide approximately 342,000 servings per day, which services only a small fraction of the US population. Therefore, the market share penetration for convention foods is likely to be very low. It will be difficult for a consumer to selectively find and choose conventional food products that contain Nor-HydroPep to any degree, making the estimates of 11.9 and 26.2 g/day as shown in Table 9 unlikely.

c. Nutritional Requirements for Protein

In 2005, the Institute of Medicine (IOM) set a Recommended Dietary Allowance (RDA) value for protein of 0.8 g/kg bw/day in adult males and females (IOM, 2005). IOM concluded that there were insufficient data to set Tolerable Upper Intake Levels (UL) for total protein or individual amino acids, but advised caution for using any single amino acid at levels significantly above that normally found in foods. Although the IOM could not set an UL for protein intake, it was noted that "the risk of adverse effects resulting from excess intakes of protein from foods appears to be very low at the highest estimated intake[s]"

RDAs for individual age groups as set by the IOM are summarized in Table 10 below.

Table 10. Recommended Daily Allowance for Proteins by IOM

Age	g/Day	g/kg bw/Day
0-6 Months	-	1.52
7-12 Months	11	1.2
1-3 Years	13	1.05
4-8 Years	19	0.95
9-13 Years	34	0.95
14-18 Years (Female)	46	0.85
14-18 Years (Male)	52	0.85
Adults 19 to >70 Years (Female)	46	0.80
Adults 19 to >70 Years (Male)	56	0.80
Pregnancy	+ 25 g extra protein	1.1
Lactation	+ 25 g extra protein	1.3

bw – body weight; g – grams; kg - kilograms

The IOM also estimated background dietary protein intakes for the U.S. population using the Continuing Survey of Food Intakes by Individuals (CSFII) (1994-1996, 1998) (IOM, 2005).
The mean adult intake for protein ranged from approximately 56 g (adult females over the age of 70) to 104 g (19- to 30-year-old males) per day. At the 90th percentile, adult protein intakes ranged from 76 g/day for adult females over 70 years of age to 142 g/day for 19- to 30-year-old males. In infants and children, mean and 90th percentile intakes ranged from 15.9 to 62.5 and 21.9 to 81.9 g/day, respectively. The mean and 90th percentile total population intakes were estimated to be approximately 75 and 114 g protein/day, respectively.

C. Estimated Intake of Protein from Nor-HydroPep

The specification for crude protein in Nor-HydroPep is >50 g/100 g. The protein content of 5 representative batches of Nor-HydroPep ranged from 51.8 to 53.2 g/100 g. Assuming a conservative estimate that Nor-HydroPep contains crude protein of 55 g/100 g, Table 11 below summarizes the estimated protein intake from consumption of all proposed food uses based on intakes outlined in Table 9.

Table 11. Estimated Protein Intake from Nor-HydroPep DM

Population Group	Age	Protein Intake (g/day)		Protein Intake (g/kg bw/day)	
		Mean	90th Percentile	Mean	90th Percentile
Children, Male/Female	1-5 years	3.7	7.4	0.23	0.45
Children, Male/Female	6-11 years	5.7	11.8	0.18	0.40
Teenagers, Male	12-18 years	6.3	12.6	0.10	0.23
Teenagers, Female	12-18 years	5.9	10.9	0.10	0.19
Adults, Male	>19 years	8.0	17.2	0.09	0.21
Adults Female	>19 years	6.0	13.0	0.08	0.18
All Ages (Male and Female)		6.5	14.4	0.10	0.23

bw – body weight; g – gram; kg – kilogram

This data shows that estimated intake of consumers (all ages) of all intended food uses containing Nor-HydroPep, at the mean and 90th percentile (11.9 g/day and 26.2 g/day), would provide 6.5 g/day and 14.4 g/day poultry protein respectively (0.10 and 0.23 g/kg bw/day). As discussed, these estimates are conservative. The intake of protein from Nor-HydroPep estimated consumption is well below the

Even assuming that 100% of the adult male (high intake-case scenario) intake of 17.2 g protein from consumption of Nor-HydroPep from the intended uses would be in addition to the IOM's estimated intake of proteins, the IOM has not set an Upper Tolerable Limit on protein intake. Therefore, the estimated intake of poultry protein from the intended use of Nor-HydroPep does not present a safety concern.

D. Estimate Amino Acid Intake from Nor-HydroPep

Assuming a conservative estimate that Nor-HydroPep contains crude protein of 55 g/100 g, Table 12 below compares the estimated amino acid intake from daily consumption of All Ages (Male and Female) mean and 90th percentile protein intake (from Table 11) to the recommended maximums for consumption of amino acids from protein supplements reported in Schaafsma (2009).

Table 12. Estimated Amino Acid Consumption from Nor-HydroPep Compared to Schaafsma, (2009) Maximum Recommendations.

Amino Acid	Nor-Hydropep Amino Acid Consumption Mean (g/day)	Nor-Hydropep Amino Acid Consumption 90th Percentile (g/day)	Schaafasma (2009) Max Daily Intake Recommendation (g/day)[1]
Alanine	0.49	1.09	2.1
Arginine	0.41	0.91	2.3
Asparagine + Aspartic Acid[2]	0.61	1.35	4.4
Cysteine	0.03	0.07	0.5
Glutamic Acid	0.93	2.06	5.1
Glycine	0.60	1.34	2.0
Histidine	0.16	0.36	1.2
Isoleucine	0.27	0.60	2.9
Leucine	0.52	1.15	5.0
Lysine	0.50	1.11	3.7
Methionine	0.13	0.29	Not permitted
Phenylalanine	0.25	0.55	2.6
Proline	0.36	0.79	4.5
Serine	0.28	0.62	3.3
Threonine	0.30	0.66	2.3
Tryptophan	0.07	0.14	0.6
Tyrosine	0.16	0.35	2.5
Valine	0.27	0.59	3.1

1. Calculation = 6.5 g/day mean protein intake and 14.4 90th percentile protein intake x AA % (g/100g protein) as per Table 4; 2. Asparagine not reported in amino acid content of Nor-HydroPep – calculation is based on aspartic acid only
g - gram

E. Dietary Exposure to Any Other Substance That is Expected to be Formed In or On Food

This section is not applicable to the Nor-HydroPep, which would be chemically stable under the proposed conditions of use.

F. Dietary Exposure to Contaminants or Byproducts

Potential contaminants of Norilia's Nor-HydroPep include microbes, heavy metals and biogenic amines. The specifications set for Nor-HydroPep place limits on the maximum permissible levels of microbes and heavy metals to assure an acceptable final product. The batch data for five different batches document quality control of the final product such that it meets these specifications (Table 6). Biogenic amines levels are discussed earlier with the stability data (Part 2, Section E).

PART 4. SELF-LIMITING LEVELS OF USE

The use of Nor-HydroPep in protein-enriched foods is self-limiting for technological reasons, such as product texture and/or flavor profile, either of which could affect consumer acceptability.

PART 5. EXPERIENCE BASED ON COMMON USE IN FOOD BEFORE 1958

While there exists broad historical evidence of the consumption of poultry and the proteins contain therein as food for human consumption, the statutory basis for the conclusion of GRAS status of Nor-HydroPep DM in this document is based on scientific procedures in accordance with 21 CFR § 170.30(a)(b). Therefore, experience based on common use in food before 1958 does not apply. A discussion of the history of safe consumption of protein isolates is discussed in Part 6.

PART 6. NARRATIVE

A. Introduction

A search of the scientific and regulatory literature was conducted through December 19, 2022. Databases searched include PubMed and Google Scholar using search terms including “protein isolate”, “poultry protein” and “protein hydrolysate”, with particular attention paid to those that supported conclusions of safety of protein hydrolysates.

1. History of Safe Consumption of Protein Isolates

Animal protein products such as casein, whey, and meat, and plant proteins are often subject to general enzymatic or microbial hydrolysis and heat to break down the peptides to break apart the bonds linking amino acids and produce smaller molecular weight proteins. This allows the protein to be absorbed more rapidly. Hydrolysates are widely used because of their solubility within broad ranges of pH, temperature, concentration, and salt content in solution (Neklyudov et al., 2000). Protein hydrolysates may be further processed to separate out the insoluble fractions which can contain fat and other non-protein components (Hou et al., 2017; Nasri, 2017). The term “isolate” is used when these other non-protein components have been partially removed to “isolate” the source protein. Protein hydrolysates derived from biological treatment (such as enzymatic hydrolysis) are a diverse mixture of inactive and active peptides of various sizes and amino acid sequences. The hydrolysate may be further fractionated and filtered to concentrate the bioactive peptides (Nasri, 2017).

Protein hydrolysates are commonly used in a wide variety of nutritional products as well as other dietary uses. Individuals who cannot digest whole or intact protein may use protein hydrolysates. Studies have shown that protein hydrolysate from a variety of food protein sources such as milk, egg, fish, rice, soybean, pea, chlorella, spirulina, oyster and mussels have a variety of dietary uses (Chalamaiah et al., 2018; Nasri, 2017; Kurozawa et al., 2009). Protein hydrolysates may be used as flavor enhancers, functional ingredients and are often used as nutritional additives to foods of low protein quality. Hydrolysates can have a decreased allergenicity in comparison with the initial protein, which can be a factor in determining the suitability of the hydrolysate as a nutrient. The main application of protein hydrolysates are for use in medical applications, food, mixed-feed, and microbiological industries (Neklyudov et al., 2000). Protein hydrolysates are also used in animal nutrition for optimizing the nutrition of domestic and companion animals, as well as their health (particularly gut health) and well-being (Hou et al., 2017).

In the case of animal proteins, slaughtering and processing of animals produces co-streams (by-products) that can be further refined to produce material that is rich in protein and amino acids (Vikman et al., 2017). Norilia manufactures their Nor-HydroPep by exposing poultry by-products to

enzymes, which is then further processed to remove insolubles and fats/oils. The manufacturing process for HydroPep DM does not selectively concentrate bioactive peptides.

2. History of Safe Consumption of Poultry-derived Protein

There has been a long history of consumption of poultry meat in the human diet. According Adler and Lawler (2012), chickens were domesticated over 4,000 years ago, and by 800 BC, chickens were consumed as a delicacy among the Romans. In the US, domestication of chickens for consumption goes back to the 1800s when households had backyard flocks for egg production and for occasional meat consumption. Eventually farmers began to select females due to increasing demand for eggs, which led to an excess of young male birds. This began the trend of raising single purpose chickens, which was either for egg or meat production.

The sale of chicken for meat began in earnest following the development of the broiler chicken, raised specifically for its meat, in the early 1920's. By the 1960's, the chicken industry was vertically integrated, with single companies involved in every state of production, processing and marking. Federal inspections became mandatory in 1959 (National Chicken Council, 2017).

Turkey production began in the early 1900's in western Nebraska after the local Agricultural Experimental Station recommended raising turkeys as a way for farmers to control grasshoppers (Scheideler and Brown, 1995). Up until the 1970's, the majority of turkey consumed was during the holidays, but by 2012 the consumption increased by 104% (University of Illinois Extension, 2022).

According to the National Chicken Council (2021), the per capita consumption of poultry was 113.4 pounds in 2020, roughly equal to red meat consumption. The protein content in chicken ranges from 23% (cooked drumsticks and thighs) to 32% (cooked breasts). The protein content of turkey (cooked, meat only) is 29% (USDA, 2017). Assuming an average 28% protein found in poultry, this equates to 39.4 gram of poultry protein consumed per person per day.[2]

There has been much research in producing proteins from byproducts of meat production for other uses (Kurozawa et al., 2008). Protein hydrolysates from animal muscle, such as mechanically deboned chicken, are rich in low molecular weight peptides (di- and tripeptides, with minimal free amino acids) and can be used for their functional properties (e.g., emulsification and foaming properties) and nutritional value (Jin et al., 2014). Since the di-and tripeptides from these hydrolysates are more easily absorbed, they may be used as a nitrogen source in sports nutrition, and general protein supplements for a wide variety of diets. Poultry protein isolates have an advantage over soy proteins for use in meat products, as soy proteins give less desirable palatability and as well as possible allergen issues to meat products (Omana et al., 2012).

B. Regulatory History of Protein Hydrolysates & Related Materials

1. U.S. Regulatory History of Protein Hydrolysates

There is a long history of recognized GRAS status for several types of protein preparations including concentrates and hydrolysates, derived from a wide variety of sources including legumes, fish, poultry and dairy. The Select Committee on GRAS Substances (SCOGS) affirmed the GRAS status of acid-hydrolyzed proteins, enzymatically-hydrolyzed proteins, and casein hydrolysates (SCOGS, 1980).

[2] 113.4 lbs x 453g/lb/ 365 days = 140 g/day x 29% =39.4

According to 21 CFR § 102.22[3], protein hydrolysates are categorized as a "non-standardized food" and are required to be labeled with the identity of the food source in which the protein was derived. Examples include hydrolyzed wheat gluten, soy protein, and casein. Correspondingly, Norilia's poultry protein isolate would be labeled as a hydrolyzed poultry (chicken and turkey) protein.

Fish protein isolate has been an acceptable food additive since 1981[4] for use as a food supplement as noted in 21 CFR § 172.340 (FDA, 2017a). The food additive regulation specifies that the protein is isolated from the edible portion of species commonly consumed as human food. Processing is limited to solvent extraction of fat and drying.

A search of FDA's GRAS Notice Inventory website[5] using the search term "poultry protein" identified a notification by Proteus Industries (GRN 168) related to Poultry Protein derived from, but are not limited to, chicken, turkey, duck, pheasant, and quail. The protein is extracted using a mild technique that relies on adjustment of pH and salt conditions that perturb the protein slightly to unfold and expose previously buried hydrophobic areas of the protein. Proteus states that the actual range of poultry protein that is applied when delivered as a solution is 0.06 - 0.80% when used as a protein coating (only); 0.04 - 0.14% when used as a batter (only); and 0.11 - 0.89% when used in both the batter and coating (together). The proposed use was limited to finished poultry products of the same species as the extracted poultry protein (Proteus Industries Inc., 2005). The FDA "no questions" letter indicated that the information in the notice was reviewed by the Food Safety Inspection Service (FSIS) of the Department of Agriculture (USDA). FSIS has regulatory authority to review the safety and suitability of ingredients added to meat and poultry products.

In addition, there are many protein concentrates, isolates or hydrolysates from other sources for use a protein source in conventional foods that have received "no questions" responses from FDA. These GRAS Notifications (GRN) are summarized in Table 13.

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
Isolated Wheat Protein	GRN26 / 1999	Use in powdered shortenings in baked goods, milk-like beverages, beverage whiteners, cheese analogues, meat and fish products, cooked meats, soups, sauces and marinades, mousses and meringues, edible films and coatings for various technical effects	1-50 g/kg food depending on application	Manildra Group (1999)	FDA (1999)

[3] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=102.22
[4] See 46 FR 38072, July 24, 1981, as amended at 47 FR 53344, Nov. 26, 1982; 54 FR 24897, June 12, 1989.
[5] https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
Coagulated Potato	GRN86 / 2002	Use in foods in general, including meat products, as a substitute for other protein products that accomplish a range of functional effects (such as water binding, emulsifying, and foaming)	0.1 to 3.0 % protein in food depending on application	AVEBE b.a. (2001)	FDA (2002)
Extracted "Seafood	GRN147 / 2004	Use as a protein source in finished seafood products of the same species as the extracted seafood protein; added to seafood of the same species or to a secondary processed seafood product of a different species, and identified as "(species) protein" on the finished product label	10% of an 8% protein solution in food depending on application	Proteus Industries Inc. (2004)	FDA (2004)
Poultry Protein	GRN 168/2005	Use as a protein source in finished protein products of the same species as the extracted protein	0.06-0.089% when delivered as a solution, depending on application	Proteus Industries Inc. (2005)	FDA (2005)
Cruciferin-rich	GRN327 / 2010	Ingredient in dairy products, grain products, fruit and vegetable juices and beverages, salad dressings, meal replacements, and nutritional bars	2-60% depending upon application. 95% in protein supplement powders	Archer Daniels Midland Co (2010)	FDA (2010)
Hydrolyzed Sardine	GRN360 / 2011	Ingredient in beverages and breakfast cereals, frozen dairy desserts and mixes, milk and milk products, fish products, pastas, hard and soft candy, soups and soup mixes, and processed fruits and vegetables and fruit and vegetable juices	0.6 g/serving (up to 30%)	Senmi Ekisu Co. Ltd. (2011)	FDA (2011a)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
Canola Protein	GRN386 / 2010	Ingredients in foods such as bakery products, snack foods, beverages, soups, dairy products, dry instant milkshake mixes and protein drinks, instant powdered nutritional beverages, processed meat and poultry products, vegetarian food products/meat analogues, and meal replacement and nutritional bars	Max 2-30% in food depending on application	BioExx Specialty Proteins Ltd. (2011)	FDA (2011b)
Potato Protein	GRN447 / 2013	For various technical affects in comminuted meat products and comminuted poultry products at levels up to 3%. For various technical effects in alcoholic beverages, baked foods and baking mixes, cheeses, dairy product analogs, egg products, fats and oils, frozen dairy desserts and mixes, fruit and water ices, gelatins, puddings, and fillings, milk products, nuts and nut products, and plant protein products at levels ranging from 0.01 to 15%. For use as sources of protein in sports drinks and protein sports bars at levels ranging from 1 to 10% and during fermentation.	0.01-15% depending upon application	Solanic B.V. (2013)	FDA (2013)
Oat Protein	GRN575 / 2015	For use as a protein source for use in foods generally, including meat and poultry	2-30% depending on application	Tate and Lyle (2015b)	FDA (2015)
Un-hydrolyzed and	GRN581 / 2016	For use as an ingredient in bakery products, snack foods, beverages	2-90% depending	World Food Processing LLC (2016)	FDA (2016a)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
		(including nutritional beverages), soups, dairy products, dry instant milk shake mixes and protein drinks, instant powdered nutritional beverages, processed meat products, vegetarian food products/meat analogues, and meal replacement/nutritional bars at levels ranging from 2-90% of the finished food.	upon application		
Pea Protein Concentrate	GRN608 / 2016	Use a as a food ingredient, formulation aid and texturizer in conventional foods such as Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; Soups and Soup Mixes For use as a supplemental protein in sports nutrition and meal replacement applications	0.96-34.3% 15-25 g/serving	Axiom Foods Inc. (2015a)	FDA (2016b)
Rice Protein Isolate	GRN609/	Use a as a food ingredient, formulation aid and texturizer in conventional foods such as Baked Goods and Baking Mixes; Beverages and Beverage Bases; Breakfast Cereals; Dairy Product Analogs; Fats and Oils; Grain Products	0.96-34.3%	Axiom Foods Inc. (2015b)	FDA (2016d)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
		and Pastas; Milk Products; Plant Protein Products; Processed Fruits and Fruit Juices; Processed Vegetables and Vegetable Juices; Soups and Soup Mixes For use as a supplemental protein in sports nutrition and meal replacement applications	15-25 g/serving		
Concentrated Milk Protein with a ≥ 60:40 Whey:Casein Ratio	GRN633 / 2016	For use as an emulsifier, flavoring agent, formulation aid, humectants, stabilizer, thickener, texturizers, and protein source in the following food categories at varying use levels depending on technical effect: meal replacements and meal supplements; powdered nutritional beverages; nutritional bars; acidified sports beverages; milk products; yogurt and fermented milk products; non-standardized cheese products; spreads, dips and cream substitutes; frozen dairy desserts and mixes; desserts and mousses; confections; snack foods; coatings and fillings; salad dressings; soups, soup mixes, and sauces	Within limits permitted by existing standards of identity and other applicable regulations	Leprino Foods Company (2016)	FDA (2016c)
Canola Protein Isolate	GRN683 / 2017	Intended for use as a protein source, thickener, water binder, emulsifier, gelling agent, foaming agent or texturizer in prepared food, meat analogues,	5-30% depending upon application	DSM Nutritional Products LLC (2017)	FDA (2017c)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
		bakery products, protein enriched bakery products, sports nutrition, weight management, beverages, dairy products, medical nutrition, elderly nutrition at use levels ranging from 5 to 30 percent.			
Mung Bean Protein Isolate	GRN684 / 2017	Intended for use as a protein source in baked goods and baking mixes; beverages and beverage bases; breakfast cereals; condiments and relishes; dairy product analogs, frozen dairy desserts and mixes; fruit and water ices; gelatins, puddings, and fillings; grain products and pasta; milk products; plant protein products; and snack foods.	3-90% depending on application	Hampton Creek (2016)	FDA (2017b)
Hemp Seed Protein Powder	GRN771/ 2018	For use as an ingredient for general use in foods, excluding USDA/FSIS regulated products and infant formula.	1-100% depending on application	Fresh Hemp Foods Ltd. (2018)	FDA (2018a)
Pea Protein Concentrate	GRN788 / 2018	Ingredient, formulation aid, source of protein, stabilizer, thickener, and texturizer in conventional foods, such as baked goods and baking mixes, beverages and beverage bases, breakfast cereals, milk products, dairy product analogs, fats and oils, grain products and pastas, plant protein products, processed fruits and fruit juices, processed vegetables and vegetable juices, and soups and soup mixes.	0.96-34.3% depending on application	Yantai Oriental Protein Tech Co. (2018)	FDA (2018b)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
Pea Protein	GRN803 / 2019	For use as a formulation aid, nutrient supplement, stabilizer and thickener, and texturizer in conventional food products including meat and poultry products	5-15 g/serving	Ingredion Incorporated and Shandong Jianyuan Bioengineering Co. Ltd. (2018)	FDA (2019a)
Pea Protein	GRN804 / 2019	Intended for use as a source of protein in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, cheeses, coffee and tea, confections and frostings, dairy product analogs, egg products, fats and oils, fish products, frozen dairy desserts, fruit and water ices, gelatins, puddings, and fillings, grain products and pastas, gravies and sauces, meat products, milk products, nut and nut products, plant protein products, poultry products, processed fruits and fruit juices, processed vegetables and vegetable juices, snack foods, soft candy, and soups and soup mixes.	1-35 /g per 100 g/food	Burcon NutraScience Corporation (2018)	FDA (2019b)
Pea Protein	GRN851 / 2020	For use as a source of protein in foods at levels ranging from 1 to 90 percent in bakery products (e.g., bread, rolls, cakes, pasta), cereals, snack foods (e.g., chips, crackers, energy bars), ready-to-drink (RTD) beverages, soups, smoothies, fruit juices, protein beverages, dairy and	2-90% depending upon application	Roquette Freres (2019)	FDA (2020a)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
		dairy alternatives (e.g., yogurt, ice cream), meal replacements, nutritional bars, clinical nutrition, fruit and vegetable preparation, meat analog products, processed meat, dry blend protein products, extruded products, chocolate and confection compound coatings, non-chocolate confections, and as a binder and extender in meat and poultry applications. Infant formula is excluded from the intended uses. It is also intended for use in specialty foods intended to meet the protein requirements for sports activity or for weight control. Pea protein isolate is also intended to be used as a binder and extender in the following meat and poultry applications: raw comminuted poultry, raw comminuted meat, sausage/hot dogs, and soups/stews/salad/similar products			
Fava Bean Protein Isolate	GRN879 / 2020	For use as a source of protein in bakery products; snack foods; beverages, soups, and nutritional beverages; imitation dairy products; meal replacement/nutritional bars; meat analogs; and dry blend protein powders	10-90% depending upon application	Yantai T.FULL Biotech Co. (2019)	FDA (2020b)
Rice Protein Hydrolysate	GRN944 / 2021	For use as a protein source in sports nutrition	1.0-83% depending	BASF Corporation (2020)	FDA (2021a)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
		protein bars; health bars (other than protein bars) and grain bars; flavored milk drinks; yogurt; frozen yogurt; fruit smoothies; meat alternatives and imitation meat products; vegetable/tomato juice including vegetable smoothies; prepared soups, dry soup mixes, and condensed soups; bread; rolls, high protein cookies; soy, vegetable, and nut-based milk analogues; meal replacements; yogurt; frozen yogurt; high protein ready-to-eat breakfast cereals; flavored milk drinks.	upon application		
Fungal protein from *Fusarium sp.* mycelia	GRN945 / 2022	For use as an ingredient in food, excluding meat and poultry products and infant formula	Up to 90% of final product	3F BIO Limited (2020)	FDA (2022)
Enzyme-treated Pea Protein	GRN948 / 2021	For use as a food ingredient, formulation aid, nutrient supplement, stabilizer and thickener, and texturizer in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, dairy product analogs, fats and oils, grain products and pastas, milk products, plant protein products, processed fruits and fruit juices, processed vegetables and vegetable juices, soups and soup mixes	0.96 - 34.3% depending upon application	Yantai Oriental Protein Tech Co. (2020)	FDA (2021b)
Soluble egg-white protein produced by *Komagataella phaffii* strain GSD-1209	GRN967 / 2021	For use as a substitute for egg-white protein in foods containing eggs; and as a source of protein in nutritional	Replacement for plant and animal proteins	Clara Foods Co. (2020)	FDA (2021c)

Substance	GRN # / Closure Date	Intended Use	Use Rate	Company	FDA "No Questions" Response
		powders and drinks; bars; and certain snack foods at levels in accordance with current good manufacturing practices (excluding infant formula, or in any products under the jurisdiction of the USDA			

FDA – U.S. Food and Drug Administration; g – gram; GRAS – Generally Recognized as Safe; GRN – GRAS Notification; kg – kilogram; USDA – United States Department of Agriculture

2. European Regulatory History for Protein Hydrolysates

In the European Union, protein hydrolysates are exempt from the definition of a food additive when used in conventional foods (EU, 2008). The European Food Safety Authority (EFSA) also reviewed the safety of the Senmi Ekisu hydrolyzed sardine protein product (GRN360) as a novel food ingredient (EFSA, 2010). The EFSA Panel concluded that hydrolyzed sardine protein was safe for use as a food ingredient at use levels up to 0.6 g/serving in foods similar to those proposed in the US in GRN360.

3. Canadian Regulatory History for Protein Hydrolysates

In a search of Health Canada's Natural Health Products Ingredient Database, a number of animal and plant derived protein hydrolysates, including those from fish, shrimp, milk, fava bean, pea, rice and whey, were found and approved for use in natural health products (Health Canada, 2017).

4. Asian Regulatory History for Protein Hydrolysates

Sardine peptides and soy protein hydrolysates products are approved in Japan under provisions for Food for Specific Health Uses as administered by the Ministry of Health, Labor and Welfare (MHLW, 2007).

C. Absorption, Distribution, Metabolism & Excretion (ADME) Studies

The absorption, digestion, and metabolism of dietary proteins are well established. After ingestion, proteins are denatured by the acid in the stomach followed by cleavage into smaller peptides by the enzyme pepsin. The peptides bonds are then hydrolyzed by a variety of enzymes in the small intestines, resulting in a mixture of free amino acids and smaller peptides. Further hydrolysis of small peptides occurs in the cells, and then free amino acids are then secreted into the portal blood or are further metabolized within the cell itself. Absorbed amino acids pass into the liver, where a portion is used while the remainder pass through into the systemic circulation and are utilized by the peripheral tissues (IOM, 2005).

Several studies have shown that hydrolysates, which are made up of primarily di- and tripeptides, are absorbed more rapidly than free amino acids and intact proteins and they are much more rapidly absorbed than whole foods. The di- and tripeptides are absorbed intact, hydrolyzed intercellularly, and then released as free amino acids or intact into the circulation (Di Pasquale, 2008).

D. Safety Studies

Sources of protein in the human diet include animal, vegetable and microbial. According to the IOM, the average minimum requirement of good-quality protein is approximately 0.6 g/kg body weight/day for normal healthy adults however higher levels of consumption have been compatible with good health (IOM, 2005).

The risks of high protein consumption was reviewed in GRN575 and included a decrease in renal function, a decrease in bone health, formation of kidney stones and allergy manifestations (Tate and Lyle, 2015a). The possibility that a high protein diet could impact cardiovascular disease has also been discussed in the literature (WHO, 2007).

1. Animal Safety Studies with Protein Hydrolysates

Hou et al. (2017) reviewed the use of protein hydrolysates in animal nutrition. In reviewing animal studies, the authors conclude that inclusion of some animal-protein hydrolysates (2-8% from porcine intestine, porcine mucosa, salmon viscera, or poultry tissue hydrolysates) or soybean protein hydrolysates in corn and soybean meal-based diets can ensure desirable rates of growth performance and feed efficiency in weanling pigs, young calves, post-hatching poultry, and fish. Thus, protein hydrolysates hold promise in optimizing the nutrition of domestic and companion animals, as well as their health (particularly gut health) and well-being.

Wergedahl et al. (2004) conducted a study in which male Wistar and Zucker rats were fed either a fish protein hydrolysate, a soy protein extract or bovine casein sodium salt. The Wistar rats were fed the test proteins for 11-12 days and the genetically obese (*fa/fa*) Zucker rats for 22 or 23 days. The fish protein hydrolysate had an effect on lipid metabolism, which was less pronounced than the soy protein extract but had a clear cardioprotective effect. No adverse reactions were reported.

Wang et al. (2016) performed a safety assessment of Maillard reaction products of chicken bone hydrolysate containing 38% protein in a subchronic rodent feeding study in Sprague-Dawley rats. Rats (5/sex/group) were administered diets containing 9, 3, 1, or 0% of chicken bone hydrolysate for 13 weeks. No mortality occurred, and no remarkable changes in general condition and behavior were observed. The consumption of chicken bone hydrolysate did not have any effect on body weight or feed and water consumption. At the same time, there was no significant increase in the weights of the heart, liver, lung, kidney, spleen, small intestine, and thymus in groups for both sexes. Serological examination showed serum alanine aminotransferase in both sexes was decreased significantly, indicating liver cell protection. No treatment-related histopathological differences were observed between the control and test groups.

2. Scientific Reviews Related to Safety of Protein Hydrolysates

Advances in separation technology in food processing has led to widespread use of protein hydrolysates in human foods and animal feed. Hydrolyzed proteins have been used for over 60 years in the treatment of children with food protein allergies in infant formulas (Schaafsma, 2009). Several reviews conclude that food-derived protein hydrolysates exert beneficial effects on human health in addition to basic nutritional effects.

In a review of the safety of protein hydrolysates by Schaafsma (2009), it was stated that no adverse effects from ingestion of protein hydrolysates has been reported. In addition, Schaafsma (2009)

states that hydrolysates derived from traditional protein sources do not lead to undesirable changes in nutritional value and metabolic effects, when these hydrolysates are compared with the intact proteins from which they are obtained. Therefore, it was concluded that protein hydrolysates can be considered safe when they are derived from proteins with a history of safe use and when they are made with food-grade proteolytic enzymes and use common food processing methods (Schaafsma, 2009).

Nasri (2017) reviewed protein hydrolysates biological activities and applications in foods for health benefits and reports that peptides released from food proteins have biological activity beyond their nutritional properties. The author notes that compared with chemical hydrolysis of the source protein, the overall amino acid composition in enzymatic protein hydrolysates is nearly similar to that of the protein substrate. Additionally, enzymatic digestion does not involve organic solvents or toxic chemicals. The author concludes that because of their human health potential and safety profiles, protein hydrolysates may be used as ingredients in functional foods to maintain human health.

Liu et al. (2016) reviewed the antioxidant activity of bioactive peptides from enzymatic hydrolysis of meat muscle and meat by-products, and concluded they are rich sources of proteins and can be regarded as good raw materials for the production of bioactive peptides. The authors concluded that antioxidant peptides obtained from animal sources could exert not only nutritional value but also bioavailability to benefit human health. Meat proteins, specifically, are thought to be a good source from which to obtain antioxidant peptides, because meat proteins contain essential amino acids in high availability that are not usually found in plant proteins.

The concept of converting by-products from animal sources for beneficial purposes has been also studied. By-products in the forms of heads, legs, bones, viscera and feather are often processed into livestock feed and pets foods (Lasekan et al., 2013). Enzymatic hydrolysis of animal by-products has been widely used to produce lipids and fractions with high amount of amino acids. In addition, a broad spectrum of food ingredients including flavor enhancers and compounds having been shown to have functional and bioactive properties (Vikman et al., 2017).

3. Safety of Enzymes and Enzyme Sources

As identified in Schaafsma (2009), when the protein source has a long history of safe use, the consumption of hydrolysates made from them does not raise a safety concern if the applied proteolytic enzymes are food grade. The important safety issues regarding enzyme preparations are toxicological properties such as ensuring they are free of contaminants including mycotoxins and antibiotics, the possibility of occupational health problems such as skin irritations, any unintended reactions, and the safety of the source organism.

The enzyme used in the manufacturing of the Nor-HydroPep are food-grade as shown in Appendix 1.

4. Allergenicity of Poultry Protein

Poultry protein hydrolysates will not introduce allergens or anti-nutrient compounds like protein hydrolysates derived from plants (Hertzler et al., 2020), milk (Leprino Foods Company, 2016), or fish (Senmi Ekisu Co. Ltd., 2011). Poultry meat allergy is rare, with worldwide prevalence ranging from 0-13%. Main route of exposure is reported to be through the ingestion of meat. The allergy is triggered within 30 mins of exposure, and allergic reaction includes oral symptoms and moderate systemic reactions in skin and gastrointestinal tract including urticaria, angioedema, nausea, emesis, diarrhea,

and asthma. Cardiovascular symptoms in case of severe anaphylaxis is rare (Thermo Fischer Scientific Inc., 2021).

E. GRAS Criteria

FDA defines "safe" or "safety" as it applies to food ingredients as:

> "…reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[6]

Amplification is provided in that the conclusion of safety is to include probable consumption of the substance in question, the cumulative effect of the substance and appropriate safety factors. It is FDA's operational definition of safety that serves as the framework against which this evaluation is provided.

Furthermore, in discussing GRAS criteria, FDA notes that:

> "…General recognition of safety requires common knowledge, throughout the expert scientific community knowledgeable about the safety of substances directly or indirectly added to food, that there is reasonable certainty that the substance is not harmful under the conditions of its intended use."
>
> "'Common knowledge' can be based on either "scientific procedures" or on experience based on common use of a substance in food prior to January 1, 1958."[7]

FDA discusses in more detail what is meant by the requirement of general knowledge and acceptance of pertinent information within the scientific community, i.e., the so-called "common knowledge element," in terms of the two following component elements:[8]

- Data and information relied upon to establish safety must be generally available, and this is most commonly established by utilizing published, peer-reviewed scientific journals; and
- There must be a basis to conclude that there is consensus (but not unanimity) among qualified scientists about the safety of the substance for its intended use, and this is established by relying upon secondary scientific literature such as published review articles, textbooks, or compendia, or by obtaining opinions of expert panels or opinions from authoritative bodies, such as JECFA and the National Academy of Sciences.

General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

[6] See 21 CFR 170.3 (e)(i) and 81 FR 54959 Available at eCFR :: 21 CFR 170.3 -- Definitions. (Accessed on 12/21/2022).
[7] See 81 FR 54959 Available at: https://www.federalregister.gov/documents/2016/08/17/2016-19164/substances-generally-recognized-as-safe (Accessed on 12/21/2022).
[8] See Footnote 1.

The apparent imprecision of the terms “appreciable,” “at the time,” and “reasonable certainty” demonstrates that the FDA recognizes the impossibility of providing absolute safety in this or any other area (Lu, 1988; Renwick, 1990; Rulis and Levitt, 2009).

As noted below, this safety assessment to ascertain GRAS status for the specified food uses meets FDA criteria for reasonable certainty of no harm by considering both the technical and common knowledge elements.

F. Norilia’s Findings on Safety of Nor-HydroPep DM

Nor-HydroPep DM has been determined by Norilia to be GRAS on the basis of scientific procedure in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act.

The following considerations were also considered for the safety evaluation:

- Consumption of proteins from poultry meat has been consumed safely for centuries in the US. The amino acid profile present in Nor-HydroPep DM is similar to the amino acid profile of a poultry protein (GRN168, Proteus Industries) which received a “no question” response by FDA.
- The estimated dietary intake of Nor-HydroPep DM at the mean and 90th percentile (11.9 g/day and 26.2 g/day), would provide 6.5 g/day and 14.4 g/day poultry protein respectively (0.10 and 0.23 g/kg bw/day). Even assuming that 100% of the adult male (high intake-case scenario) intake of 17.2 g protein from consumption of Nor-HydroPep from the intended uses would be in addition to the IOM’s estimated intake of proteins, the IOM has not set an Upper Tolerable Limit on protein intake.
- Schaafsma (2009) and Nasri (2017) concluded that protein hydrolysates derived from commonly consumed protein sources, and are manufactured using enzyme hydrolysis, without use of organic solvents and with food grade enzymes, are safe. The production process of the Nor-HydroPep DM is equivalent to the process commonly used for the production of protein hydrolysates (enzyme hydrolysis) and the enzyme used is food grade.

Norilia is not in possession of unpublished information that is relevant to the subject of this determination.

Based on the estimated daily intake from intended use, the maximum estimated per user intake of Nor-HydroPep DM from the proposed use is safe.

It is therefore reasonable to conclude that the proposed uses of Nor-HydroPep DM are safe and suitable, and meet the criteria for consideration of generally recognized as safe (GRAS) status.

G. Expert Panel Findings on Safety of Norilia’s Nor-HydroPep DM

An evaluation of the safety and GRAS status of the intended use of Norilia’s Nor-HydroPep DM has been conducted by an Expert Panel convened by GRAS Associates; the Panel consisted of Richard Kraska, PhD, Joanne Slavin, PhD; and Margitta Dziwenka, DVM, DABT, as Panel Chair. The Expert Panel reviewed Norilia’s dossier as well as other publicly available information available to them. The individuals who served as Expert Panelists are qualified to evaluate the safety of foods and food ingredients by merit of scientific training and experience.

The GRAS Expert Panel report is provided in Appendix 7.

H. Common Knowledge Elements for GRAS Conclusions

The first common knowledge element for a GRAS conclusion requires that data and information relied upon to establish safety must be generally available; this is most commonly established by utilizing studies published in peer-reviewed scientific journals. The second common knowledge element for a GRAS conclusion requires that consensus exists within the broader scientific community.

1. Public Availability of Scientific Information

All of the studies reviewed have been published in the scientific literature as reported in Part 6. The safety conclusion was based solely on published studies and other publicly available information. In addition, there is a large, publicly available, collection of GRN conclusions for a number of protein hydrolysates and isolates, including one for poultry protein, on FDA's website.

2. Scientific Consensus

The second common knowledge element for a GRAS conclusion requires that there be a basis to conclude that consensus exists among qualified scientists about the safety of the substance for its intended use. Specifically, IOM (2005) has set RDAs for protein intakes, estimated dietary protein intakes, and concluded that there were insufficient data to set Tolerable Upper Intake Levels (UL) for total protein or individual amino acids. IOM also noted "the risk of adverse effects resulting from excess intakes of protein from foods appears to be very low at the highest estimated intake[s]"

Schaafsma (2009) evaluated the available literature and relevant food legislation on the safety of protein, protein hydrolysates, fractions and free amino acids on relevant food legislation is reviewed and evaluated. It was concluded that no adverse effects from ingestion of protein hydrolysates have been reported and that hydrolysates derived from traditional protein sources does not lead to undesirable changes in nutritional value and metabolic effects when these hydrolysates are compared with the intact proteins from which they are obtained. Therefore, protein hydrolysates can be considered safe when they are derived from proteins with a history of safe use and when they are made with food-grade proteolytic enzymes and use common food processing methods (Schaafsma, 2009). Nasri (2017) also concluded the protein hydrolysates produced from enzymatic hydrolysis were safe because the process did not involve organic solvents or toxic chemicals and maintained similar amino acid profiles as the source substrate, making them suitable for the food industries.

In summary, a compelling case can be made that scientific consensus exists regarding the safety of Nor-HydroPep DM as the raw material source (chicken and turkey) have a long history of safe use, the proteolytic enzymes are food grade, and the manufacturing process does not lead to undesirable changes to the nutritional value or metabolic effects.

I. Conclusion

In consideration of the aggregate safety information available, Norilia concludes that Nor-HydroPep DM as defined in the subject notification is safe for use in processed food products to increase the level of protein in a product as a replacement for other animal or vegetable protein. The intended food categories, include soups, snacks, tomato-based vegetable juices, gravies, condiments, nutrition

bars, protein drinks, meal replacements and medical food applications. Nor-HydroPep DM will not be used in infant formulas.

Accordingly, Nor-HydroPep DM as produced by Norilia in accordance with FDA Good Manufacturing Practices and when it meets those specifications declared within the subject notification meets FDA's definition of safety in that there is "reasonable certainty of no harm under the intended conditions of use" as described herein and, therefore, is generally recognized as safe (GRAS).

PART 7. LIST OF SUPPORTING DATA AND INFORMATION IN THE GRAS NOTICE.

A. References

1. List of Acronyms

ADME	Absorption, Distribution, Metabolism and Excretion
BA	Biogenic Amines
bw	Body weight
C	Celsius
CFU	Colony forming unit
CGMP	Current Good Manufacturing Practices
COAs	Certificates of Analyses
CSFII	Continuing Survey of Food Intakes by Individuals
EDI	Estimated daily intake
EFSA	European Food Safety Authority
FD&C Act	Federal Food Drug and Cosmetics Act
FDA	U.S. Food and Drug Administration
FSIS	Food Safety Inspection Service
g	Grams
GA	GRAS Associates
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
IOM	Institute of Medicine
kg	Kilograms
mcg	Micrograms
mg	Milligrams
MT	Metric ton
NHANES	National Health and Nutrition Examination Surveys
NOAEL	No observed adverse effect level
ppm	Part per million
RDA	Recommended daily allowance
SCOGS	Select Committee on GRAS Substances
U.S.	United States
UL	Tolerable upper intake level
USDA	United States Department of Agriculture
yr	Years

2. References

3F BIO Limited (2020) *Generally Recocngized as Safe (GRAS) Notice for Mycoprotein as a Food Ingredient* Available at: https://www.fda.gov/media/145554/download.

Adler, J. and Lawler, A. (2012) 'How the Chicken Conquered the World', *Smithonian Magazine*.

Archer Daniels Midland Co (2010) *GRAS Notification for the ADM/Burcon NutraScience Canola Protein Isolates Puratein and Supertein*. Available at: http://wayback.archive-it.org/7993/20171031043650/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM269508.pdf.

Atiya Ali, M., Poortvliet, E., Stromberg, R. and Yngve, A. (2011) 'Polyamines in foods: development of a food database', *Food Nutr Res,* 55.

AVEBE b.a. (2001) *GRAS Notification for Coagulated potato protein in hydrolyzed or unhydrolyzed form*. Available at: http://wayback.archive-it.org/7993/20171031060121/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM261328.pdf.

Axiom Foods Inc. (2015a) *GRAS Notification for Pea Protein Concentrate*. Available at: https://wayback.archive-it.org/7993/20180124090026/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM495922.pdf.

Axiom Foods Inc. (2015b) *GRAS Notification for Rice Protein Concentrate*. Available at: https://www.fda.gov/media/98081/download.

BASF Corporation (2020) *GRAS Conclusion for the Use of Rice Protein Hydrolysate (PeptAIde™) in Select Foods and Beverages* Available at: https://www.fda.gov/media/144909/download.

Biji, K. B., Ravishankar, C. N., Venkateswarlu, R., Mohan, C. O. and Gopal, T. K. (2016) 'Biogenic amines in seafood: a review', *J Food Sci Technol,* 53(5), pp. 2210-8.

BioExx Specialty Proteins Ltd. (2011) *GRN386, Canola protein isolate and hydrolyzed canola protein isolate*. Available at: https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm277309.pdf.

Burcon NutraScience Corporation (2018) *Pea Protein GRAS Notice*. Available at: https://www.fda.gov/media/133517/download.

Calpis Co. Ltd. (2007) *GRN199, Concentrated hydrolyzed milk protein*. Available at: https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm263900.pdf.

Chalamaiah, M., Yu, W. and Wu, J. (2018) 'Immunomodulatory and anticancer protein hydrolysates (peptides) from food proteins: A review', *Food Chem,* 245, pp. 205-222.

Clara Foods Co. (2020) *Non-Animal Soluble Egg White Protein produced by Pichia pastoris Generally Recognized as Safe Notice* Available at: https://www.fda.gov/media/147830/download (Accessed: December 21, 2022).

Del Rio, B., Redruello, B., Linares, D. M., Ladero, V., Ruas-Madiedo, P., Fernandez, M., Martin, M. C. and Alvarez, M. A. (2018) 'Spermine and spermidine are cytotoxic towards intestinal cell cultures, but are they a health hazard at concentrations found in foods?', *Food Chem,* 269, pp. 321-326.

Di Pasquale, M. G. (2008) *Amino Acids and Proteins for the Athlete; The Anabolic Edge.* 2nd edn. Boca Raton: CRC Press.

DSM Nutritional Products LLC (2017) *The Safety and the Generally Recognized as Safe (GRAS) Status of the Proposed uses of Canola/Rapeseed Protein Isolate in Human Food*. Available at: https://www.fda.gov/media/103212/download (Accessed: December 21, 2022).

EFSA (2010) 'Scientific Opinion on the safety of "Sardine Peptide Product"', *EFSA Journal,* 8(7).

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

FDA (1999) *Agency Response Letter GRAS Notice No. GRN000026*. Available at: https://wayback.archive-it.org/7993/20171031034158/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154825.htm.

FDA (2002) *Agency Response Letter GRAS Notice No. GRN 000086*. Available at: https://wayback.archive-it.org/7993/20171031023620/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154603.htm.

FDA (2004) *Agency Response Letter GRAS Notice No. GRN 000147*. Available at: https://wayback.archive-it.org/7993/20171031022211/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153982.htm.

FDA (2005) *Agency Response Letter GRAS Notice No. GRN 000168* Nvember 8, 2017). Available at: https://wayback.archive-it.org/7993/20171031021414/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154371.htm.

FDA (2010) *Agency Response Letter GRAS Notice No. GRN 000327*. Available at: https://wayback.archive-it.org/7993/20171031012537/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm225018.htm.

FDA (2011a) *Agency Response Letter GRAS Notice No. GRN 000360*. Available at: https://wayback.archive-it.org/7993/20171031011807/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm258388.htm.
FDA (2011b) *Agency Response Letter GRAS Notice No. GRN 000386*. Available at: https://wayback.archive-it.org/7993/20171031011037/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm287632.htm.
FDA (2013) 'Agency Response Letter GRAS Notice No. GRN 000447'.
FDA (2015) *Agency Response Letter GRAS Notice No. GRN 000575*. Available at: https://wayback.archive-it.org/7993/20171030235844/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm469804.htm.
FDA (2016a) *Agency Response Letter GRAS Notice No. GRN 000581*. Available at: https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm495404.htm.
FDA (2016b) *Agency Response Letter GRAS Notice No. GRN 000608*. Available at: https://www.fda.gov/food/gras-notice-inventory/agency-response-letter-gras-notice-no-grn-000608.
FDA (2016c) *Agency Response Letter GRAS Notice No. GRN 000633*. Available at: https://www.fda.gov/food/gras-notice-inventory/agency-response-letter-gras-notice-no-grn-000633.
FDA (2016d) *Agency ResponseLetter GRAS Notice No. GRN 000609*. Available at: https://www.fda.gov/media/114232/download.
FDA (2017a) *21 CFR 172.340: Fish Protein Isolate* Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.340 (Accessed: December 21 2022).
FDA (2017b) *Agency Response Letter GRAS Notice No. GRN00684*. Available at: https://www.fda.gov/media/107787/download.
FDA (2017c) *Agency Response Letter GRAS Notice No. GRN 000683*. Available at: https://www.fda.gov/media/106478/download.
FDA (2018a) *Agency Response Letter GRAS Notice No. GRN000771*. Available at: https://www.fda.gov/media/119426/download.
FDA (2018b) *Agency Response Letter GRAS Notice No. GRN000788*. Available at: https://www.fda.gov/media/117924/download.
FDA (2019a) *Agency Response Letter GRAS Notice No. GRN 000803*. Available at: https://www.fda.gov/media/133200/download.
FDA (2019b) *Agency Response Letter GRAS Notice No. GRN 000804*. Available at: https://www.fda.gov/media/133201/download.
FDA (2020a) *Agency Response Letter GRAS Notice No. GRN 000851*. Available at: https://www.fda.gov/media/137311/download.
FDA (2020b) *Agency ResponseLetter GRAS Notice No. GRN 000879*. Available at: Agency ResponseLetter GRAS Notice No. GRN 000609.
FDA (2021a) *Agency Response Letter GRAS Notice No. GRN000944*. Available at: https://www.fda.gov/media/154922/download.
FDA (2021b) *Agency Response Letter GRAS Notice No. GRN000948*. Available at: https://www.fda.gov/media/156416/download.
FDA (2021c) *Agency Response Letter GRAS Notice No. GRN000967*. Available at: https://www.fda.gov/media/152289/download.
FDA (2022) *Agency Response Letter GRAS Notice No. GRN000945*. Available at: https://www.fda.gov/media/158580/download.
Fresh Hemp Foods Ltd. (2018) *Hemp Protein Powder GRAS Notice*. Available at: https://www.fda.gov/media/118583/download.
Hampton Creek (2016) *GRAS Notice for a Mung Bean Protein Isolate*. Available at: https://www.fda.gov/media/103224/download.
Health Canada (2017) *Health Canada Natural Health Products Ingredient Database*. Available at: http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do?lang=eng (Accessed: December 21, 2022.
Hertzler, S. R., Lieblein-Boff, J. C., Weiler, M. and Allgeier, C. (2020) 'Plant Proteins: Assessing Their Nutritional Quality and Effects on Health and Physical Function', *Nutrients,* 12(12).
Hou, Y., Wu, Z., Dai, Z., Wang, G. and Wu, G. (2017) 'Protein hydrolysates in animal nutrition: Industrial production, bioactive peptides, and functional significance', *J Anim Sci Biotechnol,* 8, pp. 24.
Ingredion Incorporated and Shandong Jianyuan Bioengineering Co. Ltd. (2018) *GRAS Notice for Pea Protein*. Available at: https://www.fda.gov/media/133516/download.
IOM (2005) *Protein and Amino Acids. In: Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients).* , Washington, DC.: Institute of Medicine, National Academy Press. Available at: https://www.nap.edu/read/10490/chapter/20?term=8.9#1021 (Accessed: November 7, 2022).
Jin, S. K., Hwang, J. W., Moon, S., Choi, Y. J., Kim, G. D., Jung, E. Y. and Yang, H. S. (2014) 'The Effects of Mechanically Deboned Chicken Hydrolysates on the Characteristics of Imitation Crab Stick', *Korean J Food Sci Anim Resour,* 34(2), pp. 192-9.
Kurozawa, L. E., Park, K. J. and Hubinger, M. D. (2008) 'Optimization of the enzymatic hydrolysis of chicken meat using response surface methodology', *J Food Sci,* 73(5), pp. C405-12.

Kurozawa, L. E., Park, K. J. and Hubingera, M. D. (2009) 'Production, Properties and Stability of Chicken Meat Protein Hydrolysate Powder ', in Haugen, S. & Meijer, S. (eds.) *Handbook of Nutritional Biochemistry: Genomics, Metabolomics and Food Supply*: Nova Science Publishers, Inc.

Lasekan, A., Abu Bakar, F. and Hashim, D. (2013) 'Potential of chicken by-products as sources of useful biological resources', *Waste Manag,* 33(3), pp. 552-65.

Leprino Foods Company (2016) *GRAS Notificaiton for Native Whey Protein*. Available at: https://wayback.archive-it.org/7993/20180123235024/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM505250.pdf (Accessed: November 9, 2022).

Liu, R., Xing, L., Fu, Q., Zhou, G. H. and Zhang, W. G. (2016) 'A Review of Antioxidant Peptides Derived from Meat Muscle and By-Products', *Antioxidants (Basel),* 5(3).

Lu, F. C. (1988) 'Acceptable daily intake: inception, evolution, and application', *Regulatory Toxicology and Pharmacology,* 8(1), pp. 45-60.

Manildra Group (1999) *Notice of a Claim for GRAS Exemption Based on GRAS Determination for Isolated Wheat Protein*. Available at: http://wayback.archive-it.org/7993/20171031060354/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM258380.pdf (Accessed: November 9, 2022).

Manninen, A. H. (2009) 'Protein hydolysates in sports nutrition', *Nutrition & Metabolism,* (6), pp. 38.

Nasri, M. (2017) 'Protein Hydrolysates and Biopeptides: Production, Biological Activities, and Applications in Foods and Health Benefits. A Review', *Adv Food Nutr Res,* 81, pp. 109-159.

National Chicken Council (2017) *Per Capita Consumption of Poultry and Livestock, 1965 to Estimated 2018, in Pounds*. Available at: http://www.nationalchickencouncil.org/about-the-industry/statistics/per-capita-consumption-of-poultry-and-livestock-1965-to-estimated-2012-in-pounds/ (Accessed: December 21, 2022).

National Chicken Council (2021) *Per Capita Consumption of Poultry and Livestock, 1965 to Forecast 2022, in Pounds*. Available at: https://www.nationalchickencouncil.org/about-the-industry/statistics/per-capita-consumption-of-poultry-and-livestock-1965-to-estimated-2012-in-pounds/ (Accessed: December 21, 2022).

Neklyudov, A., Ivankin, A. and Berdutina, A. (2000) 'Properties and uses of protein hydrolysates', *Applied Biochemistry and Microbiology,* 36(5), pp. 452-459.

Omana, D. A., Pietrasik, Z. and Betti, M. (2012) 'Evaluation of poultry protein isolate as a food ingredient: physicochemical characteristics of low-fat turkey bologna', *Poult Sci,* 91(12), pp. 3223-9.

Ozogul, Y. and Ozugul, F. (2019) 'Biogenic Amines Formation, Toxicity, Regulations in Food', in Saad, B. & Tofalo, R. (eds.) *Biogenic Amines in Food: Analysis, Occurrence and Toxicity*: Royal Society of Chemistry.

Proteus Industries Inc. (2004) *GRAS Notification for extracted "seafood species" protein*. Available at: http://wayback.archive-it.org/7993/20171031052829/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM267843.pdf (Accessed: November 9, 2022).

Proteus Industries Inc. (2005) *GRAS Notification for Poultry Protein*. Available at: http://wayback.archive-it.org/7993/20171031052505/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM268856.pdf (Accessed: November 9, 2022).

Renwick, A. (1990) 'Acceptable daily intake and the regulation of intense sweeteners', *Food Additives & Contaminants,* 7(4), pp. 463-475.

Roquette Freres (2019) *GRAS Notifiation for Roquette's Pea Protein Isolate*. Available at: https://www.fda.gov/media/134207/download (Accessed: November 9, 2022).

Rulis, A. M. and Levitt, J. A. (2009) 'FDA'S food ingredient approval process: safety assurance based on scientific assessment', *Regulatory Toxicology and Pharmacology,* 53(1), pp. 20-31.

Schaafsma, G. (2009) 'Safety of protein hydrolysates, fractions thereof and bioactive peptides in human nutrition', *Eur J Clin Nutr,* 63(10), pp. 1161-8.

Scheideler, S. E. and Brown, R. (1995) *NF95-246 Nebraska Turkey Facts. Historical Materials from University of Nebraska-Lincoln Extension* Cooperative Extension of Agriculture and Natural Resoruces, Univrsity of Nebraska-Lincoln. Available at: https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1913&context=extensionhist.

Schwarz, C., Stekovic, S., Wirth, M., Benson, G., Royer, P., Sigrist, S. J., Pieber, T., Dammbrueck, C., Magnes, C., Eisenberg, T., Pendl, T., Bohlken, J., Kobe, T., Madeo, F. and Floel, A. (2018) 'Safety and tolerability of spermidine supplementation in mice and older adults with subjective cognitive decline', *Aging (Albany NY),* 10(1), pp. 19-33.

SCOGS (1980) *Select Committee on GRAS Substances (SCOGS) Opinion: Acid hydrolyzed proteins*. Available at: https://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm261282.htm.

Senmi Ekisu Co. Ltd. (2011) *GRAS Exemption Claim for Hydrolyzed Sardine Protein*. Available at: https://wayback.archive-it.org/7993/20171031012537/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm225018.htm (Accessed: December 21, 2022).

Solanic B.V. (2013) *GRAS Exemption Claim for Potato Protein Isolates*. Available at: http://wayback.archive-it.org/7993/20171031043624/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM337463.pdf (Accessed: December 21, 2022).

Tate and Lyle (2015a) *GRAS Determination of Oat Protein for Use in Foods*. Available at: http://wayback.archive-it.org/7993/20171031035324/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM458544.pdf (Accessed: November 8, 2022).

Tate and Lyle (2015b) *GRAS Notification — Oat-Derived Protein (Proatein®)*. Available at: http://wayback.archive-it.org/7993/20171031035324/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM458544.pdf (Accessed: November 9, 2022).

Thermo Fischer Scientific Inc. (2021) *f83 Chicken Allergen*. Available at: https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f83 (Accessed: November 12, 2021.

University of Illinois Extension (2022) *Turkey Facts*: University of Illinois. Available at: https://web.extension.illinois.edu/turkey/turkey_facts.cfm (Accessed: November 9, 2022.

USDA (2017) ' Agricultural Research Service. FoodData Central: Foundation Foods. Version Current: April 2021.'.

Vikman, Y., Siipola, V., Kanerva, H., Šližyte, R. and Wikberg, H. (2017) 'Poultry By-products as a Potential Source of Nutrients', *Adv Recycling Waste Manag,* 2(142), pp. 2.

Wang, J.-Z., Sun, H.-M., Zhang, C.-H., Hu, L., Li, X. and Wu, X.-W. (2016) 'Safety assessment of Maillard reaction products of chicken bone hydrolysate using Sprague-Dawley rats', *Food & Nutrition Research,* 60(1), pp. 27827.

Wergedahl, H., Liaset, B., Gudbrandsen, O. A., Lied, E., Espe, M., Muna, Z., Mork, S. and Berge, R. K. (2004) 'Fish protein hydrolysate reduces plasma total cholesterol, increases the proportion of HDL cholesterol, and lowers acyl-CoA:cholesterol acyltransferase activity in liver of Zucker rats', *J Nutr,* 134(6), pp. 1320-7.

WHO (2007) *Protein and Amino Acid Requirements in Human Nutrition. WHO Technical Report Series 935*, Geneva, Switzerland. Available at: http://apps.who.int/iris/bitstream/10665/43411/1/WHO_TRS_935_eng.pdf?ua=1 (Accessed: October 3, 2022).

World Food Processing LLC (2016) *GRAS notification for Un-hydrolyzed and Hydrolyzed Pea Protein*. Available at: https://wayback.archive-it.org/7993/20171031024349/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm361097.htm (Accessed: November 9, 2022).

Yantai Oriental Protein Tech Co., L. (2018) *Evaluation of the Generally Recognized as Safe (GRAS) Status of Pea Protein*. Available at: https://www.fda.gov/media/132887/download (Accessed: November 9, 2022).

Yantai Oriental Protein Tech Co., L. (2020) *Evaluation of the Generally-Recognized as Safey (GRAS) Status of Enzyme Treated Pea Protein*. Available at: https://www.fda.gov/media/152479/download (Accessed: October 25, 2022).

Yantai T.FULL Biotech Co., L. (2019) *GRAS Determination of Fava Beanl Protein for Use as an Ingredient in Human Food*. Available at: https://www.fda.gov/media/134517/download (Accessed: November 9, 2022).

B. Appendices

Appendix 1 Specification for Promod™ 950L Enzyme

Sheet no: 1/1. Revision 11: 2018-07-26

BIOCATALYSTS
exceeding enzyme expectations

Promod™ 950L (P950L)

Features/Benefits

- Zero-added sulphite liquid microbial protease
- Suitable for production of yeast extracts
- A microbial alternative to papain
- Broad substrate specificity
- Kosher, Halal and non GM protease

Promod™ 950L is a microbial protease preparation with broad substrate specificity. This enzyme can be used to efficiently hydrolyse vegetable, animal and fish proteins to increase solubility, reduce viscosity and produce specific flavours. It is particularly suitable for hydrolysis of baker's and brewer's yeast to increase solubility and yields during the manufacture of yeast extracts. The enzyme is a sulphite-free microbial protease and can be used to manufacture yeast extracts with lower sulphite content.

It is also a suitable alternative to papain and the microbial origin of the product removes the variability of quality and supply associated with plant derived material.

Specification

Activity	154 Casein Protease units/g
Biological Source	*Bacillus spp.*
Form	Brown Liquid
Optimum pH Range	5.0 – 7.0
Optimum Temperature Range	50 - 60°C

Application & Dose

Promod™ 950L displays optimal activity in the pH range of pH 5.0-7.0 and at a temperature of 50-60°C. As a guideline, the enzyme should be dosed at 1.0% w/w based on the weight of yeast. Promod™ 950L will perform efficiently when the substrate is prepared in water and no pH adjustment is required during the enzyme hydrolysis step if the pH is in the optimal range. The enzyme incubation time will depend on the enzyme dose, temperature, pH and hydrolysate requirements. Trials will be required in order to determine the optimal enzyme hydrolysis conditions. The enzyme can be deactivated by increasing the temperature to 85°C for 15 minutes after the enzyme hydrolysis step.

Health & Safety

Always read the Material Safety Datasheet (MSDS) before use and retain. If you are in any doubt about recommended product handling and safety, please contact Biocatalysts before use. Generally, when using enzymes avoid contact with the skin and eyes and do not breathe dusts or aerosols containing them. MSDSs are available in other languages. Please contact Customer Services.

Storage

Liquids: Activity will remain within specification for at least 6 months from the date of manufacture when stored at 0 - 20°C.

Allergens

None present

Food Status

Material complies with the JECFA/FAO/WHO and FCC recommended specifications for enzymes used in food processing.

GM Status

This product has been manufactured using a fermentation process of a self-cloned organism, whereby genes naturally occurring in the organism have been over-expressed in order to ensure a higher level of the desired protein. This product does therefore not require labelling as GMO on food labels.

Quality & Food Safety

Biocatalysts operates a preventative risk-based Food Safety System that ensures the environment and processes are designed to produce safe products every time. FSSC22000 and FSMA compliant.

Compliance - The Company's integrated management system encompasses Quality, Food Safety, Health and Safety and GMP.

Certificates are available on request from the Customer Services Department.

Availability

Liquids: standard 25kg net plastic jerry cans. Non-standard quantities are also available for some products, please enquire.

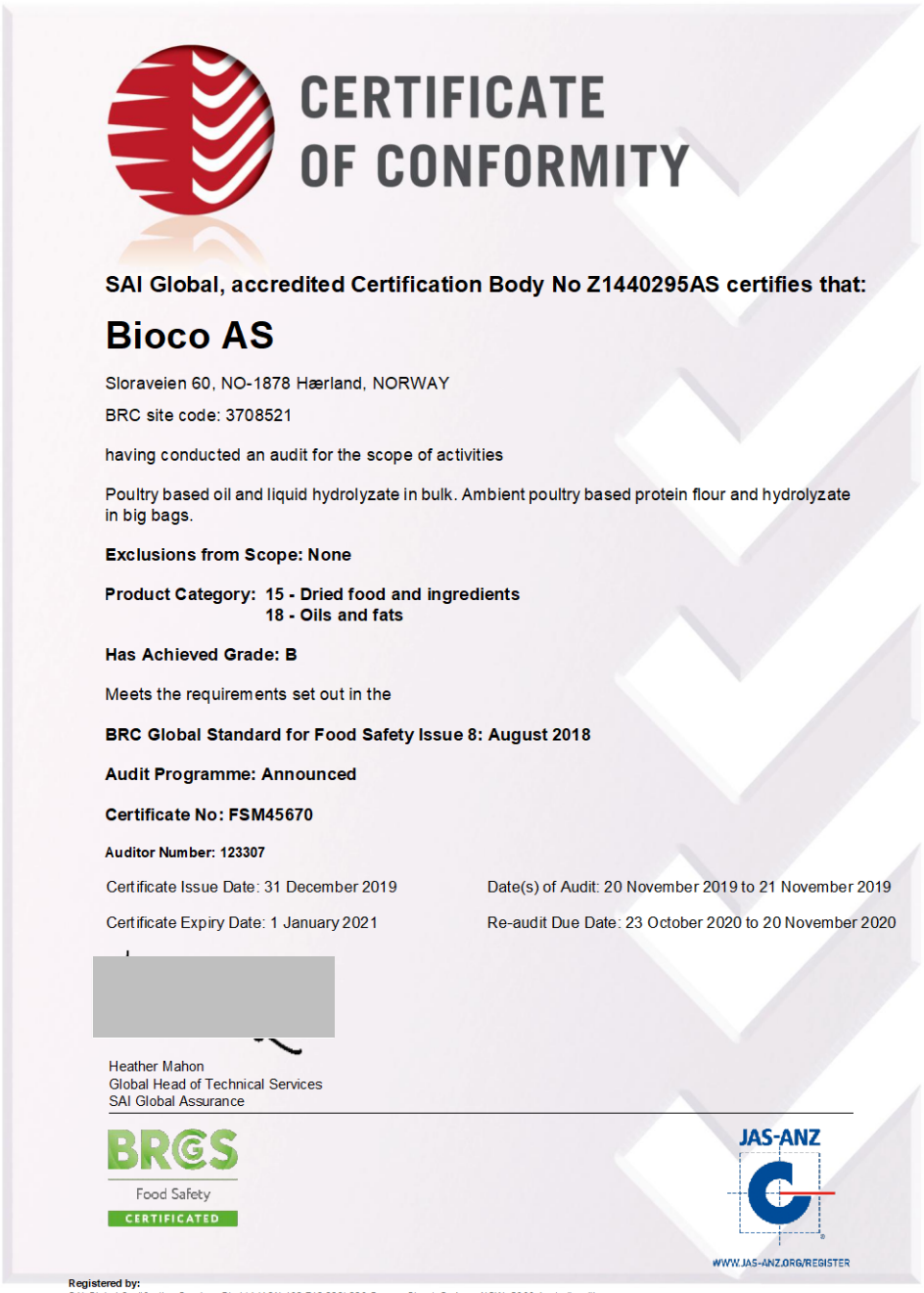
Visit our website for further relevant & current information www.biocatalysts.com

Biocatalysts Limited
Cefn Coed, Parc Nantgarw,
Cardiff, Wales,
CF15 7QQ UK
Tel: +44 (0)1443 843712
Email: sales@biocats.com

Biocatalysts Inc.
Chicago
IL, USA
Email: usaorders@biocats.com

FM 38517 EMS 575707 OHS 569745 FSSC 22000

Appendix 2 Certificate of Conformity for Food Safety Audit



CERTIFICATE OF CONFORMITY

SAI Global, accredited Certification Body No Z1440295AS certifies that:

Bioco AS

Sloraveien 60, NO-1878 Hærland, NORWAY

BRC site code: 3708521

having conducted an audit for the scope of activities

Poultry based oil and liquid hydrolyzate in bulk. Ambient poultry based protein flour and hydrolyzate in big bags.

Exclusions from Scope: None

Product Category: 15 - Dried food and ingredients
18 - Oils and fats

Has Achieved Grade: B

Meets the requirements set out in the

BRC Global Standard for Food Safety Issue 8: August 2018

Audit Programme: Announced

Certificate No: FSM45670

Auditor Number: 123307

Certificate Issue Date: 31 December 2019

Date(s) of Audit: 20 November 2019 to 21 November 2019

Certificate Expiry Date: 1 January 2021

Re-audit Due Date: 23 October 2020 to 20 November 2020

Heather Mahon
Global Head of Technical Services
SAI Global Assurance

BRCGS Food Safety CERTIFICATED

JAS-ANZ

WWW.JAS-ANZ.ORG/REGISTER

Registered by:
SAI Global Certification Services Pty Ltd (ACN 108 716 669) 680 George Street Sydney NSW 2000 Australia with SAI Global Pty Limited 680 George Street Sydney NSW 2000 Australia ("SAI Global") and subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to SAI Global upon its request. To validate certificate authenticity please visit www.brcdirectory.com

If you would like to provide feedback on the BRC Global Standard or the audit process directly to BRC, please contact tellus@brcglobalstandards.com

SAI GLOBAL

Appendix 3 Product Specification and CoAs for Nor-HydroPep DM

norilia

Vare nr.: 390065/3000004672 | Product specification **Nor-HydroPep 60 DM** | Valid from: 08.12.2020 Last changed: 13.04.2021 Version: 1. | Page 1 (2)

Product specification Nor-HydroPep 60 DM

Description:

Hydrolyzed poultry proteins manufactured from fresh chicken and turkey. Food grade poultry off-cuts and bones for use in food production.

Parameter	*Value*	*Method*
Microbiology		
Salmonella (per 25 g)	Negative	AFNOR EGS 38/01-03/15 -UMQEK
Aerobic Spores (CFU/g)	<3000	NMKL 189 - UMQKU
Anaerobic Spores (CFU/g)	<3000	NMKL 189 - UM3K8
Enterobacteriaceae 37°C (CFU/g)	<10	AFNOR 3M 01/06-09/97 - UMQI0
E-Coli (CFU/g)	<10	AFNOR 3M 01/08-06/01 - UMQIM
Clostridium perfringens (CFU/g)	<10	NMKL 95 - UMQGL
Total Plate Count (CFU/g)	<1000	AFNOR 3M 01/01-09/89 - UMQFG
Yeast (CFU/g)	<100	NMKL 98
Mold (CFU/g)	<100	NMKL 98
Chemical content		
Dry matter (g/100g)	>59	NMKL 23
Crude protein (g/100g)	>50	NMKL 6
Crude fat (g/100g)	<3	NMKL 160 mod
Ash (g/100g)	<6	NMKL 173
Heavy metals		
Lead (ppm)	< 0.1	EN ISO 17294-2:2016/EN 13805:2014
Arsenic (ppm)	< 0.1	EN ISO 17294-2:2016/EN 13805:2014
Cadimum (ppm)	< 0.1	EN ISO 17294-2:2016/EN 13805:2014
Mercury (ppm)	< 0.1	EN 16277:2012
Colour, flavour and physical properties		
Appearance	Brownish paste which may vary slightly	Visual
Odor and taste	Chicken and umami flavour	Sensory
Statement Certification		
Halal	No	
Kosher	No	
Allergy declaration	Negative	
Intolerance according to the Alba list		
Chicken including fat	Present in product	
Other information		
GMO	No	

Labelling information:
In the ingredient list as "Poultry proteins" or "Poultry Peptides". Should be used according to local legislation.

Safety information:
No special considerations, except normal handling of gele produkts with high temperatures.

Other product information:
Manufacturer of finished product is responsible for checking that additives comply with Regulations.

Dosage:
According to manufacturer's own recipe.

Packaging:
Supplied in full tank loads or IBC container with temperature control. Could also be supplied in plastic casings 1-10 kg upon request.

Storage:
Avoid direct sunlight.

Origin:
Norway

Shelf-life:
6 months.

Certificate of Analysis

Product Details

Product name:	**Nor-HydroPep 60 DM**	**Manufacturer Date:**	15-Feb-2021
Product number	3000005211	**Test Date:**	15-Feb-2021
Batch Number:	1002903572	**Retest Date:**	

Test Parameter	***Value Specification***	***Test Result***	***Approved Result***
Color, flavor and physical properties			
Appearance	Brownish paste which may vary slightly	Complies	*Approved*
Odor and taste	**Chicken and umami flavor**	**Complies**	***Approved***
Chemical content			
Dry matter (g/100g)	>59	60,7	*Approved*
Crude protein (g/100g)	**>50**	**53,2**	***Approved***
Crude fat (g/100g)	<3	2,55	*Approved*
Ash (g/100g)	**<6**	**3,67**	***Approved***
Microbiology			
Salmonella (per 25 g)	Negative / 25 g	Negative / 25 g	*Approved*
Aerobic Spores (CFU/g)	**<3000**	**<100**	***Approved***
Anaerobic Spores (CFU/g)	<3000	<100	*Approved*
Enterobacteria (CFU/g)	**<10**	**<10**	***Approved***
E-Coli (CFU/g)	<10	<10	*Approved*
Clostridium perfringens (CFU/g)	**<10**	**<10**	***Approved***
Total Plate Count (CFU/g)	<1000	<1000	*Approved*
Yeast	**<100**	**<100**	***Approved***
Mold	<100	<100	*Approved*
Heavy Metals			
Lead (ppm)	< 0,1	<0,020	*Approved*
Arsenic (ppm)	**< 0,1**	**0,069**	***Approved***
Cadmium (ppm)	< 0,1	<0,010	*Approved*
Mercury (ppm)	**< 0,1**	**<0,020**	***Approved***

Approved by producer Bioco AS for Norilia AS:

19-Apr-21

Elin Klufterud Abelsnes, Quality Manager Bioco AS

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway
Visiting adr: Lørenv. 37
NO-0585 Oslo

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70
www.norilia.no
www.norilia.com
VAT-no.:
NO 995 643 316 MVA

Bank DNB Bank ASA
SWIFT DNBANOKK
IBAN NO5270760546176 (NOK)
NO0950020447912 (EUR)
NO8670070442750 (USD)
NO4212501635152 (GBP)
NO9512500821823 (SEK)
NO5912501008808 (DKK)

Konto/Acnt.:
70760546176 (NOK)
50020447912 (EUR)
70070442750 (USD)
12501635152 (GBP)
12500821823 (SEK)
12501008808 (DKK)

Certificate of Analysis

Product Details

Product name:	Nor-HydroPep 60 DM	**Manufacturer Date:**	05-Mar-2021
Product number	3000005211	**Test Date:**	05-Mar-2021
Batch Number:	1002981948	**Retest Date:**	

Test Parameter	*Value Specification*	*Test Result*	*Approved Result*
Color, flavor and physical properties			
Appearance	Brownish paste which may vary slightly	Complies	*Approved*
Odor and taste	**Chicken and umami flavor**	**Complies**	***Approved***
Chemical content			
Dry matter (g/100g)	>59	59,7	*Approved*
Crude protein (g/100g)	**>50**	**52,3**	***Approved***
Crude fat (g/100g)	<3	1,79	*Approved*
Ash (g/100g)	**<6**	**4,09**	***Approved***
Microbiology			
Salmonella (per 25 g)	Negative / 25 g	Negative / 25 g	*Approved*
Aerobic Spores (CFU/g)	**<3000**	**<100**	***Approved***
Anaerobic Spores (CFU/g)	<3000	2300	*Approved*
Enterobacteria (CFU/g)	**<10**	**<10**	***Approved***
E-Coli (CFU/g)	<10	<10	*Approved*
Clostridium perfringens (CFU/g)	**<10**	**<10**	***Approved***
Total Plate Count (CFU/g)	<1000	<1000	*Approved*
Yeast	**<100**	**<100**	***Approved***
Mold	<100	<100	*Approved*
Heavy Metals			
Lead (ppm)	< 0,1	<0,020	*Approved*
Arsenic (ppm)	**< 0,1**	**0,061**	***Approved***
Cadmium (ppm)	< 0,1	<0,010	*Approved*
Mercury (ppm)	**< 0,1**	**<0,020**	***Approved***

Approved by producer Bioco AS for Norilia AS:

19-Apr-21

Elin Klufterud Abelsnes, Quality Manager Bioco AS

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway
Visiting adr: Lørenv. 37
NO-0585 Oslo

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70
www.norilia.no
www.norilia.com
VAT-no.:
NO 995 643 316 MVA

Bank DNB Bank ASA
SWIFT DNBANOKK
IBAN NO5270760546176 (NOK)
NO0950020447912 (EUR)
NO8670070442750 (USD)
NO4212501635152 (GBP)
NO9512500821823 (SEK)
NO5912501008808 (DKK)

Konto/Acnt.:
70760546176 (NOK)
50020447912 (EUR)
70070442750 (USD)
12501635152 (GBP)
12500821823 (SEK)
12501008808 (DKK)

Certificate of Analysis

Product Details

Product name:	Nor-HydroPep 60 DM	**Manufacturer Date:**	19-Mar-2021
Product number	3000005211	**Test Date:**	19-Mar-2021
Batch Number:	1003076382	**Retest Date:**	

Test Parameter	*Value Specification*	*Test Result*	*Approved Result*
Color, flavor and physical properties			
Appearance	Brownish paste which may vary slightly	Complies	*Approved*
Odor and taste	**Chicken and umami flavor**	**Complies**	***Approved***
Chemical content			
Dry matter (g/100g)	>59	61,4	*Approved*
Crude protein (g/100g)	**>50**	**52,1**	***Approved***
Crude fat (g/100g)	<3	2,83	*Approved*
Ash (g/100g)	**<6**	**3,84**	***Approved***
Microbiology			
Salmonella (per 25 g)	Negative / 25 g	Negative / 25 g	*Approved*
Aerobic Spores (CFU/g)	**<3000**	**<100**	***Approved***
Anaerobic Spores (CFU/g)	<3000	<100	*Approved*
Enterobacteria (CFU/g)	**<10**	**<10**	***Approved***
E-Coli (CFU/g)	<10	<10	*Approved*
Clostridium perfringens (CFU/g)	**<10**	**<10**	***Approved***
Total Plate Count (CFU/g)	<1000	<1000	*Approved*
Yeast	**<100**	**<100**	***Approved***
Mold	<100	<100	*Approved*
Heavy Metals			
Lead (ppm)	<0,1	<0,020	*Approved*
Arsenic (ppm)	**<0,1**	**<0,050**	***Approved***
Cadmium (ppm)	<0,1	<0,010	*Approved*
Mercury (ppm)	**<0,1**	**<0,020**	***Approved***

Approved by producer Bioco AS for Norilia AS:

19-Apr-21

Elin Klufterud Abelsnes, Quality Manager Bioco AS

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway
Visiting adr: Løvenv. 37
NO-0585 Oslo

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70
www.norilia.no
www.norilia.com
VAT-no.:
NO 995 643 316 MVA

Bank DNB Bank ASA
SWIFT DNBANOKK
IBAN NO5270760546176 (NOK)
NO0950020447912 (EUR)
NO8670070442750 (USD)
NO4212501635152 (GBP)
NO9512500821823 (SEK)
NO5912501008808 (DKK)

Konto/Acnt.:
70760546176 (NOK)
50020447912 (EUR)
70070442750 (USD)
12501635152 (GBP)
12500821823 (SEK)
12501008808 (DKK)

norilia

Certificate of Analysis

Product Details

Product name:	Nor-HydroPep 60 DM	**Manufacturer Date:**	26-Mar-2021
Product number	3000005211	**Test Date:**	26-Mar-2021
Batch Number:	1003125616	**Retest Date:**	

Test Parameter	***Value Specification***	***Test Result***	***Approved Result***
Color, flavor and physical properties			
Appearance	Brownish paste which may vary slightly	Complies	*Approved*
Odor and taste	Chicken and umami flavor	Complies	***Approved***
Chemical content			
Dry matter (g/100g)	>59	60,0	*Approved*
Crude protein (g/100g)	**>50**	**51,8**	***Approved***
Crude fat (g/100g)	<3	1,99	*Approved*
Ash (g/100g)	**<6**	**3,98**	***Approved***
Microbiology			
Salmonella (per 25 g)	Negative / 25 g	Negative / 25 g	*Approved*
Aerobic Spores (CFU/g)	**<3000**	**<100**	***Approved***
Anaerobic Spores (CFU/g)	<3000	<100	*Approved*
Enterobacteria (CFU/g)	**<10**	**<10**	***Approved***
E-Coli (CFU/g)	<10	<10	*Approved*
Clostridium perfringens (CFU/g)	**<10**	**<10**	***Approved***
Total Plate Count (CFU/g)	<1000	<1000	*Approved*
Yeast	**<100**	**<100**	***Approved***
Mold	<100	<100	*Approved*
Heavy Metals			
Lead (ppm)	<0,1	<0,020	*Approved*
Arsenic (ppm)	**<0,1**	**0,070**	***Approved***
Cadmium (ppm)	<0,1	<0,010	*Approved*
Mercury (ppm)	**<0,1**	**<0,020**	***Approved***

Approved by producer Bioco AS for Norilia AS:

19-Apr-21

Elin Klufterud Abelsnes, Quality Manager Bioco AS

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway
Visiting adr: Lørenv. 37
NO-0585 Oslo

Nasjonal tel.: 03070
Inttel.: +47 22 90 30 70
www.norilia.no
www.norilia.com
VAT-no.:
NO 995 643 316 MVA

Bank DNB Bank ASA
SWIFT DNBANOKK
IBAN NO5270760546176 (NOK)
NO0950020447912 (EUR)
NO8670070442750 (USD)
NO4212501635152 (GBP)
NO9512500821823 (SEK)
NO5912501008808 (DKK)

Konto/Acnt.:
70760546176 (NOK)
50020447912 (EUR)
70070442750 (USD)
12501635152 (GBP)
12500821823 (SEK)
12501008808 (DKK)

norilia

Certificate of Analysis

Product Details

Product name:	Nor-HydroPep 60 DM	**Manufacturer Date:**	11-Feb-2021
Product number	3000005211	**Test Date:**	12-Feb-2021
Batch Number:	1002863440	**Retest Date:**	

Test Parameter	*Value Specification*	*Test Result*	*Approved Result*
Color, flavor and physical properties			
Appearance	Brownish paste which may vary slightly	Complies	*Approved*
Odor and taste	Chicken and umami flavor	Complies	***Approved***
Chemical content			
Dry matter (g/100g)	>59	62	*Approved*
Crude protein (g/100g)	**>50**	**52,6**	***Approved***
Crude fat (g/100g)	<3	2,24	*Approved*
Ash (g/100g)	**<6**	**2,24**	***Approved***
Microbiology			
Salmonella (per 25 g)	Negative / 25 g	Negative / 25 g	*Approved*
Aerobic Spores (CFU/g)	**<3000**	**<100**	***Approved***
Anaerobic Spores (CFU/g)	<3000	<100	*Approved*
Enterobacteria (CFU/g)	**<10**	**<10**	***Approved***
E-Coli (CFU/g)	<10	<10	*Approved*
Clostridium perfringens (CFU/g)	**<10**	**<10**	***Approved***
Total Plate Count (CFU/g)	<1000	<1000	*Approved*
Yeast	**<100**	**<100**	***Approved***
Mold	<100	<100	*Approved*
Heavy Metals			
Lead (ppm)	<0,1	<0,020	*Approved*
Arsenic (ppm)	**<0,1**	**0,069**	***Approved***
Cadmium (ppm)	< 0,1	<0,010	*Approved*
Mercury (ppm)	**<0,1**	**<0,020**	***Approved***

Approved by producer Bioco AS for Norilia AS:

19-Apr-21

Elin Klufterud Abelsnes, Quality Manager Bioco AS

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway
Visiting adr: Lørenv. 37
NO-0585 Oslo

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70
www.norilia.no
www.norilia.com
VAT-no.:
NO 995 643 316 MVA

Bank DNB Bank ASA
SWIFT DNBANOKK
IBAN NO5270760546176 (NOK)
NO0950020447912 (EUR)
NO8670070442750 (USD)
NO4212501635152 (GBP)
NO9512500821823 (SEK)
NO5912501008808 (DKK)

Konto/Acnt.:
70760546176 (NOK)
50020447912 (EUR)
70070442750 (USD)
12501635152 (GBP)
12500821823 (SEK)
12501008808 (DKK)

Appendix 4 Stability Report

Norilia AS,
Att.: Kristine Bergerud,
Postboks 360, Økern,
0513 OSLO

Moss 011221

Shelf life study report, Nor-Hydropep 60

Nor-Hydropep 60 has been at 4°C, 20°C ,35°C and 50°C for a period of 12 months. During the shelf life test, samples has been collected for analysis. This report is based of analysis reports from Eurofins, and major findings is reported.
The raw data for this repost is attached as a spread sheet.

MATERIALS, METHODS and ANALYSIS
Materials, methods and analysis have been selected according to customer specification and contract between Eurofins and Norilia.

RESULTS

The results presented in this report is based on earlier reported results.

Dry matter

Dry matter has been analyzed at 0 and 6 months for sample stored at 4°C, 20°C ,35°C and 50°C. There has been no difference in the dry matter during storage. The dry matter content in the sample is analyzed to be 64,3 g/100g

Vitamins

Table below indicates analyzed vitamins at 0 months

Retinol	Vitamin-B12	Niacin B3	Pyridoxin B6	Kolecaciferol D3	α tocopherol	Vitamin K1
µg/100g	µg/100g	mg/100g	mg/100g	µg/100g	mg/100g	µg/100g
<21 (LOQ)	15,3	35,4	0,262	<0,25 (LOQ)	0,195	<0,8 (LOQ)

Antioxidants

The sample has initially been analyzed for BHA, BHT and Propyl gallate. There has not been found traces of these antioxidants higher than limit of quantification in either of the samples.

Eurofins Food & Feed Testing Norway AS
Postboks 3055 Kambo
N-1506 Moss, Norge
1538 MOSS

T | +47 00450
www.eurofins.no
mat@eurofins.no

Org.nr: NO 982 571 148

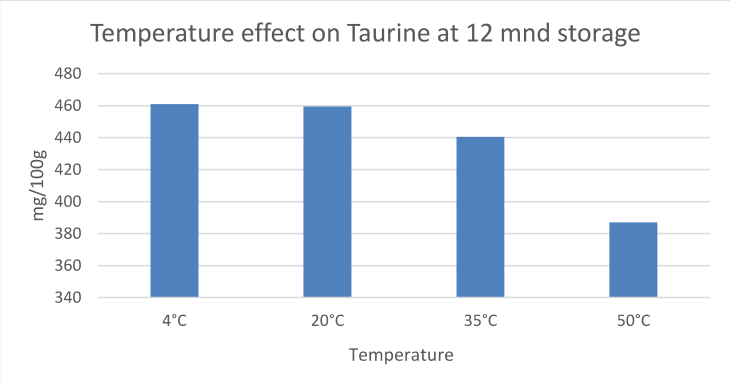
eurofins

Free amino acids
Free amino acids have been analyzed at initially and after 12 month of storage.

There has been found a decrease in amount for free amino acids when the storage temperature increase. The table below shows the sum of all free amino acids analyzed, according to earlier reports.

Temperature	Total Free AA g/100g
4°C	6,14
20°C	6,19
35°C	6,04
50°C	5,45

The same reduction can also be found for Taurine. Figure below shows the effect of temperature on Taurine degradation



The same reduction of free amino acids is normal when storing at elevated temperatures and is normally caused by oxidation, cleavage of amino group or other reaction with the amino group like formation of shiff bases. See spreadsheet for free amino acid profile

Initially other free amino acids were analyzed.

AA	Free AA
Asparagin	0,07
Glutamin	0,009
Anserin	13
β-Alanin	1,06

These amino acids were only analyzed once, in the beginning of the trial.

Eurofins Food & Feed Testing Norway AS
Postboks 3055 Kambo
N-1506 Moss, Norge
1538 MOSS
T | +47 09450
www.eurofins.no
mat@eurofins.no
Org.nr: NO 982 571 146

eurofins

Total amino acids

Total amino acids were analyzed initially and after 12 month storage at at 4°C, 20°C ,35°C and 50°C.

Temperature	Total AA
Initial	48,6
4°C	50
20°C	49,9
35°C	49,9
50°C	51,6

There has been found no significant difference in total amount of amino acids between the different storage temperatures. See spreadsheet for amino acid profile.

Fat and fatty acids

Initially total fat content was 1,46 g/100g
There was no significant difference in the fatty acid and there was not found any temperature effect on the fatty acid composition. Normally polyunsaturated fat undergo an oxidation and the concentration of these fatty acids decrease as an effect of elevated temperature due to oxdation. This effect has not been seen in this trial. See spreadsheet for fatty acid profile

Minerals and Ash

The Ash content of the Nor-Hydropep 60 is analyzed to 5,3 g/100g
Minerals analyzed are represented in table below.

Copper	Phosphorus	Iron	Iodine	Calcium	Manganese	Potassium	Sodium	Selene	Zink	Chloride	NaCl calc	Nitrate
mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	g/100g	g/100g	mg/kg
1,3	6100	19	0,5	450	530	17000	9400	0,24	8,6	0,83	1,38	7,49

Biogene amines and TVN

Biogene amines has been analyzed initially and after 12 month of storage at 4°C.

	Phenylethylamine	Histamine	Cadaverine	Putrecine	Spermidine	Spermine	Tryptamine	Tyramine	TVN
	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/100g
Initial	2,52	6,29	4,18	5,96	29,60	26,95	<5 (LOQ)	<1 (LOQ)	64,45
Initial	3,13	11,1	3,4	10,5	82,8	110	<5 (LOQ)	<1 (LOQ)	
4°C 12 mn	5,99	12,65	54,325	63,85	90,85	95,7	<5,00 (LOQ)	43,7	

Initially analysis has some different results on Biogene amines. This can be caused by storage conditions before analysis, or different batches. TVN is initially analyzed.

Eurofins Food & Feed Testing Norway AS
Postboks 3055 Kambo
N-1506 Moss, Norge
1538 MOSS

T | +47 09450
www.eurofins.no
mat@eurofins.no

Org.nr: NO 982 571 146

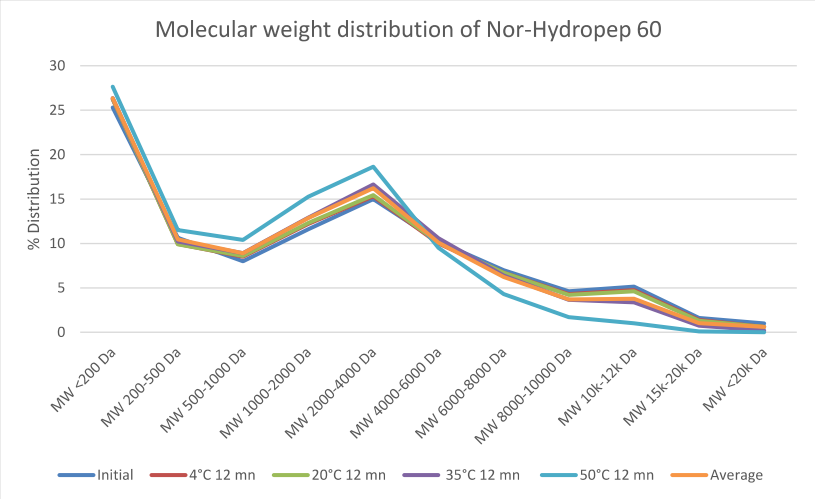
eurofins

Bioactive Compounds.
Bioactive compounds have been analyzed initially according to table and results below

Carnitine	Carnosine	Creatnine	Choline
mg/kg	mg/kg	mg/kg	mg/kg
212	2,07	1,22	785

Degree of hydrolysis and Molecular weight distribution
The degree of hydrolysis of the Nor-Hydropep 60 was analyzed to 18,5% and water soluble fraction is 50-53%.

The molecular weight distribution shown in figure below indicates a high amount free amino acids below 200 Da and a major peak around 2000-4000 Da.



Oxidation
Due to low levels of lipid content in the sample it is impossible to measure Peroxide Value and Anisidine value in Nor-Hydropep 60 at 12 month of storage at all temperatures. The analysis has the been performed with Dynamic Headspace- GCMS analysis according to table below which reports the analysis results.

Eurofins Food & Feed Testing Norway AS
Postboks 3055 Kambo
N-1506 Moss, Norge
1538 MOSS

T | +47 09450
www.eurofins.no
mat@eurofins.no

Org.nr: NO 982 571 146

Eurofins Sample Number	440-2021-0818-025/-026	440-2021-0818-027/-028	440-2021-0818-029/-030	440-2021-0818-031/-032
Sample name	Nor-HydroPep 60 4°C 12 mnd	Nor-HydroPep 60 20°C 12 mnd	Nor-HydroPep 60 35°C 12 mnd	Nor-HydroPep 60 50°C 12 mnd
	ng/g	ng/g	ng/g	ng/g
Methylamine, N,N-dimethyl-	0	0	2,2	5,5
Propanal, 2-methyl-	2,4	2,4	1,2	1,1
Furan, 3-methyl-	0	0,3	3,2	3,2
2-Butanone	9,8	17,4	33,4	53,8
Butanal, 2-methyl-	3,5	3,9	2,1	1,7
Butanal, 3-methyl-	6,8	7,9	3,9	2,6
2-Pentanone	0	0,2	1,4	2
Disulfide, dimethyl	0,5	1,9	3,7	9
Hexanal	0	0,3	0,3	0
Thiophene, 2-methyl-	0	0	0,7	2,7
Pyrazine, methyl-	1,1	3,3	5,7	6,9
Octanal	0,7	0,9	0,8	0,5
Pyrazine, 2,6-dimethyl-	2,1	7,2	16,3	22,4
Dimethyl trisulfide	1,9	2,6	6,4	15,6
Pyrazine, 2-ethyl-6-methyl-	0,7	3,7	13	14,7
Pyrazine, 2-ethyl-5-methyl-	0,1	1,3	2,2	2,2
Pyrazine, trimethyl-	0,2	1	2,1	2,1
Pyrazine, 2-methyl-5-(1-methylethyl)-	0	0,6	1,9	1,8
Pyrazine, 3-ethyl-2,5-dimethyl-	0	1	2	2,6
1-Octen-3-ol	0,1	0,3	0,4	0,1
Pyrrole	0	0,1	0,3	0,7

Eurofins Food & Feed Testing Norway AS
Postboks 3055 Kambo
N-1506 Moss, Norge
1538 MOSS

T | +47 09450
www.eurofins.no
mat@eurofins.no

Org.nr: NO 982 571 146

There has not been found any significant differences in lipid oxidation products for the different storage temperatures. The content of sulfur compounds like Dimethyldisulfide, 2- and 3-butanal increase with increasing temperature. The same trend has also trimethylamine. These compounds are directly decomposing products from amino acid degradation. These compounds are also known for unpleasant smell and taste. The furans, Pyrazines and Pyrolles found are also rearrangements of amino acids and their products.

Microbiology

The Nor-Hydropep 60 has been tested for Aerobic microorganism, Anaerobic spores, Aerobic spores, E.Coli, Enterobactericeae, Coliforms, Yeast and Mould.
There has not been found any microbiological activity in any of the samples measured, during the shelf life study.

Discussion.

The Nor-Hydropep 60 is a hydrolysate containing enzyme digested poultry protein.
The product shows almost no sign in decomposition of measured components during 12 month of storage in the temperature area 4-50°C. Hovewer there is an increasing decomposition of amino acids correlated to increasing storage temperature.
This decomposition can cause some off-flavor of the product. Especially for products stored at 35°C and higher for 12 months. Because of this it is recommended to store the Nor-Hydropep 60 at 20° or lower to achieve a good shelf life quality for 12 months

Gjermund Vogt
Project Manager Chemistry

Eurofins Food & Feed Testing Norway AS
Møllebakken 50
NO-1538 Moss
Mobile: +47 90113289

Appendix 5 Sensory Report Translation

Translation of Workshop 1Hydrolysater i flytende produkter 19, NOVEMBER 2019, ÅS

Workshop 1 Hydrolyzates in fluid products. November 19th, Ås

Page 2: Agenda

Test the hydrolzate in

- Water
- Tomato soup
- Chicken soup
- Vegetable soup
- Cold smoothie

Page 14: Preliminary conclusion

- Spray-dried hydrolyzate is mainly described as bitter and burnt. Burnt is an attribute that typically comes from the process of spray drying. The more quantity added, the more the tests are perceived as burnt and bitter.
- Tomato soup appears to be the best alternative of the three soups.

Appendix 6 Estimated Daily Intake Analysis Detail Report for Nor-HydroPep DM

Methods Utilized to Estimate the Daily Intake

The dietary exposure distributions were calculated using the Creme Food Safety® model, a scientific cloud-based software service designed and developed to calculate dietary intakes of foods, chemicals, and nutrients in populations of consumers. This is achieved by linking food consumption data from the What We Eat In America (WWEIA) portion of the National Health and Nutrition Examination Survey (NHANES) to the appropriate food composition and chemical occurrence data using a number of validated and published models, available upon request from Crème Global (https://www.cremeglobal.com/). Calculations for this intake analysis were completed using deterministic (single points) input data. Output calculation types include daily average intakes, acute exposures, as well as population statistics such as mean, percentiles, standard errors, and confidence intervals. Results are output for "Consumers Only" (i.e., consumers of the food / substance of interest), and Total Population (consumers and non-consumers). Results of the exposure assessment are given in absolute terms (mg/day) as well as relative to the consumer's body weight (mg/kg bw/day). The per unit of bodyweight exposure is calculated on a subject level using the bodyweight recorded by the NHANES data.

Proposed Use and Food Codes Utilized for Intake Calculation

The proposed uses of Nor-HydroPep DM are provided below. Nor-HydroPep DM is intended for use in soups, snacks, tomato-based vegetable juices, gravies, condiments, nutrition bars, protein drinks, meal replacements and medical food applications. The target amount per serving of finished food product (using the reference amounts customarily consumed for the food) varies as shown in the table below. U. For purposes of this intake assessment, 1 ml of liquid is assumed to be equal to 1 gram.

Intended Use of Nor-HydroPep DM

Intended Food Use Category	Proposed Food Uses	Maximum Use Levels (g) Per Serving	RACC[1]
Condiments and Relishes	Mayonnaise Other condiments	5	15 g 17 g[2]
Processed Vegetables, Vegetable Juices	Tomato-based juices	5	240 mL
Gravies & Sauces	Gravies	2	60 g
Soups & Soup Mixes	Soups	10	245 g
Snack Foods	Popcorn, pretzels, chips, & crackers	5	30 g
Not Specified	Nutrition Bars	20	40 g
Not Specified	Protein drinks & protein powder mixes	20	240 mL
Not Specified	Ready-to-drink meal replacements & nutritional beverages	20	240 mL
Herbs, Seeds, Spices, Seasonings, Blends, Extracts, and Flavorings	Seasonings for meat coatings/rubs and in seasoning pastes	2[3]	Not Applicable

Not Specified	Medical Foods (protein component only)	20[4]	240 mL

g – gram; mL – milliliter; RACC – Reference Amounts Customarily Consumed

[1] RACC based on values established in 21 CFR §101.12. When a range of values is reported for a proposed food-use, particular foods within that food-use may differ with respect to their RACC. RACCs reported with household measure were converted to g based on USDA Food Central Database (https://fdc.nal.usda.gov/).

[2] RACC for non-mayonnaise condiments (17 g) was based on average of RACCs for Barbeque sauce, tomato chili sauce et al., Major condiments, and Minor condiments. The RACC for mayonnaise is 15 g.

[3] Maximum use rate of 2 g/100 g in seasoning blend. Blended seasonings used in meat products are used at low levels, usually around 3% and rarely exceed 10% (Brown, 2009). Therefore, the consumption of Nor-HydroPep used in seasoning blends for processed meat products will be negligible.

[4] Medical foods were not included in the intake analysis because these are not consumed by the general population and are prescribed under supervision of a physician.

The food codes utilized to calculate the estimated daily intake were selected from the National Health and Nutrition Examination Survey (NHANES) 2017 – 2018 survey. Food codes that most appropriately match the intended use were selected. The food codes utilized in this analysis are shown below.

2017-2018 NHANES Food Codes Used for Intake Analysis

Food Code	Main Food Description
	SOUPS
14710100	Cheddar cheese soup, home recipe, canned or ready-to-serve
14710200	Beer cheese soup, made with milk
28310110	Beef, broth, bouillon, or consomme
28310150	Oxtail soup
28310160	Beef broth, with tomato, home recipe
28310170	Beef broth, without tomato, home recipe
28310230	Meatball soup, home recipe, Mexican style
28310320	Beef noodle soup, Puerto Rican style
28310330	Pho
28310420	Beef and rice soup, Puerto Rican style
28311010	Pepperpot soup
28311020	Menudo soup, home recipe
28311030	Menudo soup, canned, prepared with water or ready-to-serve
28315050	Beef vegetable soup with potato, pasta, or rice, chunky style, canned, or ready-to-serve
28315140	Beef vegetable soup, home recipe, Mexican style
28315150	Meat and corn hominy soup, home recipe, Mexican style
28315160	Italian Wedding Soup
28317010	Beef stroganoff soup, chunky style, home recipe, canned or ready-to-serve
28320140	Ham, noodle, and vegetable soup, Puerto Rican style
28320160	Pork vegetable soup with potato, pasta, or rice, stew type, chunky style
28320300	Pork with vegetable excluding carrots, broccoli and/or dark-green leafy; soup, Asian Style
28321130	Bacon soup, cream of, prepared with water
28331110	Lamb, pasta, and vegetable soup, Puerto Rican style
28340110	Chicken or turkey broth, bouillon, or consomme

28340120	Chicken or turkey broth, without tomato, home recipe
28340130	Chicken or turkey broth, with tomato, home recipe
28340150	Mexican style chicken broth soup stock
28340179	Beef broth, less or reduced sodium, canned or ready-to-serve
28340180	Chicken or turkey broth, less or reduced sodium, canned or ready-to-serve
28340210	Chicken rice soup, Puerto Rican style
28340220	Chicken soup with noodles and potatoes, Puerto Rican style
28340310	Chicken or turkey gumbo soup, home recipe, canned or ready-to-serve
28340510	Chicken or turkey noodle soup, chunky style, canned or ready-to-serve
28340550	Sweet and sour soup
28340580	Chicken or turkey soup with vegetables, broccoli, carrots, celery, potatoes and onions, Asian style
28340590	Chicken or turkey corn soup with noodles, home recipe
28340600	Chicken or turkey vegetable soup, canned, prepared with water or ready-to-serve
28340610	Chicken or turkey vegetable soup, stew type
28340630	Chicken or turkey vegetable soup with rice, stew type, chunky style
28340640	Chicken or turkey vegetable soup with noodles, stew type, chunky style, canned or ready-to-serve
28340660	Chicken or turkey vegetable soup, home recipe
28340670	Chicken or turkey vegetable soup with rice, home recipe, Mexican style
28340680	Chicken or turkey and corn hominy soup, home recipe, Mexican style
28340690	Chicken or turkey vegetable soup with potato and cheese, chunky style, canned or ready-to-serve
28340700	Bird's nest soup
28340750	Hot and sour soup
28340800	Chicken or turkey soup with vegetables and fruit, Asian Style
28345010	Chicken or turkey soup, cream of, canned, reduced sodium, NS as to made with milk or water
28345020	Chicken or turkey soup, cream of, canned, reduced sodium, made with milk
28345030	Chicken or turkey soup, cream of, canned, reduced sodium, made with water
28345110	Chicken or turkey soup, cream of, NS as to prepared with milk or water
28345120	Chicken or turkey soup, cream of, prepared with milk
28345130	Chicken or turkey soup, cream of, prepared with water
28345160	Chicken or turkey mushroom soup, cream of, prepared with milk
28350040	Fish stock, home recipe
28350050	Fish chowder
28350110	Crab soup, NS as to tomato-base or cream style
28350120	Crab soup, tomato-base
28350210	Clam chowder, NS as to Manhattan or New England style
28350220	Clam chowder, Manhattan
28350310	Turtle and vegetable soup
28351110	Fish and vegetable soup, no potatoes, Mexican style
28351120	Fish soup with potatoes, Mexican style

28351160	Codfish, rice, and vegetable soup, Puerto Rican style
28351170	Codfish soup with noodles, Puerto Rican style
28355110	Clam chowder, New England, NS as to prepared with water or milk
28355120	Clam chowder, New England, prepared with milk
28355130	Clam chowder, New England, prepared with water
28355140	Clam chowder, New England, reduced sodium, canned or ready-to-serve
28355210	Crab soup, cream of, prepared with milk
28355250	Lobster bisque
28355310	Oyster stew
28355350	Salmon soup, cream style
28355410	Shrimp soup, cream of, NS as to prepared with milk or water
28355420	Shrimp soup, cream of, prepared with milk
28355430	Shrimp soup, cream of, prepared with water
28355450	Seafood soup with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy
28355460	Seafood soup with potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy
28355470	Seafood soup with vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes
28355480	Seafood soup with vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes
28360100	Meat broth, Puerto Rican style
28360210	Spanish vegetable soup, Puerto Rican style
32300100	Egg drop soup
32301100	Garlic egg soup, Puerto Rican style
41601010	Bean soup, NFS
41601020	Bean with bacon or ham soup, canned or ready-to-serve
41601030	Black bean soup, home recipe, canned or ready-to-serve
41601040	Lima bean soup, home recipe, canned or ready-to-serve
41601070	Soybean soup, miso broth
41601080	Pinto bean soup, home recipe, canned or ready-to-serve
41601090	Bean soup, with macaroni, home recipe, canned, or ready-to-serve
41601110	Bean and ham soup, chunky style, canned or ready-to-serve
41601130	Bean soup, mixed beans, home recipe, canned or ready-to-serve
41601140	Bean soup, home recipe
41601160	Bean and ham soup, canned, reduced sodium, prepared with water or ready-to-serve
41601180	Bean and ham soup, home recipe
41601200	Liquid from stewed kidney beans, Puerto Rican style
41602010	Pea and ham soup, chunky style, canned or ready-to-serve
41602020	Garbanzo bean or chickpea soup, home recipe, canned or ready-to-serve
41602030	Split pea and ham soup
41602050	Split pea soup
41602070	Split pea soup, canned, reduced sodium, prepared with water or ready-to-serve
41602090	Split pea and ham soup, canned, reduced sodium, prepared with water or ready-to-serve

41603010	Lentil soup, home recipe, canned, or ready-to-serve
58155410	Soupy rice with chicken, Puerto Rican style
58155510	Soupy rice mixture with chicken and potatoes, Puerto Rican style
58400000	Soup, NFS
58400100	Noodle soup, NFS
58400200	Rice soup, NFS
58401010	Barley soup, home recipe, canned, or ready-to-serve
58401200	Barley soup, sweet, with or without nuts, Asian Style
58402010	Beef noodle soup, canned or ready-to-serve
58402020	Beef dumpling soup, home recipe, canned or ready-to-serve
58402030	Beef rice soup, home recipe, canned or ready-to-serve
58402100	Beef noodle soup, home recipe
58403010	Chicken or turkey noodle soup, canned or ready-to-serve
58403040	Chicken or turkey noodle soup, home recipe
58403050	Chicken or turkey noodle soup, cream of, home recipe, canned, or ready-to-serve
58403060	Chicken or turkey noodle soup, reduced sodium, canned or ready-to-serve
58403100	Noodle and potato soup, Puerto Rican style
58404010	Chicken or turkey rice soup, canned, or ready-to-serve
58404030	Chicken or turkey rice soup, home recipe
58404040	Chicken or turkey rice soup, reduced sodium, canned, prepared with water or ready-to-serve
58404050	Chicken or turkey rice soup, reduced sodium, canned, prepared with milk
58404100	Rice and potato soup, Puerto Rican style
58404500	Matzo ball soup
58404510	Chicken or turkey soup with dumplings and potatoes, home recipe, canned, or ready-to-serve
58404520	Chicken or turkey soup with dumplings, home recipe, canned or ready-to-serve
58407010	Instant soup, noodle
58407030	Soup, mostly noodles
58407035	Soup, mostly noodles, reduced sodium
58407050	Instant soup, noodle with egg, shrimp or chicken
58408010	Wonton soup
58408500	Noodle soup with vegetables, Asian style
58409000	Noodle soup, with fish ball, shrimp, and dark green leafy vegetable
58421000	Sopa seca, Mexican style, NFS
58421010	Sopa Seca de Fideo, Mexican style, made with dry noodles, home recipe
58421020	Sopa de Fideo Aguada, Mexican style noodle soup, home recipe
58421060	Sopa seca de arroz, home recipe, Mexican style
58421080	Sopa de tortilla, Mexican style tortilla soup, home recipe
63415100	Soup, fruit
71801000	Potato soup, NS as to made with milk or water
71801010	Potato soup, cream of, prepared with milk
71801020	Potato soup, prepared with water
71801100	Potato and cheese soup

71803010	Potato chowder
71851010	Plantain soup, Puerto Rican style
72302000	Broccoli soup, prepared with milk, home recipe, canned or ready-to-serve
72302020	Broccoli soup, prepared with water, home recipe, canned, or ready-to-serve
72302100	Broccoli cheese soup, prepared with milk, home recipe, canned, or ready-to-serve
72306000	Watercress broth with shrimp
72307000	Spinach soup
72308000	Dark-green leafy vegetable soup with meat, Asian style
72308500	Dark-green leafy vegetable soup, meatless, Asian style
73501000	Carrot soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
73501010	Carrot with rice soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
73502000	Squash, winter type, soup, home recipe, canned, or ready-to-serve
74601000	Tomato soup, NFS
74601010	Tomato soup, cream of, prepared with milk
74602010	Tomato soup, prepared with water, or ready-to-serve
74602050	Tomato soup, instant type, prepared with water
74602200	Tomato soup, canned, reduced sodium, prepared with water, or ready-to-serve
74602300	Tomato soup, canned, reduced sodium, prepared with milk
74603010	Tomato beef soup, prepared with water
74604010	Tomato beef noodle soup, prepared with water
74604100	Tomato beef rice soup, prepared with water
74604500	Tomato noodle soup, canned, prepared with water or ready-to-serve
74604600	Tomato noodle soup, canned, prepared with milk
74605010	Tomato rice soup, prepared with water
74606010	Tomato vegetable soup, prepared with water
74606020	Tomato vegetable soup with noodles, prepared with water
75600150	Soup, cream of, NFS
75601000	Asparagus soup, cream of, NS as to made with milk or water
75601010	Asparagus soup, cream of, prepared with milk
75601020	Asparagus soup, cream of, prepared with water
75601100	Borscht
75601200	Cabbage soup, home recipe, canned or ready-to-serve
75601210	Cabbage with meat soup, home recipe, canned or ready-to-serve
75603010	Celery soup, cream of, prepared with milk, home recipe, canned or ready-to-serve
75603020	Celery soup, cream of, prepared with water, home recipe, canned or ready-to-serve
75604010	Corn soup, cream of, prepared with milk
75604020	Corn soup, cream of, prepared with water
75604600	Gazpacho
75605010	Leek soup, cream of, prepared with milk
75607000	Mushroom soup, NFS
75607010	Mushroom soup, cream of, prepared with milk
75607020	Mushroom soup, cream of, prepared with water

75607040	Mushroom soup, with meat broth, prepared with water
75607050	Mushroom soup, cream of, low sodium, prepared with water
75607060	Mushroom soup, cream of, NS as to made with milk or water
75607080	Mushroom with chicken soup, cream of, prepared with milk
75607090	Mushroom soup, cream of, canned, reduced sodium, NS as to made with milk or water
75607100	Mushroom soup, cream of, canned, reduced sodium, prepared with milk
75607140	Mushroom soup, cream of, canned, reduced sodium, prepared with water
75608010	Onion soup, cream of, prepared with milk
75608100	Onion soup, French
75608200	Onion soup, made from dry mix
75609010	Pea soup, prepared with milk
75611010	Vegetable soup, cream of, prepared with milk
75612010	Zucchini soup, cream of, prepared with milk
75646010	Shav soup
75647000	Seaweed soup
75649010	Vegetable soup, canned, prepared with water or ready-to-serve
75649040	Vegetable soup, reduced sodium, canned, ready to serve
75649050	Vegetable soup, made from dry mix
75649110	Vegetable soup, home recipe
75649150	Vegetable noodle soup, home recipe
75650990	Minestrone soup, reduced sodium, canned or ready-to-serve
75651000	Minestrone soup, home recipe
75651010	Minestrone soup, canned, prepared with water, or ready-to-serve
75651020	Vegetable beef soup, canned, prepared with water, or ready-to-serve
75651030	Vegetable beef noodle soup, prepared with water
75651040	Vegetable noodle soup, canned, prepared with water, or ready-to-serve
75651070	Vegetable rice soup, canned, prepared with water or ready-to-serve
75651080	Vegetable beef soup with rice, canned, prepared with water or ready-to-serve
75651110	Vegetable chicken rice soup, canned, prepared with water or ready-to-serve
75651140	Vegetable soup with chicken broth, home recipe, Mexican style
75651150	Vegetable noodle soup, reduced sodium, canned, prepared with water or ready-to-serve
75652010	Vegetable beef soup, home recipe
75652030	Vegetable beef soup, canned, prepared with milk
75652040	Vegetable beef soup with noodles or pasta, home recipe
75652050	Vegetable beef soup with rice, home recipe
75656010	Vegetable soup, Spanish style, stew type
75656020	Vegetable soup, chunky style
75656040	Vegetable soup, with pasta, chunky style
75656060	Vegetable beef soup, chunky style
75657000	Vegetable broth, bouillon
POPCORN	
54403001	Popcorn, NFS

54403005	Popcorn, movie theater, with added butter
54403006	Popcorn, movie theater, unbuttered
54403010	Popcorn, air-popped, unbuttered
54403040	Popcorn, air-popped, with added butter or margarine
54403045	Popcorn, popped in oil, unbuttered
54403046	Popcorn, popped in oil, with added butter or margarine
54403051	Popcorn, microwave, NFS
54403052	Popcorn, microwave, plain
54403053	Popcorn, microwave, plain, light
54403054	Popcorn, microwave, low sodium
54403055	Popcorn, microwave, unsalted
54403056	Popcorn, microwave, butter flavored
54403057	Popcorn, microwave, butter flavored, light
54403058	Popcorn, microwave, cheese flavored
54403059	Popcorn, microwave, kettle corn
54403061	Popcorn, microwave, kettle corn, light
54403062	Popcorn, microwave, other flavored
54403080	Popcorn, ready-to-eat packaged, NFS
54403081	Popcorn, ready-to-eat packaged, plain
54403082	Popcorn, ready-to-eat packaged, plain, light
54403083	Popcorn, ready-to-eat packaged, low sodium
54403084	Popcorn, ready-to-eat packaged, unsalted
54403085	Popcorn, ready-to-eat packaged, butter flavored
54403086	Popcorn, ready-to-eat packaged, butter flavored, light
54403087	Popcorn, ready-to-eat packaged, cheese flavored
54403088	Popcorn, ready-to-eat packaged, cheese flavored, light
54403089	Popcorn, ready-to-eat-packaged, kettle corn
54403091	Popcorn, ready-to-eat packaged, kettle corn, light
54403092	Popcorn, ready-to-eat packaged, other flavored
54403110	Popcorn, caramel coated
54403120	Popcorn, caramel coated, with nuts
54403160	Popcorn, chocolate coated
POTATO CHIPS	
54402610	Potato chips, restructured, multigrain
71200010	Potato chips, NFS
71200100	Potato chips, plain
71200110	Potato chips, barbecue flavored
71200120	Potato chips, sour cream and onion flavored
71200130	Potato chips, cheese flavored
71200140	Potato chips, other flavored
71200200	Potato chips, ruffled, plain
71200210	Potato chips, ruffled, barbecue flavored

71200220	Potato chips, ruffled, sour cream and onion flavored
71200230	Potato chips, ruffled, cheese flavored
71200240	Potato chips, ruffled, other flavored
71200300	Potato chips, restructured, plain
71200310	Potato chips, restructured, flavored
71200400	Potato chips, baked, plain
71200410	Potato chips, baked, flavored
71201050	Potato chips, reduced fat
71201060	Potato chips, fat free
71201200	Potato chips, restructured, reduced fat, lightly salted
71201210	Potato chips, restructured, fat free
71202000	Potato chips, unsalted
71202100	Potato chips, reduced fat, unsalted
71202500	Potato chips, lightly salted
71202510	Potato chips, restructured, lightly salted
71203010	Potato chips, popped, plain
71203020	Potato chips, popped, flavored
71203030	Potato chips, popped, NFS
71205020	Potato sticks, plain
71205030	Potato sticks, flavored
71205040	Potato sticks, fry shaped
PRETZELS/SNACK MIX	
54402200	Snack mix
54408000	Pretzels, NFS
54408015	Pretzels, hard, NFS
54408016	Pretzels, hard, plain, salted
54408017	Pretzels, hard, plain, lightly salted
54408030	Pretzels, hard, plain, unsalted
54408035	Pretzels, hard, flavored
54408070	Pretzels, hard, multigrain
54408081	Pretzels, hard, plain, gluten free
54408082	Pretzels, hard, flavored, gluten free
54408105	Pretzel chips, hard, plain
54408110	Pretzel chips, hard, flavored
54408115	Pretzel chips, hard, gluten free
54408190	Pretzels, hard, coated, NFS
54408200	Pretzels, hard, chocolate coated
54408210	Pretzels, hard, white chocolate coated
54408250	Pretzels, hard, yogurt coated
54408260	Pretzels, hard, coated, gluten free
54408290	Pretzels, hard, filled, NFS
54408300	Pretzels, hard, cheese filled

54408310	Pretzels, hard, peanut butter filled
54408400	Pretzels, soft, NFS
54408405	Pretzels, soft, ready-to-eat, NFS
54408410	Pretzels, soft, ready-to-eat, salted, buttered
54408411	Pretzels, soft, ready-to-eat, unsalted, buttered
54408415	Pretzels, soft, ready-to-eat, salted, no butter
54408416	Pretzels, soft, ready-to-eat, unsalted, no butter
54408420	Pretzels, soft, ready-to-eat, cinnamon sugar coated
54408422	Pretzels, soft, ready-to-eat, coated or flavored
54408430	Pretzels, soft, ready-to-eat, topped with meat
54408432	Pretzels, soft, ready-to-eat, topped with cheese
54408450	Pretzels, soft, from frozen, NFS
54408455	Pretzels, soft, from frozen, salted
54408456	Pretzels, soft, from frozen, unsalted
54408460	Pretzels, soft, from frozen, cinnamon sugar coated
54408462	Pretzels, soft, from frozen, coated or flavored
54408465	Pretzels, soft, from frozen, topped with meat
54408466	Pretzels, soft, from frozen, topped with cheese
54408470	Pretzels, soft, filled with cheese
54408475	Pretzels, soft, from school lunch
54408480	Pretzels, soft, multigrain
54408485	Pretzels, soft, gluten free
54408486	Pretzels, soft, gluten free, cinnamon sugar coated
54408487	Pretzels, soft, gluten free, coated or flavored
54420220	Snack mix, plain (Chex Mix)
PORK	
22709010	Pork skin rinds
TORTILLA, CORN, OTHER CHIPS	
41310900	Bean chips
41410015	Soy chips
54318000	Chips, rice
54401011	Corn nuts
54401021	Corn chips, plain
54401026	Corn chips, flavored
54401031	Corn chips, plain (Fritos)
54401035	Corn chips, flavored (Fritos)
54401055	Cheese flavored corn snacks
54401065	Cheese flavored corn snacks, reduced fat
54401075	Tortilla chips, plain
54401081	Cheese flavored corn snacks (Cheetos)
54401085	Tortilla chips, flavored
54401090	Corn chips, reduced sodium

54401095	Tortilla chips, popped
54401110	Tortilla chips, nacho cheese flavor (Doritos)
54401111	Tortilla chips, cool ranch flavor (Doritos)
54401112	Tortilla chips, other flavors (Doritos)
54401121	Tortilla chips, reduced fat, plain
54401122	Tortilla chips, reduced fat, flavored
54401170	Tortilla chips, low fat, unsalted
54402080	Tortilla chips, reduced sodium
54404000	Popcorn chips, plain
54404010	Popcorn chips, other flavors
54404020	Popcorn chips, sweet flavors
54406010	Onion flavored rings
54406200	Shrimp chips
54420210	Multigrain chips (Sun Chips)
54440020	Cracker chips
71220000	Vegetable chips
71905410	Plantain chips
71980200	Taro chips
73410210	Sweet potato chips
VEGETABLE JUICE, OTHER FRUIT JUICE	
78101000	Vegetable and fruit juice, 100% juice, with high vitamin C
74301100	Tomato juice, 100%
74301150	Tomato juice, 100%, low sodium
74302000	Tomato juice cocktail
74303000	Tomato and vegetable juice, 100%
74303100	Tomato and vegetable juice, 100%, low sodium
75132000	Mixed vegetable juice
MEAL REPLACEMENTS	
95101000	Nutritional drink or shake, ready-to-drink (Boost)
95101010	Nutritional drink or shake, ready-to-drink (Boost Plus)
95102000	Nutritional drink or shake, ready-to-drink (Carnation Instant Breakfast)
95103000	Nutritional drink or shake, ready-to-drink (Ensure)
95103010	Nutritional drink or shake, ready-to-drink (Ensure Plus)
95104000	Nutritional drink or shake, ready-to-drink, sugar free (Glucerna)
95105000	Nutritional drink or shake, ready-to-drink (Kellogg's Special K Protein)
95106000	Nutritional drink or shake, ready-to-drink (Muscle Milk)
95106010	Nutritional drink or shake, ready-to-drink, light (Muscle Milk)
95110000	Nutritional drink or shake, ready-to-drink (Slim Fast)
95110010	Nutritional drink or shake, ready-to-drink, sugar free (Slim Fast)
95110020	Nutritional drink or shake, high protein, ready-to-drink (Slim Fast)
95120000	Nutritional drink or shake, ready-to-drink, NFS
95120010	Nutritional drink or shake, high protein, ready-to-drink, NFS

95120020	Nutritional drink or shake, high protein, light, ready-to-drink, NFS
95120050	Nutritional drink or shake, liquid, soy-based
NUTRITION BARS	
53710800	Cereal or granola bar (Kashi Chewy)
53710802	Cereal or granola bar (Kashi Crunchy)
53720100	Nutrition bar (Balance Original Bar)
53720200	Nutrition bar (Clif Bar)
53720210	Nutrition bar (Clif Kids Organic Zbar)
53720300	Nutrition bar (PowerBar)
53720400	Nutrition bar (Slim Fast Original Meal Bar)
53720500	Nutrition bar (Snickers Marathon Protein Bar)
53720600	Nutrition bar (South Beach Living Meal Bar)
53720610	Nutrition bar (South Beach Living High Protein Bar)
53720700	Nutrition bar (Tiger's Milk)
53720800	Nutrition bar (Zone Perfect Classic Crunch)
53729000	Nutrition bar or meal replacement bar, NFS
PROTEIN AND NUTRITIONAL POWDERS	
92900300	Sports drink, dry concentrate, not reconstituted
95201000	Nutritional powder mix (Carnation Instant Breakfast)
95201010	Nutritional powder mix, sugar free (Carnation Instant Breakfast)
95201200	Nutritional powder mix (EAS Whey Protein Powder)
95201300	Nutritional powder mix (EAS Soy Protein Powder)
95201500	Nutritional powder mix, high protein (Herbalife)
95201600	Nutritional powder mix (Isopure)
95201700	Nutritional powder mix (Kellogg's Special K20 Protein Water)
95202000	Nutritional powder mix (Muscle Milk)
95202010	Nutritional powder mix, light (Muscle Milk)
95210000	Nutritional powder mix (Slim Fast)
95210010	Nutritional powder mix, sugar free (Slim Fast)
95210020	Nutritional powder mix, high protein (Slim Fast)
95220000	Nutritional powder mix, NFS
95220010	Nutritional powder mix, high protein, NFS
95230000	Nutritional powder mix, whey based, NFS
95230010	Nutritional powder mix, protein, soy based, NFS
95230020	Nutritional powder mix, protein, light, NFS
95230030	Nutritional powder mix, protein, NFS
SMOOTHIE AND GRAIN DRINKS	
11553120	Fruit smoothie, with whole fruit and dairy, added protein
64134020	Fruit smoothie, with whole fruit, no dairy, added protein
78101110	Fruit and vegetable smoothie, added protein
78101118	Fruit and vegetable smoothie, non-dairy, added protein
MUSTARD AND OTHER CONDIMENTS	

74406060	Buffalo sauce
75503090	Horseradish
75506010	Mustard
75506100	Honey mustard dip
75511010	Hot pepper sauce
75534550	Wasabi paste
81302060	Horseradish sauce
81308100	Fry sauce
TOMATO-BASED CONDIMENTS	
74401010	Ketchup
74401110	Ketchup, reduced sodium
74402010	Tomato chili sauce
74402100	Salsa, NFS
74402110	Salsa, pico de gallo
74402150	Salsa, red, commercially prepared
74402200	Salsa, red, homemade
74402210	Taco sauce
74402250	Enchilada sauce, red
74406010	Barbecue sauce
74406100	Steak sauce
74406500	Cocktail sauce
MAYONNAISE	
81302040	Sandwich spread
81302050	Tartar sauce
83100200	Salad dressing, NFS, for sandwiches
83107000	Mayonnaise, regular
83110000	Mayonnaise-type salad dressing
83204000	Mayonnaise, light
83204030	Mayonnaise, reduced fat, with olive oil
83204050	Mayonnaise-type salad dressing, light
DIPS, GRAVIES, OTHER SAUCES	
13411000	White sauce or gravy
28500000	Gravy, poultry
28500040	Gravy, beef
28501010	Gravy, beef, fat free
28501110	Gravy, poultry, fat free
28520000	Gravy, made with soy sauce
28520010	Gravy, NFS
89901030	Gravy, for use with vegetables
CRACKERS	
51184000	Breadsticks, hard, NFS
51184100	Breadsticks, hard, reduced sodium

51185000	Croutons
51187000	Melba toast
51188500	Zwieback toast
51306000	Breadsticks, hard, whole wheat
51808050	Breadsticks, hard, gluten free
54001000	Crackers, NFS
54102050	Crackers, oatmeal
54103000	Crackers, breakfast biscuit
54200100	Crackers, butter, reduced sodium
54201010	Crackers, matzo, reduced sodium
54204020	Crackers, wheat, reduced sodium
54204030	Crackers, woven wheat, reduced sodium
54301010	Crackers, butter, plain
54301020	Crackers, butter, flavored
54301030	Crackers, butter (Ritz)
54301100	Crackers, butter, reduced fat
54304000	Crackers, cheese
54304005	Crackers, cheese (Cheez-It)
54304020	Crackers, cheese (Goldfish)
54304100	Crackers, cheese, reduced fat
54304110	Crackers, cheese, reduced sodium
54304150	Crackers, cheese, whole grain
54305010	Crackers, crispbread
54305020	Crackers, flatbread
54307000	Crackers, matzo
54308000	Crackers, milk
54318500	Rice cake
54319000	Crackers, rice
54319005	Crackers, rice and nuts
54319020	Popcorn cake
54319500	Rice paper
54326000	Crackers, multigrain
54328000	Crackers, sandwich
54328100	Crackers, sandwich, peanut butter filled
54328105	Crackers, sandwich, peanut butter filled (Ritz)
54328110	Crackers, sandwich, reduced fat, peanut butter filled
54328120	Crackers, whole grain, sandwich, peanut butter filled
54328200	Crackers, sandwich, cheese filled
54328210	Crackers, sandwich, cheese filled (Ritz)
54336000	Crackers, water
54336100	Crackers, wonton
54337010	Crackers, woven wheat

54337020	Crackers, woven wheat, plain (Triscuit)
54337030	Crackers, woven wheat, flavored (Triscuit)
54337060	Crackers, woven wheat, reduced fat
54338000	Crackers, wheat
54338010	Crackers, wheat, plain (Wheat Thins)
54338020	Crackers, wheat, flavored (Wheat Thins)
54338100	Crackers, wheat, reduced fat
54339000	Crackers, corn
54340100	Crackers, gluten free, plain
54340110	Crackers, gluten free, flavored
54402700	Pita chips
54440010	Bagel chips
56116000	Noodles, chow mein

EDI's of Intake of Nor-HydroPep DM from the Proposed Uses

The EDIs provided below include EDIs from use in conventional foods for ages 1+ years.

Table 1. EDIs of INGREDIENT from All Proposed Food and Beverage Uses in Conventional Foods (Per Capita)

Population Group	Age (Years)	N	Per Capita (g/person/day)		Per Capita (g/kg bw/day)	
			Mean	90th Percentile	Mean	90th Percentile
Female/Male Children	1 to 5	541	5.7	13.1	0.35	0.79
Female/Male Children	6 to 11	613	9.3	20.4	0.29	0.66
Male Teenager	12 to 18	350	9.3	19.3	0.16	0.33
Female Teenager	12 to 18	329	9.9	21.9	0.16	0.39
Male Adult	19+	1882	9.4	21.3	0.13	0.30
Female Adult	19+	1713	12.9	31.0	0.15	0.35
All Ages	1 to 110	5483	10.3	23.6	0.16	0.39

bw – body weight; mg – milligram; kg – kilogram

Table 2. EDIs of INGREDIENT from All Proposed Food and Beverage Uses in Conventional Foods (Consumer Only)

Population Group	Age (Years)	N	Consumer Only (g/person/day)		Consumer Only Intake (g/kg bw/day)	
			Mean	90th Percentile	Mean	90th Percentile
Female/Male Children	1 to 5	541	6.7	13.5	0.41	0.81
Female/Male Children	6 to 11	613	10.3	21.4	0.32	0.69
Male Teenager	12 to 18	350	10.8	19.9	0.19	0.34
Female Teenager	12 to 18	329	11.5	22.9	0.19	0.42
Male Adult	19+	1882	10.9	23.6	0.15	0.33
Female Adult	19+	1713	14.5	31.3	0.17	0.39
All Ages	1 to 110	5483	11.9	26.2	0.19	0.42

bw – body weight; mg – milligram; kg – kilogram

Food Intakes

Food Intake Reports of the food categories are provided below. All intakes are in grams and N equals the number of individuals reporting eating the foods and the "Percentage" is the percent of the population the "N" represents. "Per capita" intake refers to the estimated intake averaged over all individuals surveyed, regardless of whether they consumed food products in which the INGREDIENT is intended to be added. from the selected food codes in one of the two days of the survey. Individuals were considered "consumers" if they reported consumption of one or more food products on either Day 1 or Day 2 of the survey.

Table 1. Summary of Consumption of All Foods Grams/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	49.83	128.24	541	86.70	58.11	152.05
Children (6-11 years)	Male/Female	76.54	211.94	613	90.01	84.62	221.75
Teenage (12-18 years)	Female	81.06	237.33	350	88.16	94.77	256.65
Teenage (12-18 years)	Male	85.73	259.14	329	83.08	99.64	274.72
Adults (19+ years)	Female	94.38	278.80	1882	84.97	109.46	304.87
Adults (19+ years)	Male	118.36	339.91	1713	84.59	133.31	370.49
All ages	Total Population	96.85	279.87	5483	82.59	111.92	303.54

Table 2. Summary of Consumption of All Foods Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	3.16	7.97	541	86.70	3.69	8.71
Children (6-11 years)	Male/Female	2.36	6.39	613	90.01	2.61	6.98
Teenage (12-18 years)	Female	1.41	3.87	350	88.16	1.65	4.59
Teenage (12-18 years)	Male	1.43	4.32	329	83.08	1.67	4.68
Adults (19+ years)	Female	1.31	3.84	1882	84.97	1.52	4.23
Adults (19+ years)	Male	1.36	3.71	1713	84.59	1.53	3.92
All ages	Total Population	1.53	4.31	5483	82.59	1.77	4.67

Table 3. Summary of Consumption of Soups Grams/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	24.41	93.23	126	20.19	126.66	263.84
Children (6-11 years)	Male/Female	35.61	128.92	131	19.24	182.72	346.71
Teenage (12-18 years)	Female	40.84	160.13	91	22.92	215.69	408.28
Teenage (12-18 years)	Male	39.38	152.90	74	18.69	238.97	476.33
Adults (19+ years)	Female	51.15	224.56	543	24.51	231.83	404.13
Adults (19+ years)	Male	59.67	247.00	414	20.44	297.66	494.00

All ages	Total Population	49.80	216.60	1405	21.16	244.44	442.15

Table 4. Summary of Consumption of Soups Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	1.58	6.32	126	20.19	8.21	15.45
Children (6-11 years)	Male/Female	1.11	3.98	131	19.24	5.68	11.23
Teenage (12-18 years)	Female	0.70	2.72	91	22.92	3.68	6.67
Teenage (12-18 years)	Male	0.69	2.55	74	18.69	4.19	7.83
Adults (19+ years)	Female	0.70	2.82	543	24.51	3.17	5.81
Adults (19+ years)	Male	0.69	2.85	414	20.44	3.46	7.12
All ages	Total Population	0.78	2.96	1405	21.16	3.84	7.26

Table 5. Summary of Consumption of Snack Foods Grams/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	18.92	42.46	468	75.00	25.44	50.50
Children (6-11 years)	Male/Female	25.96	68.73	496	72.83	34.89	78.48
Teenage (12-18 years)	Female	21.87	62.45	271	68.26	32.11	70.67
Teenage (12-18 years)	Male	23.57	63.71	240	60.61	36.75	85.17
Adults (19+ years)	Female	15.75	45.27	1237	55.85	26.62	59.32
Adults (19+ years)	Male	18.75	49.21	1057	52.20	33.38	67.22
All ages	Total Population	18.28	49.22	3803	57.28	30.37	64.68

Table 6. Summary of Consumption of Snack Foods Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	1.19	2.83	468	75.00	1.60	2.94
Children (6-11 years)	Male/Female	0.82	2.02	496	72.83	1.10	2.19
Teenage (12-18 years)	Female	0.36	1.02	271	68.26	0.53	1.18
Teenage (12-18 years)	Male	0.41	1.09	240	60.61	0.64	1.61
Adults (19+ years)	Female	0.21	0.56	1237	55.85	0.35	0.80
Adults (19+ years)	Male	0.21	0.56	1057	52.20	0.38	0.79
All ages	Total Population	0.33	0.90	3803	57.28	0.55	1.22

Table 7. Summary of Consumption of Condiments Gram/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	4.26	14.00	244	39.10	10.13	23.27
Children (6-11 years)	Male/Female	8.84	26.68	373	54.77	15.79	34.39
Teenage (12-18 years)	Female	10.21	25.95	190	47.86	20.52	40.09
Teenage (12-18 years)	Male	11.71	31.12	213	53.79	19.45	34.00
Adults (19+ years)	Female	8.87	22.50	1100	49.66	17.32	41.49
Adults (19+ years)	Male	16.32	42.51	1185	58.52	26.00	58.21

All ages	Total Population	11.37	30.00	3310	49.86	20.69	45.33

Table 8. Summary of Consumption of Condiments Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.25	0.84	244	39.10	0.60	1.35
Children (6-11 years)	Male/Female	0.27	0.75	373	54.77	0.48	1.03
Teenage (12-18 years)	Female	0.17	0.44	190	47.86	0.35	0.58
Teenage (12-18 years)	Male	0.18	0.49	213	53.79	0.30	0.63
Adults (19+ years)	Female	0.12	0.30	1100	49.66	0.23	0.51
Adults (19+ years)	Male	0.19	0.48	1185	58.52	0.30	0.65
All ages	Total Population	0.17	0.44	3310	49.86	0.30	0.67

Table 9. Summary of Consumption of Dips, Gravies, and Sauces Gram/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.19	0.00	6	0.96	30.43	110.94
Children (6-11 years)	Male/Female	1.46	0.00	25	3.67	35.90	86.23
Teenage (12-18 years)	Female	0.48	0.00	5	1.26	39.46	64.76
Teenage (12-18 years)	Male	1.64	0.00	6	1.52	67.63	180.00
Adults (19+ years)	Female	1.26	0.00	69	3.12	36.57	74.81
Adults (19+ years)	Male	1.71	0.00	78	3.85	49.21	98.60
All ages	Total Population	1.34	0.00	189	2.85	42.71	90.00

Table 10. Summary of Consumption of Dips, Gravies, and Sauces Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.01	0.00	6	0.96	1.89	6.76
Children (6-11 years)	Male/Female	0.05	0.00	25	3.67	1.11	2.37
Teenage (12-18 years)	Female	0.01	0.00	5	1.26	0.71	1.17
Teenage (12-18 years)	Male	0.02	0.00	6	1.52	0.93	2.04
Adults (19+ years)	Female	0.02	0.00	69	3.12	0.45	0.76
Adults (19+ years)	Male	0.02	0.00	78	3.85	0.59	1.12
All ages	Total Population	0.02	0.00	189	2.85	0.61	1.12

Table 11. Summary of Consumption of Vegetable Juice Gram/Day (2017-2018)

		Per Capita Intake		Consumer-only Intake			
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.22	0.00	5	0.80	49.22	62.00
Children (6-11 years)	Male/Female	1.11	0.00	2	0.29	134.00	139.50
Teenage (12-18 years)	Female	0.38	0.00	1	0.25	248.00	248.00
Teenage (12-18 years)	Male	4.77	0.00	2	0.51	196.37	248.00
Adults (19+ years)	Female	3.05	0.00	39	1.76	171.45	290.22
Adults (19+ years)	Male	4.61	0.00	32	1.58	256.78	624.19

All ages	Total Population	3.22	0.00	82	1.24	204.69	372.00

Table 12. Summary of Consumption of Vegetable Juice Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.02	0.00	5	0.80	4.51	6.08
Children (6-11 years)	Male/Female	0.03	0.00	2	0.29	4.10	4.23
Teenage (12-18 years)	Female	0.00	0.00	1	0.25	2.84	2.84
Teenage (12-18 years)	Male	0.07	0.00	2	0.51	2.71	2.85
Adults (19+ years)	Female	0.05	0.00	39	1.76	2.78	5.52
Adults (19+ years)	Male	0.04	0.00	32	1.58	2.41	5.90
All ages	Total Population	0.04	0.00	82	1.24	2.71	5.25

Table 13. Summary of Consumption of Nutrition Bars Gram/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.29	0.00	6	0.96	29.96	74.25
Children (6-11 years)	Male/Female	1.25	0.00	14	2.06	28.56	48.61
Teenage (12-18 years)	Female	0.55	0.00	4	1.01	29.46	39.00
Teenage (12-18 years)	Male	0.60	0.00	10	2.53	42.93	103.17
Adults (19+ years)	Female	1.78	0.00	54	2.44	40.85	94.52
Adults (19+ years)	Male	1.90	0.00	53	2.62	41.93	74.46
All ages	Total Population	1.56	0.00	141	2.12	39.87	75.48

Table 14. Summary of Consumption of Nutrition Bars Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.02	0.00	6	0.96	1.61	3.06
Children (6-11 years)	Male/Female	0.04	0.00	14	2.06	0.84	1.57
Teenage (12-18 years)	Female	0.01	0.00	4	1.01	0.51	0.70
Teenage (12-18 years)	Male	0.01	0.00	10	2.53	0.60	1.34
Adults (19+ years)	Female	0.03	0.00	54	2.44	0.59	1.13
Adults (19+ years)	Male	0.02	0.00	53	2.62	0.51	1.21
All ages	Total Population	0.02	0.00	141	2.12	0.59	1.29

Table 15. Summary of Consumption of Protein Drinks Gram/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.11	0.00	8	1.28	8.41	16.88
Children (6-11 years)	Male/Female	0.58	0.00	6	0.88	39.53	87.75
Teenage (12-18 years)	Female	1.79	0.00	8	2.02	38.10	151.84
Teenage (12-18 years)	Male	0.97	0.00	11	2.78	46.60	107.65
Adults (19+ years)	Female	5.90	0.00	87	3.93	115.75	391.50
Adults (19+ years)	Male	9.38	0.00	75	3.70	174.49	485.20

All ages	Total Population	5.89	0.00	195	2.94	132.33	405.76

Table 16. Summary of Consumption of Protein Drinks Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.01	0.00	8	1.28	0.60	1.27
Children (6-11 years)	Male/Female	0.01	0.00	6	0.88	1.02	1.82
Teenage (12-18 years)	Female	0.03	0.00	8	2.02	0.63	2.71
Teenage (12-18 years)	Male	0.01	0.00	11	2.78	0.67	1.20
Adults (19+ years)	Female	0.09	0.00	87	3.93	1.83	6.37
Adults (19+ years)	Male	0.10	0.00	75	3.70	1.91	5.27
All ages	Total Population	0.08	0.00	195	2.94	1.74	5.09

Table 17. Summary of Consumption of Meal Replacements Gram/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	1.42	0.00	5	0.80	137.44	226.80
Children (6-11 years)	Male/Female	1.73	0.00	5	0.73	198.82	307.94
Teenage (12-18 years)	Female	4.93	0.00	4	1.01	700.11	1280.00
Teenage (12-18 years)	Male	3.09	0.00	7	1.77	138.43	310.87
Adults (19+ years)	Female	6.61	0.00	55	2.48	229.02	412.00
Adults (19+ years)	Male	6.02	0.00	43	2.12	247.03	376.62
All ages	Total Population	5.38	0.00	119	1.79	234.60	381.23

Table 18. Summary of Consumption of Meal Replacements Grams/Kg (Body Weight)/Day (2017-2018)

		Per Capita Intake			Consumer-only Intake		
Age Group	**Gender**	**Mean**	**90th**	**N**	**Percentage**	**Mean**	**90th**
Children (1-5 years)	Male/Female	0.08	0.00	5	0.80	8.15	15.26
Children (6-11 years)	Male/Female	0.04	0.00	5	0.73	4.37	5.16
Teenage (12-18 years)	Female	0.12	0.00	4	1.01	17.21	32.24
Teenage (12-18 years)	Male	0.04	0.00	7	1.77	1.86	4.21
Adults (19+ years)	Female	0.10	0.00	55	2.48	3.59	4.78
Adults (19+ years)	Male	0.08	0.00	43	2.12	3.15	5.07
All ages	Total Population	0.08	0.00	119	1.79	3.67	5.22

Appendix 7 Expert Panel Report

THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF THE PROPOSED USES OF NORILIA AS'S NOR-HYDROPEP DM

December 22, 2022

Foreword

An independent panel of experts ("Expert Panel") was convened by GRAS Associates, LLC on behalf of their client, Norilia AS ("Norilia"), to evaluate the safety and Generally Recognized as Safe (GRAS) status of Norilia's proposed uses of Nor-HydroPep DM in conventional foods. The members of this Expert Panel† are qualified to serve in this capacity by qualification of scientific training and experience in the safety of food and food ingredients.

Discussion

Nor-HydroPep DM is hydrolyzed poultry protein and is primarily composed of protein-derived peptides with lesser amounts of fat, moisture, and ash. Nor-HydroPep DM is rich in amino acids including the eight essential amino acids in addition to other non-essential amino acids. Nor-HydroPep DM is manufactured from raw turkey and chicken carcasses and the Expert Panel has reviewed the quality specifications Norilia has set for these raw materials and has no safety concerns. Nor-HydroPep DM is manufactured using enzyme hydrolysis under Current Good Manufacturing Practices (CGMP) and no safety concerns were identified by the Expert Panel. Norilia has set specifications that are appropriate and sufficient for an ingredient intended for human consumption and are verified using appropriate methods. Norilia has also demonstrated that their production process consistently yields a reproducible product, as detailed in the GRAS dossier, to the satisfaction of the Expert Panel.

Norilia has conducted a stability study of Nor-HydroPep DM at various temperatures ranging from 4°C to 50°C for a period of 12 months. During the stability study, samples were collected for analysis of dry matter, vitamin content, antioxidant level, free and total amino acids, fat and fatty acid content, mineral and ash content bioactive content, biogenic amines formation, molecular weight distribution, oxidation product formation, and microbiology. The Expert Panel agrees with Norilia that the results from their stability study are sufficient to conclude that the ingredient is well-suited for use in conventional foods.

Norilia intends to use their Nor-HydroPep DM as an ingredient in processed foods (excluding infant formulas) and medical foods as a replacement for other protein sources. The intended use levels

† Dr. Dziwenka, Chair of the Expert Panel, holds a Doctor of Veterinary Medicine degree from the University of Saskatchewan and is a Diplomate with the American Board of Toxicology. She has over 24 years' experience as a practicing veterinarian and 20 years of experience in research, preclinical regulatory toxicology, and safety evaluation of food and animal feed additives and GRAS dossier preparation. Dr. Kraska holds a PhD in Pharmacology and has over 35 years of experience related to assessing safety of food additives, GRAS ingredients and food contact materials. Dr. Kraska worked on GRAS and food additive safety issues within FDA's Division of Food and Color Additives earlier in his career, and subsequently continued working within this area in the private sector. Dr. Slavin is a professor in the Department of Food Science and Nutrition at the University of Minnesota. Dr. Slavin holds a Ph.D. in Nutritional Sciences and has authored more than 300 publications related to dietary fiber, carbohydrates, whole grains, protein, and the role of diet in disease prevention. . All three panelists have extensive technical backgrounds in the evaluation of food ingredient safety and in participating in deliberations of GRAS Expert Panels.

vary but range from 5 to 10 g per serving for the processed foods and up to 20 g per serving when used as a protein source in nutrition bars, protein drinks, meal replacements and medical food applications. The intake analysis for Norilia's Nor-HydroPep DM was conducted utilizing information from the 2017 – 2018 National Health and Nutrition Examination Survey . The Expert Panel reviewed Norilia's calculations of the estimated dietary exposures outlined in Part 3 of the dossier and has no questions regarding the estimated intakes and accepts that the highest intake of their Nor-HydroPep DM would be in adult males, with an estimated mean and 90th percentile consumer-only intake of 14.5 and 31.3 g/day, respectively. On a body weight basis, the highest intake would be in children 1 – 5 years of age with a mean and 90th percentile intake of 0.41 and 0.81 mg/kg bw/day, respectively. The Expert Panel agrees that the total daily intake estimations are likely overestimates and that it is unlikely that consumers would ingest all of the Nor-HydroPep DM -fortified foods on a daily basis. Norilia estimated the mean and 90th percentile intake of protein and amino acids from consumption of their Nor-HydroPep DM and the Expert Panel has no concerns with these estimations.

The Expert Panel reviewed the information in Part 6 of Norilia's dossier and considered the following evidence as a basis for the safety evaluation of their Nor-HydroPep DM. Nor-HydroPep DM is produced under CGMP and Norilia's manufacturing procedures and the specifications established are adequate to define a suitable purity to be considered food grade. The evaluation of five nonconsecutive lots of Nor-HydroPep DM indicates that it is consistently able to be produced to those specifications. The Expert Panel reviewed the typical amino acid profile of Nor-HydroPep DM and the comparison to Proteus Industries' poultry protein in GRN 168 and has no concerns regarding the profile. Norilia based their conclusion of safety on the long history of consumption and wide use of protein isolates, specifically poultry derived protein and protein isolates, as well as animal and human safety studies conducted with protein hydrolysates. The Expert Panel notes that Norilia does not selectively isolate bioactive peptides during their manufacturing process for No-HydroPep DM. The Expert Panel evaluated the information provided by Norilia and does raise any safety concerns.

The composite evidence presented in Norilia's GRAS dossier, which included animal and human studies conducted with protein hydrolysates, as well as the long history of consumption of poultry protein and other information available in the published literature, demonstrate the safety of Norilia's Nor-HydroPep DM for human consumption at the intended use levels.

Conclusion

The Expert Panel individually and collectively performed a critical evaluation of the data provided by Norilia for their Nor-HydroPep DM, as well as publicly available published information obtained from peer-reviewed journals relevant to this safety evaluation.

The Expert Panel evaluated key evidence---specifically, the studies conducted with protein hydrolysates and the long history of human consumption of poultry protein and concurs with Norilia's conclusion that the ingestion of their Nor-HydroPep DM for the intended uses results in intakes that are safe.

Thus, the Expert Panel unanimously concludes that the proposed uses of Norilia's Nor-HydroPep DM, manufactured as described in Norilia's GRAS dossier, and declared within the subject notification meets the FDA definition of safety in that there is "reasonable certainty of no harm under the intended conditions of use" as described herein, and Norilia's Nor-HydroPep DM is generally recognized as safe (GRAS).

This declaration is made in accordance with FDA's food ingredient safety standard, i.e., reasonable certainty of no harm under the intended conditions of use. It is our opinion that other qualified and competent scientists reviewing the same publicly available information would reach the same conclusions.

Margitta Dziwenka, DVM, DABT
Panel Chair

Rich Kraska, Ph.D.

Joanne Slavin, Ph.D.

END

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE (Subpart E of Part 170)

Form Approved: OMB No. 0910-0342; Expiration Date: 07/31/2022
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER	DATE OF RECEIPT
001132	Feb 13, 2023
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see Instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration,5001 Campus Drive, College Park, MD 20740-3835.

SECTION A – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

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

3 Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd):* _____

4 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):* _____

SECTION B – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position or Title
Øystein Danielsen	Director Ingredientes
Organization *(if applicable)*	
Norilia AS	
Mailing Address *(number and street)*	
Lørenveien 37	

City	State or Province	Zip Code/Postal Code	Country
Oslo	.	0585	Norway

Telephone Number	Fax Number	E-Mail Address
+47 9576 5880		oystein.danielsen@norilia.no

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

Name of Contact Person	Position or Title
William J. Rowe	President, CEO
Organization *(if applicable)*	
GRAS Associates, LLC	
Mailing Address *(number and street)*	
11810 Grand Park Ave, Suite 500	

City	State or Province	Zip Code/Postal Code	Country
North Bethesda	Maryland	20852	United States of America

Telephone Number	Fax Number	E-Mail Address
519-341-3667	888-531-3466	amozingo@gras-associates.com

SECTION C – GENERAL ADMINISTRATIVE INFORMATION

1. Name of notified substance, using an appropriately descriptive term

Hydrolyzed poultry protein or poultry protein isolate (tradename Nor-HydroPep DM)

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

☐ Electronic Submission Gateway

☒ Electronic files on physical media

☐ Paper

If applicable give number and type of physical media

1 CD

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

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

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

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

☐ a) GRAS Notice No. GRN _____

☐ b) GRAS Affirmation Petition No. GRP _____

☐ c) Food Additive Petition No. FAP _____

☐ d) Food Master File No. FMF _____

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

6. Statutory basis for conclusions of GRAS status *(Check one)*

☒ Scientific procedures *(21 CFR 170.30(a) and (b))* ☐ Experience based on common use in food *(21 CFR 170.30(a) and (c))*

7. Does the submission (including information that you are incorporating) contain information that you view as trade secret or as confidential commercial or financial information? (see 21 CFR 170.225(c)(8) and 170.250(d) and (e))

☐ Yes *(Proceed to Item 8*

☒ No *(Proceed to Section D)*

8. 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, information is designated at the place where it occurs in the submission

☐ No

9. 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

SECTION D – INTENDED USE

1. Describe the intended conditions of use of the notified substance, including the foods in which the substance will be used, the levels of use in such foods, and the purposes for which the substance will be used, including, when appropriate, a description of a subpopulation expected to consume the notified substance.

The ingredient is intended for use in processed food products (excluding infant formula) as a flavoring and source of protein in soups, snacks, tomato-based vegetable juices, gravies, condiments, nutrition bars, protein drinks, meal replacements, and medical food applications. The intended use levels vary with 2 grams per serving in seasonings, gravies and sauces, between 5-10 grams per serving for processed foods and up to 20 grams per serving when used as a protein source in protein drinks, nutrition bars, meal replacements and medical food applications.

2. Does the intended use of the notified substance include any use in product(s) subject to regulation by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture?

(Check one)

☒ Yes ☐ No

3. If your submission contains trade secrets, do you authorize FDA to provide this information to the Food Safety and Inspection Service of the U.S. Department of Agriculture?

(Check one)

☒ Yes ☐ No , you ask us to exclude trade secrets from the information FDA will send to FSIS.

SECTION E – PARTS 2 -7 OF YOUR GRAS NOTICE

(check list to help ensure your submission is complete – PART 1 is addressed in other sections of this form)

☒ PART 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect (170.230).

☒ PART 3 of a GRAS notice: Dietary exposure (170.235).

☒ PART 4 of a GRAS notice: Self-limiting levels of use (170.240).

☒ PART 5 of a GRAS notice: Experience based on common use in foods before 1958 (170.245).

☒ PART 6 of a GRAS notice: Narrative (170.250).

☒ PART 7 of a GRAS notice: List of supporting data and information in your GRAS notice (170.255)

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

☒ Yes ☐ No

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

☒ Yes ☐ No

SECTION F – SIGNATURE AND CERTIFICATION STATEMENTS

1. The undersigned is informing FDA that Norilia AS
(name of notifier)

has concluded that the intended use*(s)* of Hydrolyzed poultry protein or poultry protein isolate (tradename Nor-HydroPep DM)
(name of notified substance)

described on this form, as discussed in the attached notice, is (are) not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is generally recognized as safe recognized as safe under the conditions of its intended use in accordance with § 170.30.

2. Norilia AS *(name of notifier)* agrees to make the data and information that are the basis for the conclusion of GRAS status available to FDA if FDA asks to see them; agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so; agrees to send these data and information to FDA if FDA asks to do so.

Lørenveien 37, 0585 Oslo, Norway
(address of notifier or other location)

The notifying party certifies that this GRAS notice is a complete, representative, and balanced submission that includes unfavorable, as well as favorable information, pertinent to the evaluation of the safety and GRAS status of the use of the substance.The notifying party certifies that the information provided herein is accurate and complete to the best or his/her knowledge. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

3. Signature of Responsible Official, Agent, or Attorney	Printed Name and Title	Date (mm/dd/yyyy)
Amy Mozingo Digitally signed by Amy Mozingo Date: 2023.02.07 12:30:06 -05'00'	Amy Mozingo on behalf of William J. Rowe, President	02/06/2023

SECTION G – 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)
	G10611_FDA Form 3667.pdf Nor-HydroPep DM_GRAS Notice Transmittal Letter.pdf Norilia Poultry Protein GRAS Conclusion_21Dec2022_FINAL_Signed.pdf	CD

OMB Statement: Public reporting burden for this collection of information is estimated to average 170 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: Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, **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.

From: Amy Mozingo
To: Downey, Jason
Cc: William J. Rowe
Subject: RE: [EXTERNAL] FW: GRN 001132 - FDA"s Questions for the Notifier
Date: Thursday, August 10, 2023 4:30:52 PM
Attachments: image001.png
image002.png
GRN 1132_Response to FDA 27July2023 Questions_10Aug2023.pdf

Hi Jason,

Please find attached the responses to questions posed in your July 27th email.
If there are any more questions, or concerns that the responses do not adequately address FDA/USDA questions, please let me know. I am readily available for a call to discuss (see cell phone number below).
Best Regards
Amy

Amy Mozingo, MS
VP US Nutra Regulatory Sciences
GRAS Associates a Nutrasource Pharmaceutical and Nutraceutical Services company
O: 301-461-8929| C: 772-532-3454
LinkedIn | Twitter | Blog

From: Downey, Jason <Jason.Downey@fda.hhs.gov>
Sent: Friday, July 28, 2023 12:05 PM
To: Amy Mozingo <amozingo@gras-associates.com>
Cc: William J. Rowe <wrowe@nutrasource.ca>
Subject: RE: [EXTERNAL] FW: GRN 001132 - FDA's Questions for the Notifier

Hi Amy,
Thanks for confirming receipt and the timeline.
Have a great weekend!
Jason

From: Amy Mozingo <amozingo@gras-associates.com>
Sent: Friday, July 28, 2023 12:01 PM
To: Downey, Jason <Jason.Downey@fda.hhs.gov>
Cc: William J. Rowe <wrowe@nutrasource.ca>
Subject: [EXTERNAL] FW: GRN 001132 - FDA's Questions for the Notifier
Importance: High

Good Afternoon Dr. Downey,
Thank you for your email. I am confirming receipt of the questions for GRN 1132. Per the transmittal letter, William Rowe has authorized me to communicate directly with FDA on this notification. We intend to provide a response within 10 business days (on or before August 10th).
Regards
Amy

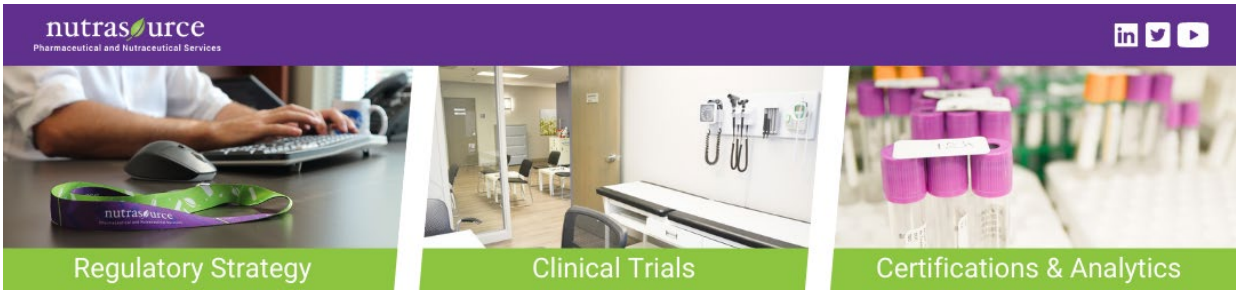
Amy Mozingo, MS
VP US Nutra Regulatory Sciences
GRAS Associates a Nutrasource Pharmaceutical and Nutraceutical Services company
O: 301-461-8929| C: 772-532-3454
LinkedIn | Twitter | Blog

From: William J. Rowe <wrowe@nutrasource.ca>
Sent: Thursday, July 27, 2023 4:03 PM
To: Amy Mozingo <amozingo@gras-associates.com>
Subject: FW: GRN 001132 - FDA's Questions for the Notifier
Importance: High

William J. Rowe, BA
President, CEO and Co-founder
O: 519-341-3360 | C: 519-827-8129

nutrasource
Pharmaceutical and Nutraceutical Services
Certifications GRAS nutrasource asia

LinkedIn | Twitter | Blog



From: Downey, Jason <Jason.Downey@fda.hhs.gov>
Sent: Thursday, July 27, 2023 3:54 PM
To: William J. Rowe <wrowe@nutrasource.ca>
Subject: GRN 001132 - FDA's Questions for the Notifier

Hi William,

During our evaluation of GRN 001132, regarding Norilia's intended uses of hydrolyzed poultry protein in food, we noted questions and points in need of clarification, which are listed below. Please provide responses to these requests within **10 business days**. If you foresee any issue with this timeline or you have any other questions, please contact me as soon as possible.

Thank you in advance for your attention to our comments.

Sincerely,

Jason

Jason Downey, Ph.D. (he/him/his)
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
jason.downey@fda.hhs.gov

FDA's Questions for the Notifier

1. You provided the intended uses of hydrolyzed poultry protein in Table 8 on page 17 of GRN 001132. Please provide the maximum use levels as a percentage for each of the food categories in which the ingredient is intended to be used.
2. Please confirm that the intended uses of hydrolyzed poultry protein (including the use in medical foods) would be substitutional for uses of other animal and vegetable protein sources added to food and therefore will not increase the cumulative dietary exposure to protein.
3. According to our fortification policy (21 CFR 104.20), FDA does not consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. If your intended uses of hydrolyzed poultry protein are not substitutional, please explain how your intended uses in meat, poultry, or fish products and snack foods are consistent with FDA's fortification policy.
4. We note that a medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation (21 CFR 101.9(j)(8)). See also FDA's recently updated guidance document on medical foods.

   Please specify the types of medical foods in which the ingredient is intended to be use, the target population with a disease or condition the dietary management of which cannot be achieved by the modification of the normal diet alone and provide a provide a basis for concluding the intended use of hydrolyzed poultry protein is GRAS. If you are not able to provide this information, we recommend that you remove the medical food use from the intended uses of the ingredient.
5. On page 35 you state that the prevalence of poultry meat allergy is rare with a worldwide occurrence of 0 – 13%. It was not clear where you obtained the provided numerical data range, as 13% seems relatively high, please elaborate. In addition, please provide more details in your narrative describing the current state of science regarding allergy to poultry meat as well as assurance that sensitive consumers will be protected because products containing your ingredient will be labeled in the ingredient list. (see, Wanniang, N., Codreanu-Morel, F., Kuehn, A. et al. Poultry Meat allergy: a Review of Allergens and Clinical Phenotypes. Curr Treat Options Allergy 9, 187–203 (2022), for a recent review of the subject of poultry-related allergy)]
6. On page 16, the notice states that the notified substance results in a "bitter and burnt" flavoring effect. This is generally considered an undesirable flavoring effect which seems to suggest the ingredient is not suitable for its intended use within meat and poultry products. Please explain why these flavors would be wanted in soups. Alternatively, please provide additional suitability data that demonstrates the notified substance imparts desirable flavor

attributes in meat and poultry products.

7. In the notice, use levels for FSIS regulated products appear to be as a flavoring agent in soups at levels of up to 2.45% and in seasoning blends/rubs for meat and poultry products generally at levels of up to 2%. Please confirm the use level for use in soups and clarify for seasoning blends whether this is as a percentage of the seasoning blend or the total product formula.

GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
T: 519.341.3667 | F: 888.531.3466
www.gras-associates.com

August 10, 2023

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety
Division of Petition Review
5001 Campus Drive
College Park, MD 20740-3835

Attention: Dr. Jason Downey
Re: GRN 001132—Response to Questions Posed in an Email Dated July 27, 2023

Dear Dr. Downey:

Per your request, GRAS Associates, LLC, acting as the agent for Norilia AS, is providing a response to FDA's request.

FDA Request:
During our evaluation of GRN 001132, regarding Norilia's intended uses of hydrolyzed poultry protein in food, we noted questions and points in need of clarification, which are listed below. Please provide responses to these requests within 10 business days. If you foresee any issue with this timeline or you have any other questions, please contact me as soon as possible.

FDA Question 1:
You provided the intended uses of hydrolyzed poultry protein in Table 8 on page 17 of GRN 001132. Please provide the maximum use levels as a percentage for each of the food categories in which the ingredient is intended to be used.

Response:
Table 1 below provides the use levels as a percentage for each of the food categories in which the ingredient is intended to be used.

Table 1. Proposed Intended use for Nor-HydroPep DM

Food Category (per 21CFR170.3)	Proposed Food Uses	Maximum Use Levels (g) per serving	Maximum Use Levels (% of finished food)	RACC[1]
Condiments and Relishes	Mayonnaise and other condiments	5	29	15-17 g

Food Category (per	Proposed Food Uses	Maximum Use Levels (g) per serving	Maximum Use Levels (% of finished food)	RACC[1]
Processed Vegetables, Vegetable Juices	Tomato-based juices	5	2	240 mL
Gravies & Sauces	Gravies	2	3	60 g
Herbs, Seeds, Spices, Seasonings, Blends, Extracts, and Flavorings	Seasonings for meat coatings/rubs and in seasoning pastes	N/A[2]	2	Not applicable
Soups & Soup Mixes	Soups	10	4	245 g
Snack Foods	Popcorn, pretzels, chips, & crackers	5	17	30 g
Not Specified	Nutrition Bars	20	50	40 g
Not Specified	Protein drinks & protein powder mixes	20	8	240 mL
Not Specified	Ready-to-drink meal replacements & nutritional beverages	20	8	240 mL
Not Specified	Medical Foods (protein component only) for enteral tube feeding	20[3]	8	RACC Not Specified (240 mL)

g – gram; mL – milliliter; RACC – Reference Amounts Customarily Consumed

1. RACC based on values established in 21 CFR §101.12. When a range of values is reported for a proposed food-use, particular foods within that food-use may differ with respect to their RACC. RACCs reported with household measure were converted to g based on USDA Food Central Database (https://fdc.nal.usda.gov/).

2. Maximum use rate of 2g/100 g in seasoning blend. Blended seasonings used in meat products are used at low levels, usually around 3% and rarely exceed 10% (Brown, 2009). Therefore, the consumption of Nor-HydroPep used in seasoning blends for processed meat products will be negligible.

3. Medical foods are not included in the intake analysis because these are not consumed by the general population and are prescribed under the supervision of a physician. Medical Food use is limited to enteral tube feeding and serving size based on the serving size of a meal replacement/nutritional beverage RACC.

FDA Question 2:

Please confirm that the intended uses of hydrolyzed poultry protein (including the use in medical foods) would be substitutional for uses of other animal and vegetable protein sources added to food and therefore will not increase the cumulative dietary exposure to protein.

Response:

The use of hydrolyzed poultry protein would be substituted for uses of other animal and vegetable protein sources in conventional food and medical food (specifically enteral tube feeding); therefore, the intended use of hydrolyzed poultry protein will not increase the cumulative dietary exposure to protein.

• • •

FDA Question 3:
According to our fortification policy (21 CFR 104.20), FDA does not consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. If your intended uses of hydrolyzed poultry protein are not substitutional, please explain how your intended uses in meat, poultry, or fish products and snack foods are consistent with FDA's fortification policy.
Response:
The use of hydrolyzed poultry protein would be substituted for uses of other animal and vegetable protein sources in conventional foods. The notification also includes the use as a flavoring. The intended use of hydrolyzed poultry protein in snack foods and meat, poultry and fish products is as a flavoring, not as a source of protein.

FDA Question 4:
We note that a medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation (21 CFR 101.9(j)(8)). See also FDA's recently updated guidance document on medical foods.
Please specify the types of medical foods in which the ingredient is intended to be use, the target population with a disease or condition the dietary management of which cannot be achieved by the modification of the normal diet alone and provide a provide a basis for concluding the intended use of hydrolyzed poultry protein is GRAS. If you are not able to provide this information, we recommend that you remove the medical food use from the intended uses of the ingredient.
Response:
Hydrolyzed poultry protein is not a medical food. The intended use of the hydrolyzed poultry protein is to serve as a source of protein in nutritionally complete formulas for enteral tube feeding. The hydrolyzed poultry protein would be a substitute for other protein sources.

FDA Question 5:
On page 35 you state that the prevalence of poultry meat allergy is rare with a worldwide occurrence of 0 – 13%. It was not clear where you obtained the provided numerical data range, as 13% seems relatively high, please elaborate. In addition, please provide more details in your narrative describing the current state of science regarding allergy to poultry meat as well as assurance that sensitive consumers will be protected because products containing your ingredient will be labeled in the ingredient list. (see, Wanniang, N., Codreanu-Morel, F., Kuehn, A. et al. Poultry Meat allergy: a Review of Allergens and Clinical Phenotypes. Curr Treat Options Allergy 9, 187–203 (2022), for a recent review of the subject of poultry-related allergy)].
Response:
Thank you for the opportunity to clarify and amend. The previous range reported was incorrectly positioned as allergy from consumption of poultry; however, the range reported appears to include inhalation of vapor during cooking or skin contact (Thermo Fischer Scientific Inc., 2021). The recently published article suggested for review provides an estimate of chicken meat intolerance/allergy specific to consumption of chicken meat as 0.6-5% (Wanniang et al., 2022).

While allergy to other poultry products such as turkey or duck occur, chicken meat allergy is most studied, likely due to volume of consumption. Food allergies from poultry consumption may occur in both adults and children and may be an IgE-mediated or non-IgE mediated food allergy (Wanniang et al., 2022).
IgE-mediated food allergy can be a primary allergy to poultry or secondary allergy in individuals allergic to eggs or bird feathers or to fish. The occurrence is most common in adolescents and young adults and those with primary allergies to poultry meat (Wanniang et al., 2022). IgE-mediated symptoms range from mild to severe anaphylaxis (Wanniang et al., 2022). Non IgE-mediated food allergy to poultry is most common in infants and children and is essentially characterized by vomiting with possible delayed onset of diarrhea (Wanniang et al., 2022). Foods containing the hydrolyzed poultry protein will display the ingredient in the ingredients list, and individuals with known poultry protein allergy will be informed of the presence and avoid use. In cases where the hydrolyzed poultry protein is used as a natural flavor in a flavoring/spice mix Norilia will encourage declaration of the hydrolyzed poultry protein in the ingredients listing to inform the consumer of the presence of the poultry protein.

FDA Question 6:
On page 16, the notice states that the notified substance results in a “bitter and burnt” flavoring effect. This is generally considered an undesirable flavoring effect which seems to suggest the ingredient is not suitable for its intended use within meat and poultry products. Please explain why these flavors would be wanted in soups. Alternatively, please provide additional suitability data that demonstrates the notified substance imparts desirable flavor attributes in meat and poultry products.
Response:
The human taste buds sense salty, sweet, bitter, sour and savory/umami (Gravina et al., 2013). Bitter flavors “ground” intense flavors in a dish and also cut down on the sweetness (McCormick & Company Inc., 2023). As noted in the notification, the use levels will be determined by cGMP. Use of the hydrolyzed poultry protein in amounts higher than required to produce the intended effect of “rounding out a flavor profile” would become unpalatable for consumers; hence the use would be limited by consumer acceptance.

FDA Question 7:
In the notice, use levels for FSIS regulated products appear to be as a flavoring agent in soups at levels of up to 2.45% and in seasoning blends/rubs for meat and poultry products generally at levels of up to 2%. Please confirm the use level for use in soups and clarify for seasoning blends whether this is as a percentage of the seasoning blend or the total product formula.
Response:
The use levels in soups is up to 4% as consumed. As noted in the submission, sensory analysis was conducted using hydrolyzed poultry protein in soups. Based on consumer perception of the spray-dried hydrolysate having bitter and burnt flavor notes, use levels will likely be below the maximum of 4% due to consumer acceptability. Use in the seasonings/flavoring category is based on use of 2 g of hydrolyzed poultry protein per 100 g of seasoning. As noted in the Proposed Intended use for Nor-HydroPep DM Table footnote #2 above (Table 1), blended seasonings used in meat products are used at low levels, usually around 3% and rarely exceed

10% (Brown, 2009). The intended maximum use of Norilia's hydrolyzed poultry protein in seasoning is 2% and therefore the seasoning will be a small portion of the food consumed.

References:

Brown, P. (2009) 'Spices, Seasonings, and Flavors', *Ingredients in Meat Products*. New York,: Springer-Verlag, pp. 199-210.
Gravina, S. A., Yep, G. L. and Khan, M. (2013) 'Human biology of taste', *Ann Saudi Med,* 33(3), pp. 217-22.
McCormick & Company Inc. (2023) *Tart and Bitter Flavor Profiles*. Available at: https://www.mccormick.com/articles/mccormick/tart-and-bitter-flavor-profiles (Accessed: August 3, 2023.
Thermo Fischer Scientific Inc. (2021) *f83 Chicken Allergen*. Available at: https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f83 (Accessed: November 12, 2021.
Wanniang, N., Codreanu-Morel, F., Kuehn, A. and Morisset, M. (2022) 'Poultry Meat allergy: a Review of Allergens and Clinical Phenotypes', *Current Treatment Options in Allergy,* 9(3), pp. 187-203.

Thank you for the opportunity to clarify and respond to questions. Should there be any more questions or requests for information, please contact me directly.

Sincerely,

Amy Mozingo, MS
Vice President US Nutra Regulatory Sciences
GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
amozingo@gras-associates.com

GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
T: 519.341.3667 | F: 888.531.3466
www.gras-associates.com

September 5, 2023

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety
Division of Petition Review
5001 Campus Drive
College Park, MD 20740-3835

Attention: Dr. Jason Downey
Re: GRN 001132—Response to Questions Posed in an Email Dated August 22, 2023

Dear Dr. Downey:

Per your request, GRAS Associates, LLC, acting as the agent for Norilia, is providing a response to FDA's request.

FDA's Question for the Notifier

On pages 10-11, the notifier states that an aqueous solution of the hydrolysate is evaporated to 60% dry matter (DM) and then spray dried to produce the final ingredient. We note that the spray drying step indicates that the final ingredient should contain significantly more than 60% DM; however, the results from the batch analyses presented in Table 6 on page 13 demonstrate that the DM content in the final ingredient is approximately 60%. Please clarify whether the subject of GRN 001132 is hydrolyzed poultry protein (in a paste form) containing >60% DM, and not the spray-dried form.

If the spray dried form is also the subject of GRN 001132, please provide the specifications and the results from the analyses of a minimum of three non-consecutive batches for the spray-dried form. In addition, considering the difference in the protein content of the two forms, please address the use levels of the spray-dried form as well as the dietary exposure from the intended uses, including whether the uses of the two forms of hydrolyzed poultry protein are substitutional for each other on a protein basis.

Response

Thank you for the opportunity to clarify and provide additional information. The paste form (tradename Nor-HydroPep) and the spray dried form (tradename Nor-HydroPep 90 SD) are both subject of GRN 001132. The spray dried form and paste form would be substitutional for each other on a protein basis. The specifications for Nor-HydroPep 90 SD and results of three non-consecutive batches are provided in Table 1 and certificates of analysis are provided as Appendix A.

• • •

Table 1. Specifications and Batch Results for Norillia's Nor-HydroPep 90 SD

Physical & Chemical Parameters	Norilia's Specifications for Nor-HydroPep 90 SD	Testing Method	Nor-HydroPep 90 SD Representative Lots		
			Batch 21-10414	Batch 22-04373	Batch 22-07573
Appearance	Free-flowing beige-like colored powder	Visual	Complies	Complies	Complies
Odor and Taste	Chicken and umami flavor	Sensory	Complies	Complies	Complies
Dry Matter (g/100g)	>94	NMKL 23	96.9	96.5	95.6
Crude Protein (g/100g)	>80	NMKL 6	87.3	85.7	84.7
Crude Fat (g/100g)	<6	NMKL 160 mod	2.74	4.69	4.23
Ash (g/100g)	<8	NMKL 173	7.22	7.16	7.97
Collagen (g/100g)	>16	calculation	29.12	29.44	30.16
Hydroxyprollin (g/100g)	>2	ISO 13903:2005	3.64	3.68	3.77
Lead (ppm)	<0.1	EN ISO 17294-2:2016/EN 13805:2014	<0.02	<0.02	<0.02
Arsenic (ppm)	<0.3	EN ISO 17294-2:2016/EN 13805:2014	0.081	0.14	0.23
Cadmium (ppm)	<0.1	EN ISO 17294-2:2016/EN 13805:2014	0.01	<0.01	<0.01
Mercury (ppm)	<0.1	EN 16277:2012	0.02	<0.02	<0.02

Physical & Chemical Parameters	Norilia's Specifications for Nor-HydroPep 90 SD	Testing Method	Nor-HydroPep 90 SD Representative Lots		
			Batch 21-10414	Batch 22-04373	Batch 22-07573
Total Plate Count (CFU/g)	<100,000	AFNOR 3M 01/01-09/89-UMQFG	<1000	<1000	<1000
Yeast (CFU/g)	<100	NMKL 98	<100	<100	<100
Mold (CFU/g)	<100	NMKL 98	<100	NR	<100
***E. coli* (CFU/g)**	<10	AFNOR 3M 01/08-06/01 - UMQIM	<10		<10
***Salmonella spp.* (per 25 g)**	Negative	AFNOR EGS 38/01-03/15 - UMQEK	Negative	Negative	Negative
Aerobic Spores (CFU/g)	<100	NMKL 189 - UMQKU	<100	71	<100
Anaerobic Spores (CFU/g)	<200	NMKL 189 – UM3K8	<100	<10	<100
Enterobacteriaceae 37ºC (CFU/g)	<10	AFNOR 3M 01/06-09/97 - UMQI0	<10	<10	<10
***Clostridium perfringens* (CFU/g)**	<10	NMKL 95 – UMQGL	<10	<10	<10
***Bacillus cereus* (CFU/g)**	<1000	NMLK 67	<100	<10	<100

AFNOR – French Standardization Association; C – Celsius; CFU – Colony forming units; EN – European Standard; g – grams; NMLK – Nordic Committee on Food Analysis; NR – Not reported; ppm – parts per million

The proposed use of spray dried powder is the same as Nor-HydroPep with levels of use adjusted based on protein content. Table 3 provides the proposed use for spray dried powder adjusted based on the protein content.

• • •

Table 2. Proposed Intended Use for Nor-HydroPep 90 SD

Food Category (per 21CFR170.3)	Proposed Food Uses	Maximum Use Levels (g) per serving	Maximum Use Levels (% of finished food)	RACC[1]
Condiments and Relishes	Mayonnaise and other condiments	3.1	21	15-17 g
Processed Vegetables, Vegetable Juices	Tomato-based juices	3.1	1.3	240 mL
Gravies & Sauces	Gravies	1.2	2	60 g
Herbs, Seeds, Spices, Seasonings, Blends, Extracts, and Flavorings	Seasonings for meat coatings/rubs and in seasoning pastes	N/A[2]	1.2	Not applicable
Soups & Soup Mixes	Soups	6.1	2.5	245 g
Snack Foods	Popcorn, pretzels, chips, & crackers	3.1	10.3	30 g
Not Specified	Nutrition Bars	12.2	30.5	40 g
Not Specified	Protein drinks & protein powder mixes	12.2	5.1	240 mL
Not Specified	Ready-to-drink meal replacements & nutritional beverages	12.2	5.1	240 mL
Not Specified	Medical Foods (protein component only) for enteral tube feeding	12.2[3]	5.1	RACC Not Specified (240 mL)

g – gram; mL – milliliter; RACC – Reference Amounts Customarily Consumed

1. RACC based on values established in 21 CFR §101.12. When a range of values is reported for a proposed food-use, particular foods within that food-use may differ with respect to their RACC. RACCs reported with household measure were converted to g based on USDA Food Central Database (https://fdc.nal.usda.gov/).
2. Maximum use rate of 1.2g/100 g in seasoning blend. Blended seasonings used in meat products are used at low levels, usually around 3% and rarely exceed 10% (Brown, 2009). Therefore, the consumption of Nor-HydroPep 90 SD used in seasoning blends for processed meat products will be negligible.
3. Medical foods are not included in the intake analysis because these are not consumed by the general population and are prescribed under the supervision of a physician. Medical Food use is limited to enteral tube feeding and serving size based on the serving size of a meal replacement/nutritional beverage RACC.

The specification for crude protein in Nor-HydroPep 90 SD is >80 g/100 g. The protein content of 3 representative batches ranged from 84.7 to 97.3 g/100 g. Assuming a conservative estimate that the spray dried powder Nor-HydroPep 90 SD contains crude protein of 90 g/100 g, Table 3 below summarizes the estimated protein intake from consumption of all proposed food uses based on intakes outlined in Table 2.

• • •

Table 3. Summary of Estimated Daily Mean and 90th Percentile Intake for Nor-HydroPep 90 SD from All Intended Food Uses Based on Consumer-Only Population (Based on NHANES 2017–2018 Survey)

Population Group		Ingredient Intake (g/day)		Ingredient Intake (g/kg bw/day)	
	N	Mean	90th Percentile	Mean	90th Percentile
Children (1-5 years) Male/Female Combined	541	4.1	8.2	0.25	0.49
Children (6-11 years) Male/Female Combined	613	6.3	13.1	0.20	0.42
Teenage (12-18 years) Female	350	6.6	12.2	0.12	0.21
Teenage (12-18 years) Male	329	7.0	14.0	0.12	0.26
Adults (19+ years) Female	1882	6.7	14.4	0.09	0.20
Adults (19+ years) Male	1713	8.9	19.1	0.10	0.24
All Ages	5483	7.3	16.0	0.12	0.26

bw – body weight; kg – kilograms; g – grams; yr. – year

Should there be any more questions or requests for information, please contact me directly.

Sincerely,

Amy Mozingo, MS
Vice President US Nutra Regulatory Sciences
GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
amozingo@gras-associates.com

Appendix A. Certificates of Analysis

Certificate of Analysis

Product Number: 3000007861
Product name: Nor-HydroPep 90 SD
Batch Number: 21-10414

Manufacture Date: 03-Sep-21
Test Date: 13- Sep– 20-Nov -2021
Retest Date: 03-Sep- 2023

Parameter	Specification	Test Result	Test date	Test method	Approved
Color, flavor and physical properties					
Appearance	Free - flowing powder	Complies	*10-Sep-2021*	Visual	Approved
Odor and taste	Chicken and umami flavor	Complies	*10-Sep-2021*	Sensory	Approved
Color	Beige-like colored powder, which may vary slightly	Complies	*10-Sep-2021*	Visual	Approved
Chemical content					
Dry matter (g/100g)	>94	96,9	*13– 22-sep-2021*	NMKL 23	*Approved*
Crude protein (g/100g)	>80	87,3	*13– 22-sep-2021*	NMKL 6	*Approved*
Hydroxyprollin (g/100g)	>2	3,64	*13– 22-sep-2021*	ISO 13903:2005	*Approved*
Collagen (g/100g)	>16	29,12	*13– 22-sep-2021*	calculation	*Approved*
Crude fat (g/100g)	<6	2,74	*13– 22-sep-2021*	NMKL 160 mod	*Approved*
Ash (g/100g)	<8	7,22	*13– 22-sep-2021*	NMKL 173	*Approved*
Microbiology					
Salmonella (per 25 g)	Negative / 25 g	Negative / 25 g	*14– 20-Sep-2021*	AFNOR EGS 38/01-03/15 -UMQEK	*Approved*
Salmonella (per 10g)	Absent / 10g	Absent / 10g	*20 - Nov 2021*	E.P2.6.13 USP <62>	*Approved*
Aerobic Spores (CFU/g)	100	<100	*14– 20-Sep-2021*	NMKL 189 - UMQKU	*Approved*
Anaerobic Spores (CFU/g)	200	<100	*14– 20-Sep-2021*	NMKL 189 - UM3K8	*Approved*
Enterobacteria (CFU/g)	<10	<10	*14– 20-Sep-2021*	AFNOR 3M 01/06-09/97 - UMQI0	*Approved*
E. Coli (CFU/g)	<10	<10	*14– 20-Sep-2021*	AFNOR 3M 01/08-06/01 - UMQIM	*Approved*
E. Coli	Absent / 10g	Absent/10 g	*05-Nov 2021*	E.P2.6.13 USP <62>	*Approved*
Bacillus Cereus	<1000	<100	*14– 20-Sep-2021*	NMKL 67	*Approved*
Clostridium perfringens (CFU/g)	<10	<10	*14– 20-Sep-2021*	NMKL 95 - UMQGL	*Approved*
Total Plate Count (CFU/g)	<500 000	<1000	*14– 20-Sep-2021*	AFNOR 3M 01/01-09/89 - UMQFG	*Approved*
Yeast	<100	<100	*14– 20-Sep-2021*	NMKL 98	*Approved*
Mold	<100	<100	*14– 20-Sep-2021*	NMKL 98	*Approved*
Heavy Metals					
Lead (ppm)	< 0,1	< 0,020	*13– 22-Sep-2021*	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Arsenic (ppm)	< 0,1	0,081	*13– 22-Sep-2021*	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Cadmium (ppm)	< 0,1	0,01	*13– 22-Sep-2021*	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Mercury (ppm)	< 0,1	0,02	*13– 22-Sep-2021*	EN 16277:2012	*Approved*

Approved by:
10-Dec-2021

Elin Klufterud Abelsnes, Quality Manager Bioco AS

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70

VAT-no.:
NO 995 643 316 MVA

Visiting adr: Lørenv. 37
NO-0585 Oslo

www.norilia.no
www.norilia.com

Certificate of Analysis

Product Number: 3000007861
Product name: Nor-HydroPep 90 SD
Batch Number: 22-04373

Manufacture Date: 17.03.2022
Test Date: 24.05 - 27.04.2022
Retest Date:

Parameter	Specification	Test Result	Test date	Test method	Approved
Color, flavor and physical properties					
Appearance	Free - flowing powder	Complies	*24-may-2022*	Visual	Approved
Odor and taste	Chicken and umami flavor	Complies	*24-may - 2022*	Sensory	Approved
Color	Beige-like colored powder, which may vary slightly	Complies	*24-may - 2022*	Visual	Approved
Chemical content					
Dry matter (g/100g)	>94	96,5	*03-june-2022*	NMKL 23	*Approved*
Crude protein (g/100g)	>80	85,7	*03-june-2022*	NMKL 6	*Approved*
Collagen	>16	29,44	*03-june-2022*	Calculation	*Approved*
Hydroxyprolin (g/100g)	>2	3,68	*03-june-2022*	ISO 13903:2005	*Approved*
Crude fat (g/100g)	<6	4,69	*03-june-2022*	NMKL 160 mod	*Approved*
Ash (g/100g)	<8	7,16	*03-june-2022*	NMKL 173	*Approved*
Microbiology					
Salmonella (per 25 g)	Negative / 25 g	Negative	*27-may-2022*	AFNOR EGS 38/01-03/15 -UMQEK	*Approved*
Salmonella (per 10g)	Absent / 10g	Absent/10g	*27-april-2022*	EP.2.6.13 / USP <62>	
Aerobic Spores (CFU/g)	100	71	*03-june-2022*	NMKL 189 - UMQKU	*Approved*
naerobic Spores (CFU/g)	200	<10	*03-june-2022*	NMKL 189 - UM3K8	*Approved*
Enterobacteria (CFU/g)	<10	<10	*27-may-2022*	AFNOR 3M 01/06-09/97 - UMQI0	*Approved*
E. Coli (CFU/g)	<10	<10	*27-may-2022*	AFNOR 3M 01/08-06/01 - UMQIM	*Approved*
E. Coli (per 10g)	Absent / 10g	Absent/10g	*27-april-2022*	EP.2.6.13 / USP <62>	
Bacillus Cereus	<1000	<100	*27-may-2022*	NMKL 67	*Approved*
Clostridium perfringens (CFU/g)	10	<10	*27-may-2022*	NMKL 95 - UMQGL	*Approved*
Total Plate Count (CFU/g)	<100 000	<1000	*03-june-2022*	AFNOR 3M 01/01-09/89 - UMQFG	*Approved*
Yeast	<100	<100	*03-june-2022*	NMKL 98	*Approved*

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70

VAT-no.:
NO 995 643 316 MVA

Visiting adr: Lørenv. 37
NO-0585 Oslo

www.norilia.no
www.norilia.com

Mold	<100	<100	*03-june-2022*	NMKL 98	*Approved*

Heavy Metals

Lead (ppm)	< 0,1	<0,02	*03-june-2022*	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Arsenic (ppm)	< 0,17	0,14	*03-june-2022*	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Cadmium (ppm)	< 0,1	<0,01	*03-june-2022*	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Mercury (ppm)	< 0,1	<0,02	*03-june-2022*	EN 16277:2012	*Approved*

Approved by:

Mona Strand Pettersen, Quality Manager Bioco AS

05.05.2022

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70

VAT-no.:
NO 995 643 316 MVA

Visiting adr: Lørenv. 37
NO-0585 Oslo

www.norilia.no
www.norilia.com

Certificate of Analysis

Product Number: 3000007861
Product name: Nor-HydroPep 90 SD
Batch Number: 22-07573

Manufacture Date: 30-May 2022
Test Date: 13-July – 05-Aug- 2022
Retest Date: 30-May- 2024

Parameter	Specification	Test Result	Test date	Test method	Approved
Color, flavor and physical properties					
Appearance	Free - flowing powder	Complies		Visual	Approved
Odor and taste	Chicken and umami flavor	Complies		Sensory	Approved
Color	Beige-like colored powder, which may vary slightly	Complies		Visual	Approved
Chemical content					
Dry matter (g/100g)	>94	95,6	13 –20.July 2022	NMKL 23	*Approved*
Crude protein (g/100g)	>80	84,7	13 –20.July 2022	NMKL 6	*Approved*
Hydroxyprollin (g/100g)	>2	3,77	13 –20.July 2022	ISO 13903:2005	*Approved*
Collagen (g/100g)	>16	30,16	13 –20.July 2022	calculation	*Approved*
Crude fat (g/100g)	<6	4,23	13 –20.July 2022	NMKL 160 mod	*Approved*
Ash (g/100g)	<9	7,97	13 –20.July 2022	NMKL 173	*Approved*
Microbiology					
Salmonella (per 25 g)	Negative / 25 g		*12-18. July 2022*	AFNOR EGS 38/01-03/15 -UMQEK	*Approved*
Salmonella (per 10g)	Absent / 10g	Absent / 10g	*13.july- 05.aug 2022*	E.P2.6.13 USP <62>	*Approved*
Aerobic Spores (CFU/g)	100	<100	*12-18. July 2022*	NMKL 189 - UMQKU	*Approved*
Anaerobic Spores (CFU/g)	200	<100	*12-18. July 2022*	NMKL 189 - UM3K8	*Approved*
Enterobacteria (CFU/g)	<10	<10	*12-18. July 2022*	AFNOR 3M 01/06-09/97 - UMQI0	*Approved*
E. Coli (CFU/g)	<10	<10	*12-18. July 2022*	AFNOR 3M 01/08-06/01 - UMQIM	*Approved*
E. Coli	Absent / 10g	Absent/10 g	*13.july- 05.aug 2022*	E.P2.6.13 USP <62>	*Approved*
Bacillus Cereus	<1000	<100	*12-18. July 2022*	NMKL 67	*Approved*
Clostridium perfringens (CFU/g)	<10	<10	*12-18. July 2022*	NMKL 95 - UMQGL	*Approved*
Total Plate Count (CFU/g)	<100 000	<1000	*12-18. July 2022*	AFNOR 3M 01/01-09/89 - UMQFG	*Approved*
Yeast	<100	<100	*12-18. July 2022*	NMKL 98	*Approved*
Mold	<100	<100	*12-18. July 2022*	NMKL 98	*Approved*
Heavy Metals					
Lead (ppm)	< 0,1	<0,020	13 –20.July 2022	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Arsenic (ppm)	< 0,25	0,23	13 –20.July 2022	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Cadmium (ppm)	< 0,1	<0,010	13 –20.July 2022	EN ISO 17294-2:2016/EN 13805:2014	*Approved*
Mercury (ppm)	< 0,1	<0,020	13 –20.July 2022	EN 16277:2012	*Approved*

Approved by:
16-Dec-2022

Elin Klufterud Abelsnes, Quality Manager Bioco AS

Norilia AS
POB 360 Økern
NO-0513 OSLO
Norway

Nasjonal tel.: 03070
Int.tel.: +47 22 90 30 70

VAT-no.:
NO 995 643 316 MVA

Visiting adr: Lørenv. 37
NO-0585 Oslo

www.norilia.no
www.norilia.com

GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
T: 519.341.3667 | F: 888.531.3466
www.gras-associates.com

September 21, 2023

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety
Division of Petition Review
5001 Campus Drive
College Park, MD 20740-3835

Attention: Dr. Jason Downey
Re: GRN 001132—Response to Questions Posed in an Email Dated September 19, 2023

Dear Dr. Downey:

Per your request, GRAS Associates, LLC, acting as the agent for Norilia, is providing a response to FDA's request for clarification.

FDA's Question for the Notifier

The amendment and COAs specify a limit on total plate count at <100,000 CFU/g with three nonconsecutive batches measuring <1,000 CFU/g. Based on the batch measurements and the limit set for the paste form of the ingredient, it seems like the specifications for the spray dried form would limit total plate count to <1,000 CFU/g. Can the notifier confirm the specifications for the spray dried form of the ingredient limit total plate count to <1,000 CFU/g?

Response

Thank you for the opportunity to confirm. The Notifier confirms the specification for the limit on total plate count is <1,000 CFU/g.
The updated specifications for Nor-HydroPep 90 SD with results of three non-consecutive batches are provided in Table 1.

• • •

Table 1. Specifications and Batch Results for Norillia's Nor-HydroPep 90 SD

Physical & Chemical Parameters	Norilia's Specifications for Nor-HydroPep 90 SD	Testing Method	Nor-HydroPep 90 SD Representative Lots		
			Batch 121-10414	Batch 22-04373	Batch 22-07573
Appearance	Free-flowing beige-like colored powder	Visual	Complies	Complies	Complies
Odor and Taste	Chicken and umami flavor	Sensory	Complies	Complies	Complies
Dry Matter (g/100g)	>94	NMKL 23	96.9	96.5	95.6
Crude Protein (g/100g)	>80	NMKL 6	87.3	85.7	84.7
Crude Fat (g/100g)	<6	NMKL 160 mod	2.74	4.69	4.23
Ash (g/100g)	<8	NMKL 173	7.22	7.16	7.97
Collagen (g/100g)	>16	calculation	29.12	29.44	30.16
Hydroxyprollin (g/100g)	>2	ISO 13903:2005	3.64	3.68	3.77
Lead (ppm)	<0.1	EN ISO 17294-2:2016/EN 13805:2014	<0.02	<0.02	<0.02
Arsenic (ppm)	<0.3	EN ISO 17294-2:2016/EN 13805:2014	0.081	0.14	0.23
Cadmium (ppm)	<0.1	EN ISO 17294-2:2016/EN 13805:2014	0.01	<0.01	<0.01
Mercury (ppm)	<0.1	EN 16277:2012	0.02	<0.02	<0.02
Total Plate Count (CFU/g)	<1,000	AFNOR 3M 01/01-09/89-UMQFG	<1000	<1000	<1000
Yeast (CFU/g)	<100	NMKL 98	<100	<100	<100

Physical & Chemical Parameters	Norilia's Specifications for Nor-HydroPep 90 SD	Testing Method	Nor-HydroPep 90 SD Representative Lots		
			Batch 121-10414	Batch 22-04373	Batch 22-07573
Mold (CFU/g)	<100	NMKL 98	<100	NR	<100
***E. coli* (CFU/g)**	<10	AFNOR 3M 01/08-06/01 - UMQIM	<10		<10
***Salmonella spp.* (per 25 g)**	Negative	AFNOR EGS 38/01-03/15 - UMQEK	Negative	Negative	Negative
Aerobic Spores (CFU/g)	<100	NMKL 189 - UMQKU	<100	71	<100
Anaerobic Spores (CFU/g)	<200	NMKL 189 – UM3K8	<100	<10	<100
Enterobacteriaceae 37ºC (CFU/g)	<10	AFNOR 3M 01/06-09/97 - UMQI0	<10	<10	<10
***Clostridium perfringens* (CFU/g)**	<10	NMKL 95 – UMQGL	<10	<10	<10
***Bacillus cereus* (CFU/g)**	<1000	NMLK 67	<100	<10	<100

AFNOR – French Standardization Association; C – Celsius; CFU – Colony forming units; EN – European Standard; g – grams; NMLK – Nordic Committee on Food Analysis; NR – Not reported; ppm – parts per million

Should there be any more questions or requests for information, please contact me directly.

Sincerely,

Amy Mozingo, MS
Vice President US Nutra Regulatory Sciences
GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
amozingo@gras-associates.com

From:	Amy Mozingo
To:	Downey, Jason
Subject:	[EXTERNAL] Re: GRN 001132 - FDA"s Questions to the Notifier
Date:	Monday, December 4, 2023 5:29:54 PM
Attachments:	image001.png image002.png Outlook-ioibxa3a.png Outlook-d05mbjts.png GRN 1132_Response to FDA 29Nov2023 Questions.pdf

Hi Jason,

Please find attached the responses to FDA's questions/request for clarification per your 29th November email.

Should you have any more questions please let me know.

Best Regards,

Amy

Amy Mozingo, MS

VP US Nutra Regulatory Sciences

GRAS Associates a Nutrasource Pharmaceutical and Nutraceutical Services company

O: 301-461-8929| C: 772-532-3454

LinkedIn | Twitter | Blog

From: Amy Mozingo <amozingo@gras-associates.com>
Sent: November 29, 2023 8:48 AM
To: Downey, Jason <Jason.Downey@fda.hhs.gov>
Subject: RE: GRN 001132 - FDA's Questions to the Notifier

Hi Jason,
I am confirming receipt of the request for clarification and will provide a response before December 12th.
Regards
Amy

Amy Mozingo, MS
VP US Nutra Regulatory Sciences
GRAS Associates a Nutrasource Pharmaceutical and Nutraceutical Services company
O: 301-461-8929| C: 772-532-3454
LinkedIn | Twitter | Blog

From: Downey, Jason <Jason.Downey@fda.hhs.gov>
Sent: Tuesday, November 28, 2023 11:14 AM
To: Amy Mozingo <amozingo@gras-associates.com>

Subject: GRN 001132 - FDA's Questions to the Notifier

Hi Amy,

I hope you had a nice Thanksgiving!

We identified a couple of points from GRN 001132 (Norilia's hydrolyzed poultry protein) and an amendment that we need some clarification on. Those requests are below. Please provide a response to these requests within 10 business days. If you foresee any issue with this timeline or you have any other questions, please contact me as soon as possible.

Thank you!

Jason

Jason Downey, Ph.D. (he/him/his)
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
jason.downey@fda.hhs.gov

FDA's Questions to the Notifier

1. In your GRAS notice (Table 9, page 18) you provide the dietary exposure estimates for several U.S. populations, including the population described as "All ages". Please confirm that the "All ages" population refers to the U.S. population aged 1 year and older.

2. In your amendment dated September 5, 2023, you state, "Table 3 below summarizes the estimated *protein intake* from consumption of all proposed food…" Please confirm that the estimates of dietary exposure provided in Table 3 of the amendment are for the whole ingredient, i.e., hydrolyzed poultry protein, and not only for its protein component.

3. In your GRAS notice, your intended uses include use of hydrolyzed poultry protein as the protein component in "medical foods." In your August 10, 2023, amendment (Question 4), you described this food category as "nutritionally complete formulas for enteral tube feeding."

   In our Question 4 of that amendment, we provided the regulatory definition of "medical food." Based on that definition, food that is administered enterally under the supervision of a physician does not meet the definition of medical food if it is not also "intended for the specific dietary

management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

It is not clear from your descriptions whether you intend to use hydrolyzed poultry protein in medical food or in general nutritional beverages, which may also be delivered through an enteral tube but are not considered to be medical foods. Considering the above, please clarify which term (medical food or general nutritional beverages) describes the intended uses of hydrolyzed poultry protein, and please cite examples of products in which you intend for hydrolyzed poultry protein to be used to help us determine whether this type of products meets the definition of medical food. We note that while your August 10, 2023, amendment stated the subject of the notice is for use as an ingredient in and not itself medical food, GRAS status attaches to the intended use of a substance, not the substance itself; so, intended use must be adequately described and considered.

GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
T: 519.341.3667 | F: 888.531.3466
www.gras-associates.com

December 4, 2023

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety
Division of Petition Review
5001 Campus Drive
College Park, MD 20740-3835

Attention: Dr. Jason Downey
Re: GRN 001132—Response to Questions Posed in an Email Dated November 28, 2023

Dear Dr. Downey:

Per your request, GRAS Associates, LLC, acting as the agent for Norilia, is providing a response to FDA's request.

FDA's Question for the Notifier

Question 1: *In your GRAS notice (Table 9, page 18) you provide the dietary exposure estimates for several U.S. populations, including the population described as "All ages". Please confirm that the "All ages" population refers to the U.S. population aged 1 year and older.*

Response

Thank you for the opportunity to clarify. The "All ages" category presented in Table 9 of the original GRAS notice was reflective of the "Total Population" in the NHANES survey data set and included infants under 1 year of age. For clarity, we have recalculated the intake to reflect the intake of the U.S. population aged 1 year and older, presented in Table 1 below, which resulted in minimal changes.

Table 1. Summary of Estimated Daily Mean and 90th Percentile Intake for Nor-HydroPep DM from All Intended Food Uses Based on Consumer-Only Population (Based on NHANES 2017–2018 Survey)

Population Group		Ingredient Intake (g/day)		Ingredient Intake (g/kg bw/day)	
	N	Mean	90th Percentile	Mean	90th Percentile
Children (1-5 years) Male/Female Combined	541	6.7	13.5	0.41	0.81
Children (6-11 years) Male/Female Combined	613	10.3	21.4	0.32	0.69
Teenage (12-18 years) Female	350	10.8	19.9	0.19	0.34
Teenage (12-18 years) Male	329	11.5	22.9	0.19	0.42
Adults (19+ years) Female	1882	10.9	23.6	0.15	0.33
Adults (19+ years) Male	1713	14.5	31.3	0.17	0.39
Total Population (age 1+ years) Male/Female Combined	5428	12.0	26.2	0.19	0.42

bw – body weight; kg – kilograms; g – grams; yr. – year

• • •

Question 2: *In your amendment dated September 5, 2023, you state, "Table 3 below summarizes the estimated protein intake from consumption of all proposed food…" Please confirm that the estimates of dietary exposure provided in Table 3 of the amendment are for the whole ingredient, i.e., hydrolyzed poultry protein, and not only for its protein component.*

Response

Thank you for the opportunity to clarify. Estimated protein intake from Nor-HydroPep DM was calculated by using a conservative assumption of 55% percent crude protein based on the protein content of 5 representative batches of Nor-HydroPep which ranged from 51.8 to 53.2 g/100 g (Table 11, page 20 in the original GRAS notice). This table has been replicated below and the title updated to reflect this is the expected protein intake for Nor-HydroPep DM or Nor-HydroPep 90 SD as these products are used as substitutes for each other (Table 2). This table has also been corrected to reflect the total population aged 1 year and older.

The following information has been corrected to clarify that Table 3 in the amendment dated September 5, 2023, and replicated here as Table 3, presented the total intake of Nor-HydroPep 90 SD. The specification for crude protein in Nor-HydroPep 90 SD is >80 g/100 g. The protein content of 3 representative batches ranged from 84.7 to 97.3 g/100 g. Assuming a conservative estimate that the spray dried powder Nor-HydroPep 90 SD contains crude protein of 90 g/100 g, Table 3 below summarizes the estimated total intake of Nor-HydroPep 90 SD from consumption of all proposed food uses described in the GRAS notice and based on the estimated protein intake outlined in Table 2 of this amendment. This table has also been corrected to reflect the total population aged 1 year and older.

Table 2. Summary of Estimated Daily Mean and 90th Percentile Intake of Protein from Nor-HydroPep DM or Nor-HydroPep 90 SD from All Intended Food Uses Based on Consumer-Only Population (Based on NHANES 2017–2018 Survey)

Population Group		Ingredient Intake (g/day)		Ingredient Intake (g/kg bw/day)	
	N	Mean	90th Percentile	Mean	90th Percentile
Children (1-5 years) Male/Female Combined	541	3.7	7.4	0.23	0.45
Children (6-11 years) Male/Female Combined	613	5.7	11.8	0.17	0.38
Teenage (12-18 years) Female	350	5.9	10.9	0.10	0.19
Teenage (12-18 years) Male	329	6.3	12.6	0.10	0.23
Adults (19+ years) Female	1882	6.0	13.0	0.08	0.18
Adults (19+ years) Male	1713	8.0	17.2	0.09	0.21
Total Population (age 1+ years) Male/Female Combined	5428	6.6	14.4	0.10	0.23

bw – body weight; kg – kilograms; g – grams; yr. – year

• • •

Table 3. Summary of Estimated Daily Mean and 90th Percentile Intake for Nor-HydroPep 90 SD from All Intended Food Uses Based on Consumer-Only Population (Based on NHANES 2017–2018 Survey)

Population Group		Ingredient Intake (g/day)		Ingredient Intake (g/kg bw/day)	
	N	Mean	90th Percentile	Mean	90th Percentile
Children (1-5 years) Male/Female Combined	541	4.1	8.2	0.25	0.50
Children (6-11 years) Male/Female Combined	613	6.3	13.1	0.19	0.42
Teenage (12-18 years) Female	350	6.6	12.1	0.11	0.21
Teenage (12-18 years) Male	329	7.0	14.0	0.12	0.25
Adults (19+ years) Female	1882	6.7	14.4	0.09	0.20
Adults (19+ years) Male	1713	8.9	19.1	0.10	0.24
Total Population (age 1+ years) Male/Female Combined	5428	7.3	16.0	0.12	0.25

bw – body weight; kg – kilograms; g – grams; yr. – year

Question 3: *In your GRAS notice, your intended uses include use of hydrolyzed poultry protein as the protein component in "medical foods." In your August 10, 2023, amendment (Question 4), you described this food category as "nutritionally complete formulas for enteral tube feeding."*

In our Question 4 of that amendment, we provided the regulatory definition of "medical food." Based on that definition, food that is administered enterally under the supervision of a physician does not meet the definition of medical food if it is not also "intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

It is not clear from your descriptions whether you intend to use hydrolyzed poultry protein in medical food or in general nutritional beverages, which may also be delivered through an enteral tube but are not considered to be medical foods. Considering the above, please clarify which term (medical food or general nutritional beverages) describes the intended uses of hydrolyzed poultry protein, and please cite examples of products in which you intend for hydrolyzed poultry protein to be used to help us determine whether this type of products meets the definition of medical food. We note that while your August 10, 2023, amendment stated the subject of the notice is for use as an ingredient in and not itself medical food, GRAS status attaches to the intended use of a substance, not the substance itself; so, intended use must be adequately described and considered.

Response

The intended use does not include use in medical foods.

Should there be any more questions or requests for information, please contact me directly.

Sincerely,

Amy Mozingo, MS

Vice President US Nutra Regulatory Sciences
GRAS Associates, LLC
11810 Grand Park Ave
Suite 500
North Bethesda, MD 20852
amozingo@gras-associates.com

From: Amy Mozingo
To: Downey, Jason
Subject: Re: [EXTERNAL] Re: GRN 001132 - FDA"s Questions to the Notifier
Date: Tuesday, December 5, 2023 11:49:27 AM
Attachments: image001.png
image002.png
Outlook-degjzxqa.png
Outlook-uv5vbzss.png

Hi Jason,
Yes, the general (non-medical food) enteral tube feeding solutions are still in-scope as an intended use.
Regards
Amy

Amy Mozingo, MS
VP US Nutra Regulatory Sciences
GRAS Associates a Nutrasource Pharmaceutical and Nutraceutical Services company
O: 301-461-8929| C: 772-532-3454
LinkedIn | Twitter | Blog

From: Downey, Jason <Jason.Downey@fda.hhs.gov>
Sent: December 5, 2023 11:37 AM
To: Amy Mozingo <amozingo@gras-associates.com>
Subject: RE: [EXTERNAL] Re: GRN 001132 - FDA's Questions to the Notifier

Hi Amy,
For clarity of the record, can you confirm that general (non-medical food) enteral tube feeding solutions are still in-scope as an intended use?
Thank you!
Jason

From: Amy Mozingo <amozingo@gras-associates.com>
Sent: Monday, December 4, 2023 5:30 PM
To: Downey, Jason <Jason.Downey@fda.hhs.gov>
Subject: [EXTERNAL] Re: GRN 001132 - FDA's Questions to the Notifier

Hi Jason,
Please find attached the responses to FDA's questions/request for clarification per your 29th November email.
Should you have any more questions please let me know.
Best Regards,
Amy

Amy Mozingo, MS
VP US Nutra Regulatory Sciences
GRAS Associates a Nutrasource Pharmaceutical and Nutraceutical Services company
O: 301-461-8929| C: 772-532-3454
LinkedIn | Twitter | Blog

From: Amy Mozingo <amozingo@gras-associates.com>
Sent: November 29, 2023 8:48 AM
To: Downey, Jason <Jason.Downey@fda.hhs.gov>
Subject: RE: GRN 001132 - FDA's Questions to the Notifier

Hi Jason,
I am confirming receipt of the request for clarification and will provide a response before December 12th.
Regards
Amy

Amy Mozingo, MS
VP US Nutra Regulatory Sciences
GRAS Associates a Nutrasource Pharmaceutical and Nutraceutical Services company
O: 301-461-8929| C: 772-532-3454
LinkedIn | Twitter | Blog

part, is strictly prohibited. Please notify the sender by return e-mail and delete this e-mail from your system. Unless explicitly and conspicuously designated as a "Service Order", this e-mail does not constitute a contract offer, a contract amendment, or an acceptance of a contract offer. This e-mail does not constitute a consent to the use of sender's contact information for direct marketing purposes or for transfers of data to third parties

---

From: Downey, Jason <Jason.Downey@fda.hhs.gov>
Sent: Tuesday, November 28, 2023 11:14 AM
To: Amy Mozingo <amozingo@gras-associates.com>
Subject: GRN 001132 - FDA's Questions to the Notifier

Hi Amy,

I hope you had a nice Thanksgiving!

We identified a couple of points from GRN 001132 (Norilia's hydrolyzed poultry protein) and an amendment that we need some clarification on. Those requests are below. Please provide a response to these requests within 10 business days. If you foresee any issue with this timeline or you have any other questions, please contact me as soon as possible.

Thank you!

Jason

Jason Downey, Ph.D. (he/him/his)
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
jason.downey@fda.hhs.gov

FDA's Questions to the Notifier

1. In your GRAS notice (Table 9, page 18) you provide the dietary exposure estimates for several U.S. populations, including the population described as "All ages". Please confirm that the "All ages" population refers to the U.S. population aged 1 year and older.

2. In your amendment dated September 5, 2023, you state, "Table 3 below summarizes the

estimated *protein intake* from consumption of all proposed food…" Please confirm that the estimates of dietary exposure provided in Table 3 of the amendment are for the whole ingredient, i.e., hydrolyzed poultry protein, and not only for its protein component.

3. In your GRAS notice, your intended uses include use of hydrolyzed poultry protein as the protein component in "medical foods." In your August 10, 2023, amendment (Question 4), you described this food category as "nutritionally complete formulas for enteral tube feeding."

   In our Question 4 of that amendment, we provided the regulatory definition of "medical food." Based on that definition, food that is administered enterally under the supervision of a physician does not meet the definition of medical food if it is not also "intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

   It is not clear from your descriptions whether you intend to use hydrolyzed poultry protein in medical food or in general nutritional beverages, which may also be delivered through an enteral tube but are not considered to be medical foods. Considering the above, please clarify which term (medical food or general nutritional beverages) describes the intended uses of hydrolyzed poultry protein, and please cite examples of products in which you intend for hydrolyzed poultry protein to be used to help us determine whether this type of products meets the definition of medical food. We note that while your August 10, 2023, amendment stated the subject of the notice is for use as an ingredient in and not itself medical food, GRAS status attaches to the intended use of a substance, not the substance itself; so, intended use must be adequately described and considered.