Meeting

Corn Protein Discussion Paper

Committee Paper for Discussion - ACNFP/157/06

Advisory Committee for Novel Foods and Processes

Application for Authorisation as a Novel Food for Corn Protein.

Application number RP1238

Issue

An application has been received under the novel food authorisation process (regulation 2015/2283 as repatriated) for corn protein. The Committee is asked to advise on whether the available data provides an adequate basis for a risk assessment, and whether the novel food is safe and not nutritionally disadvantageous under the proposed use and use levels.

Background

1. On the 6th September 2021, the FSA received the submission for corn protein from Cargill R&D Centre Europe BV.

2. The novel food is derived from corn slurry which undergoes chemical treatment and subsequent washing with aqueous hydrogen peroxide. Filtration yields a wet corn protein raw material which is then washed with ethanol. After draining the solvent, the corn protein product undergoes drying using heat and vacuum. The final product is a corn protein concentrate (CPC) powder with ≥ 65% protein.

3. The novel food can also be a corn protein isolate (CPI) if heat resistant alpha-amylase enzyme is used prior to the chemical treatment step. This yields a corn protein isolate powder with ≥ 85% protein. The protein is proposed for use as a functional ingredient in plant-based food products, cereal-based products, desserts, food supplements and processed meat products.

4. The application dossier is attached as **Annex A** and the annex to the dossier is attached as **Annex B**. These contain confidential information.

This application

Identification

5. The applicant states that the novel food is sourced from the kernels of corn (*Zea mays*) which is not genetically modified. The corn can be sourced from the EU or outside the EU (Annex A: p2 dossier and Annex D: Annexes – Annex 1_2_1_Conf updated – lists countries from where corn is sourced).

Production Process

6. The applicant states that CPC and CPI are both manufactured from corn gluten slurry (CGS). CGS is formed by wet milling corn in water and includes a number of steps – steeping, grinding, germ separation, fibre separation, starch separation, and protein concentration (Annex A: p3 dossier). Aqueous sulphur dioxide is used as an antimicrobial preservative during this part of the process (Annex D: Annexes – Annex 1_2_1_Conf updated).

7. CGS is pH adjusted, jet cooked and mixed with heat resistant alpha-amylase. This ensures that the soluble starch can be separated from the insoluble protein by filtration. Where this step is used, the final product will by CPI. If this step is not used, the final product will be CPC (Annex A: p3 dossier and Annex D: response to RFI letter – jet cooking conditions).

8. The applicant states that the pH and calcium concentration are adjusted to decrease the sulphite concentration and the presence of certain mycotoxins. The insoluble material is collected by filtration and washed with 1 to 3 volumes of aqueous hydrogen peroxide (0.1 – 1.0% hydrogen peroxide). This yields a corn protein raw material. (Annex A: p3 dossier).

9. The applicant states that the corn protein raw material is washed with food grade ethanol in a continuous counter current fashion. After draining the ethanol, the remaining solid material is dried under heat and vacuum to the desired specified levels. This step plays a critical role in reducing the microbial content of the novel food ingredient (Annex A: p3 dossier).

10. The applicant has provided a detailed description of the production process and specification sheets for the processing agents in Annex D: Annexes – Annex 1_2_1_Conf updated and Annex 1_2_4_TIDS respectively).

11. The applicant has provided a copy of the FSSC 22000 certification and the HACCP plan (Annex D: Annexes – Annex 1_2_2_FSSC and Annex 1_3_3_Conf respectively).

Composition

12. The applicant has provided analytical data provided for five samples of CPC in Table 1 below and five samples of CPI in Table 2 below (Annex A: p3 – 6 dossier). These analyses demonstrate that the CPC and CPI meets the proposed specification for the novel food.

Table 1. Analytical results for 5 batches of Corn Protein Concentrate (CPC)

Parameter	Limits	Method	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Loss on drying (%)	≤ 12	CRA Method MOIST.04	5.16	5.18	5.09	4.84	5.34
Protein (%)	≥ 65	CRA PROTE.03	69.25	68.30	67.85	68.73	69.78
Fat (%)	-	CRA FATCR.01	0.04	0.04	0	0	0.03
Soluble carbohydrates (%)	-	CRA SACCH.03	0.05	0.15	0.12	0.16	0.14
Ethyl alcohol (g/kg)	10	CRA SACCH.03	0.06	0.25	0.70	0.00	0.00

Sulphur dioxide (ppm)	100	AOAC 990.28	26.3	19.7	20.8	23	29.6
Aerobic plate count (cfu/g)	10,000	AOAC 990.12	180	90	260	10	80
Enterobacteriaceae (cfu/g)	10	AOAC 2003.01	10	10	10	10	10
Salmonella spp. (cfu/25g)	Absent	AOAC 2004.03	Absent	Absent	Absent	Absent	Absent
Yeast (cfu/g)	5,000	FDA-BAM 7th Ed.	10	10	10	10	10
Mould (cfu/g)	5,000	FDA-BAM 7th Ed.	10	10	10	10	10
Cadmium (ppm)	0.1	*	0.018	0.016	0.02	0.024	0.021
Arsenic (ppm)	0.1	*	0.015	0.011	0.014	0.013	0.015
Lead (ppm)	0.2	*	0.026	0.024	0.023	0.037	0.021
Mercury (ppm)	-	*	0.01	0.01	0.01	0.01	0.01

Aflatoxin B1 (ppb)	2	**	1	1	1	1	1
Aflatoxin B2 (ppb)	-	**	1	1	1	1	1
Aflatoxin G1 (ppb)	-	**	1	1	1	1	1
Aflatoxin G2 (ppb)		**	1	1	1	1	1
SUM aflatoxins B1+B2+G1+G2 (ppb)	4	-	1	1	1	1	1
Deoxynivalenol (ppb)	800	Internal SOP based on JAOAC Vol. 88 #4, 2005	100	100	100	100	100
Fumonisin B1 (ppb)	-		300	200	200	200	200
Fumonisin B2 (ppb)	-		300	300	300	300	300
Sum of fumonisins B1+B2 (ppb)	1,500	-	600	500	500	500	500
HT-2 toxin (ppb)	-	***	5	5	5	5	5
T-2 (ppb)	-	***	5	5	5	5	5

SUM HT-2+T-2 (ppb)	40	-	5	5	5	5	5
Ochratoxin A (ppb)	6	Internal SOP based on AOAC 2000.03	1	1	1	1	1
Zearalenone (ppb)	200	Internal SOP based on JAOAC Vol. 88 #6, 2005	12.5	12.5	12.5	12.5	12.5
Phytic acid (%)	-	Analytical Biochemistry 77:536-539 (1977)	1.34	1.28	1.31	1.28	1.3
Total polyphenols (ppm)	-	Miletic et al (2012) Phenolic content of plum AJCS 9(4) 681-687.	491	491	491	491	491
Pesticides (ppm)	-	AOAC 2007.01	0.01	0.01	0.01	0.01	0.01
Hydrogen peroxide (mg/L)	-	Chin, H.S. and Cortes	0.01	0.01	0.01	0.01	0.01

* J. AOAC vol 90 (2007) 844-856;

** Internal SOP based on AOAC 994.08 or 999.07 or 2000.08;

*** Internal SOP based on J Ag Food Chem Vol. 42 #4, 1994

Table 2. Analytical results for 5 batches of Corn Protein Concentrate (CPI)

Parameter	Limits	Method	Batch 6	Batch 7	Batch 8	Batch 9	Batch 10
Loss on drying (%)	≤ 12	CRA Method MOIST.04	4.42	4.97	4.46	4.54	3.86
Protein (%)	≥ 65	CRA PROTE.03	90.65	89.65	90.55	90.05	91.40
Fat (%)	-	CRA FATCR.01	0.02	0.07	0.05	0.04	0.06
Soluble carbohydrates (%)	-	CRA SACCH.03	0.24	0.37	0.21	0.42	0.30
Ethyl alcohol (g/kg)	10	CRA SACCH.03	0.28	0.01	0.04	0.00	0.00
Sulphur dioxide (ppm)	100	AOAC 990.28	51.0	49.4	44.4	52.7	53.8
Aerobic plate count (cfu/g)	10,000	AOAC 990.12	3,700	110	80	50	10
Enterobacteriaceae (cfu/g)	10	AOAC 2003.01	10	10	10	10	10

Salmonella spp. (cfu/25g)	Absent	AOAC 2004.03	Absent	Absent	Absent	Absent	Absent
Yeast (cfu/g)	5,000	FDA-BAM 7th Ed.	10	10	10	10	10
Mould (cfu/g)	5,000	FDA-BAM 7th Ed.	10	10	10	10	10
Cadmium (ppm)	0.1	*	0.031	0.027	0.028	0.028	0.029
Arsenic (ppm)	0.1	*	0.019	0.018	0.016	0.018	0.018
Lead (ppm)	0.2	*	0.030	0.026	0.021	0.019	0.021
Mercury (ppm)	-	*	0.01	0.01	0.01	0.01	0.01
Aflatoxin B1 (ppb)	2	**					
Aflatoxin B2 (ppb)	-	**					
Aflatoxin G1 (ppb)	-	**					
Aflatoxin G2 (ppb)		**					

SUM aflatoxins B1+B2+G1+G2 (ppb)	4	-	1	1	1	1	1
Deoxynivalenol (ppb)	800	Internal SOP based on JAOAC Vol. 88 #4, 2005	100	100	100	100	100
Fumonisin B1 (ppb)	-		100	100	200	200	100
Fumonisin B2 (ppb)	-		100	200	200	200	200
Sum of fumonisins B1+B2 (ppb)	1,500	-	100	300	400	400	300
HT-2 toxin (ppb)		***	5	5	5	5	5
T-2 (ppb)		***	5	5	5	5	5
SUM HT-2+T-2 (ppb)	40	-	5	5	5	5	5
Ochratoxin A (ppb)	6	Internal SOP based on AOAC 2000.03	1	1	1	1	1
Zearalenone (ppb)	200	Internal SOP based on JAOAC Vol. 88 #6, 2005	12.5	12.5	12.5	12.5	12.5

Phytic acid (%)	-	Analytical Biochemistry 77:536-539 (1977)	0.78	0.77	0.84	0.76	0.81
Total polyphenols (ppm)	-	Miletic et al (2012) Phenolic content of plum AJCS 9(4) 681-687.	491	491	491	491	491
Pesticides (ppm)	-	AOAC 2007.01	0.01	0.01	0.01	0.01	0.01
Hydrogen peroxide (mg/L)	-	Chin, H.S. and Cortes	0.01	0.01	0.01	0.01	0.01

* J. AOAC vol 90 (2007) 844-856;

** Internal SOP based on AOAC 994.08 or 999.07 or 2000.08;

*** Internal SOP based on J Ag Food Chem Vol. 42 #4, 1994

13. The certificates of analysis and the laboratory accreditation can be found in Annex B: Annex_1_3_1_1_CoAs and Annex_1_3_1_3_Lab_accreditations respectively.

14. The applicant has stated that the pesticide screen reported in the Tables 1 and 2 is sufficient for corn, however, they have provided the certificate of analysis for one batch of corn which covers a range of pesticide residues (Annex D: Response to RFI letter and Annexes – Annex 1_3_1_4).

15. The applicant states that the content of PAH’s or PCB’s and dioxins in the novel food were not determined as this is not required under Regulation (EU) 1881/2006 (Annex D – Response to RFI letter).

Stability

16. The applicant has provided analytical data provided for five batches of CPI. These were initially analysed in 2018 and then re-tested between March – July 2021. The results are reported in Table 3 (Annex A: p7 dossier). The results provided meet the specification limits for corn protein isolate (see Table 4).

Table 3. Results from stability study on 5 batches of Corn Protein Isolate (CPI)

Lot number	APC (cfu/g)	Ebac (cfu/g)	Salmonella	Yeast	Mould (cfu/g)	LOD (%)	protein (%, db)	fat (%, db)
Analysis 2019								
Batch 11	10	10	Absent	*	10	1.9	88.9	0.2
Batch 12	1,702	10	Absent	*	*	1.8	88.3	0.3
Batch 13	350	10	Absent	10	10	-	-	-
Batch 14	3,100	10	Absent	10	10	-	-	-
Batch 15	3,900	10	Absent	10	10	-	-	-
Analysis 2021								
Batch 11	10	10	Absent	10	10	2.15	87.2	0.3
Batch 12	10	10	Absent	10	10	3.29	87.3	0.1

Batch 13	130	10	Absent	10	10	-	-	-
Batch 14	3,200	10	Absent	10	10	-	-	-
Batch 15	960	10	Absent	10	10	-	-	-

Batches 11 and 12 analysed in March 2021; Batches 13, 14 and 15 analysed in July 2021

Note: APC=Aerobic Plate Count; Ebac= Enterobacteriaceae; LOD=Loss On Drying, db=dry basis

*Yeast and moulds were not analysed in these two samples.

17. The applicant states that no degradation products are expected to form during storage, and the greater amounts of complex carbohydrates in CPC are not expected to result in lower stability (Annex A: p7 dossier).

18. The internal stability study report to evidence this is provided in Annex B: Annex_1_3_2_stability – [**confidential**].

19. The applicant states that stability data for CPC has not been provided, because the data for CPI (Table 3) is believed to be representative of CPC as the protein content of CPI is higher (Annex A: p7 dossier).

Specification

20. The specification parameters for CPC and CPI reported in Table 4 were assessed using internationally recognised methods or are otherwise determined using internally developed and validated methods (Annex A: p8 dossier).

Table 4. Specifications for CPC and CPI

Specifications	CPC Limits	CPI Limits

Loss on drying (%)	≤ 12	≤ 12
Protein (%, dry basis)	≥ 65	≥ 85
Ethyl alcohol (g/kg)	10	10
Sulphur dioxide (mg/kg)	100	100
Aerobic plate counts (cfu/g)	10,000	10,000
Enterobacteriaceae (cfu/g)	10	10
Salmonella (cfu/25g)	Absence	Absence
Yeasts (cfu/g)	5,000	5,000
Moulds (cfu/g)	5,000	5,000
Lead (mg/kg)	0.2	0.2

History of Use

21. The applicant states that corn (*Zea mays*) has a long history of safe use worldwide. Considering the solid body of knowledge and the fact that this cereal has been a pillar of the human diet for thousands of years, the applicant believes that a specific literature search on the history of the plant source is not necessary (Annex A: p8 dossier).

22. The applicant states that CPC and CPI have no history of use in the EU (Annex A: p8 dossier).

Proposed Use

23. The applicant states that corn protein is proposed to be used as a source of protein and a functional ingredient in plant-based food products, cereal-based products, desserts, food supplements and processed meat products. The novel food is not intended to be used as a protein source in infant formula or follow-formula (Annex A: p9 dossier).

24. The applicant has identified 18 foods categories where the novel food is intended to be used. These are listed in Table 5 (Annex A: p9 – 10 dossier).

Table 5. Proposed intended uses and use levels for corn proteins

Food categories	FoodEx2 code	Maximum proposed maximum use (%)
Bakery products (A0BX1)	Bakery products including flatbread and pizza crust (all types including gluten-free), gluten free biscuits, bread, English muffins, and muffins	10
Batters (06.6)1	Batter/breading/coating for frying	10
Breakfast cereals (A00CV) and breakfast cereals, plain(A04LH)	RTE (Ready-To-Eat) cereal, all types	50
Dairy imitates (A0BXC) and ice cream, milk-imitate based (A02QB)	All types of dairy analogues products including imitation cheese and sour cream, cream substitute, non-dairy topping, margarine and margarine-like spreads, tofu frozen dessert, rice dessert bar, ices and sorbet	10

Meat imitates (A03TE)	Meat analogues & vegetarian food products including vegetable protein, vegetarian meat loaf, vegetarian stew, meatless bacon, chicken analogues, breakfast link, fish stick, vegetarian frankfurter, luncheon meat, meatball, vegetarian burger or patty, vegetarian dishes (i.e., pot pie, chili, stew, stroganoff)	25
Dishes excluding pasta or rice dishes, sandwiches and pizza (A03VC)	Pre-packaged products with sauce including frozen meals; canned products such as Chef Boyardee products and creamed vegetables; box mixes such as Hamburger Helper, Rice-A-Roni, Easy Mac, and scalloped and mashed potato; pot pie	10
Milk imitates (A03TH)	Milk substitutes including soy milk, almond milk, rice milk, coconut milk, and other imitation milks	12
Nut butters and spreadables (A0EZP, A05RA)	Only spreads and butters: nut butters including almond, cashew, and peanut (excluding full-fat peanut butter)	10
Pasta, cooked (A007D)	Cooked pastas including macaroni, spaghetti noodles, lasagne noodles, ravioli, other pasta noodles	5
Processed or preserved meats (A0BXT)	Processed and preserved meats including sausage, luncheon meats, frankfurter, cured ham, pastrami, pate, pepperoni, salami, chicken nuggets, patties	10
Protein and protein components for sports people (A03SA)	Only non-reconstituted powder mix (protein powders, milkshake mixes, etc.)	70
Food for sporting people (A06FR)	Food for sporting people (A06FR) beverage high in protein	12

Sauces, cream-based (A043V)	Cream-based sauces including cheese sauce, cream sauce, milk sauce, lemon-butter sauce, hollandaise sauce, horseradish sauce	25
Salad dressing (A045K)	vegan mayonnaise/salad dressing that uses plant proteins	5
Cereal bars (A06DY), muesli and similar mixed breakfast cereals (A06DZ), snacks other than chips (A06EB) and chips, crisps, fries and dough-based analogues (A06EA)	Snack foods including cereal and granola bars, crackers, extruded potato chips, pretzel/snack mix, tortilla chips, corn chips, other veggie/puff chips	50
Soft candies and analogues (A0EQP)	Aerated confections such as marshmallows (A035H)	2
	Gum drops (A035K)	25
	Gummy candies (A035L)	25
Confectionary including chocolate (A06EJ)	Chocolate and similar (A0EQD) including fillings and coatings	40
	Chocolate/cocoa-based products (A0EQS) including fillings and coatings	40
	Chocolate substitutes (A034T) including fillings and coatings	40

25. The applicant states that the EFSA data for the adequate reference (AR)[1] [1]
The level of a nutrient in the diet that meets the daily needs of half the people in a typical healthy population.

2 The level of a nutrient that is likely to meets the need of almost all the people in a population.]

" href="#">(footnote) intake and population reference intake (PRI)2 values in adults is 0.66 protein/kg bw/day and 0.83 g protein/kg bw/day respectively (EFSA, 2017). For infants, children and adolescents, EFSA (2017) report the AR and PRI values as 0.66 g protein/kg bw/day and 0.83 – 1.31 g protein/kg bw/day respectively (Annex A: p10 – 11 dossier).

26. The applicant refers to EFSA reports which state that 18% of the total protein intake may derive from protein isolates (EFSA, 2012; EFSA 2017). Based on the earlier quoted AR and the PRI values, the applicant determined that the average adult would consume 0.12g of protein/kg bw/day and 0.15g of protein/kg bw/day from plant based protein sources. However, the applicant reports that the estimated intake for corn protein would be slightly higher based on nutritional surveys: 0.18 g/kg bw/day and 0.24 g/kg bw/day in females and males, respectively (Annex A: p11 – 12 dossier).

27. The applicant has estimated the exposure of the EU population to corn protein based on the assumption that meat contributes an average 35% of the total protein intake, which is replaced by other protein sources, such as protein isolates (Annex A: p12 dossier). This data can be seen in Table 6.

Table 6. Estimated exposure to corn protein for EU population groups

	Estimated contribution (%)	**Exposure based on AR (g/BW bw/day)**	**Exposure based on PRI (g/kg bw/day)**	**Exposure based on Nutritional surveys (g/kg bw/day)**
Adults (> 18 years old)				
Vegetarians and vegans	35	0.23	0.29	0.35 – 0.47
Athletes and sports people	35	0.42 – 0.7*	----	----
Meat-eaters	18	0.12	0.15	0.18 – 0.24
Athletes and sports people	18	0.22 – 0.36*	----	----

Adolescents (10 – 17 y)	18	0.12	0.16	----
Athletes and sports people	35	0.42 – 0.56**	----	----
Children (3 – 9 y)	18	0.12	0.16	----
Toddlers (12 – 35 months)	18	0.12	0.16	----
Infants (12 months)	18	0.12	0.16	----

AR – The level of a nutrient in the diet that meets the daily needs of half the people in a typical healthy population

PRI – the level of a nutrient that is likely to meets the need of almost all the people in a population

*Values derived from Egan (2016)

** Values derived from Desbrow et al. (2014)

Note: values without asterisk were obtained from EFSA (2012) and Rippin et al. (2017). (see last column for nutritional surveys)

28. The applicant has estimated the corn protein exposure from the novel food and other sources using EFSA food database, national surveys and published references. Based on this data, the applicant states that the exposure to corn protein rarely exceeds 0.2 g/day on average and 2 g/day at the 95th percentile (Annex A: p13 dossier and Annex B: Annex 1_6_4: Sheet 4).

29. The applicant has reviewed the potential exposure of fumonisins to consumers of the novel food as these mycotoxins were detected during the compositional analysis (see Tables 1 and 2). The estimated exposure to mycotoxins was determined to be 180 to 1150 ng/kg BW/day. These results are

presented in Table 7 (Annex A: p14 dossier).

Table 7. Estimated exposure to total fumonisins (B1, B2, B3) from corn protein for EU population groups

	AR for protein (g/kg BW/day)	**Fumonisin exposure AR (ng/BW bw/day)**	**PRI for protein (g/kg bw/day)**	**Fumonisin exposure PRI (ng/kg bw/day)**	**Nutritional surveys (g/kg bw/day)**	**Fumonisin exposure surveys (ng/kg bw/day)**
Vegetarians and vegans	0.23	345	0.29	435	0.35 – 0.47	525-705
Athletes and sports people	0.42 – 0.7*	630 – 1,050	-	-	-	-
Meat-eaters	0.12	180	0.15	225	0.18 – 0.24	270 – 360
Athletes and sports people	0.22 – 0.36*	330 – 540	-	-	-	-
Adolescents (10 – 17 y)	0.12	180	0.16	240	-	-
Athletes and sports people	0.42 – 0.56**	630 – 840	-	-	-	-

Children (3 – 9 y)	0.12	180	0.16	240	-	-
Toddlers (12 – 35 months)	0.12	180	0.16	240	-	-
Infants (12 months)	0.12	180	0.16	240	-	-

*Values derived from Egan et al. (2016)

** Values derived from Desbrow et al. (2014) Note: average values for males and females.

30. The applicant refers to the review by EFSA (2018) which states that the tolerable daily intake for each form of fumonisin: B1, B2, B3 and B4, is 1,000 ng/kg BW/day (Annex A: p14 dossier).

31. The applicant has reviewed the published literature and provided a summary of fumonisin exposure levels from corn consumption in different sub-populations (Annex A: Table 10 (p14 – 16 dossier).

32. The applicant remarks that this data is likely to lead to an overestimation of the exposure in consumers of the novel food due to a number of different factors that impact on the level of fumonisins found in corn. (Annex A: p17 dossier).

Absorption, Distribution, Metabolism and Excretion (ADME)

33. The applicant states that the novel food is derived from corn (*Zea mays*) and mainly contains macronutrients (e.g. protein, fibre, etc.) present in the source material. Since these substances are normal components of the diet, they are

expected to be absorbed, digested, metabolised and excreted identically to the plant source (corn). The applicant concludes ADME studies are not necessary (Annex A: p17 dossier).

Nutritional Information

34. The applicant has reported the analytical data from nutritional analysis of CPC and CPI (Annex A: p17 – 18 dossier). The average values for macronutrients and micronutrients in CPC and CPI are reproduced in Table 8.

Table 8. The average content of macronutrients and micronutrients from five batches of CPC and CPI

Nutritional Parameter	CPC	CPI
Total Fat (as triglycerides) (%) Monounsaturated fatty acids (%) Polyunsaturated fatty acids (%) Trans fatty acids (%)	0.15	0.08
	0.03	0.02
	0.06	0.04
Cholesterol (mg/kg)	0.01	0.01
	1.0	1.0
Total starch (%)	19.8	2.3
Dietary fibre (%)	3.9	4.5
Insoluble fibre (%) Soluble fibre (%)	3.4	4.5
	1.2	0.2
Protein (%)	68.8	90.46
Ash (%)	1.53	1.10

Calcium (mg/kg)	3250	2840
Iron (mg/kg)	120	57.6
Potassium (mg/kg)	208	215
Sodium (mg/kg)	530	329
Vitamin D (µg/kg)	37.1	5
Vitamin B3 (mg/kg)	5	36.6
Anthocyanin (mg/kg)	3.8	25
Total carotene (µg/kg)	0.25	12.8
Mass balance *(%)	96.96	98.44

35. The applicant has reported the amino acid profile which is based on the mean of three samples is provided in Table 9 (Annex A: 19 dossier). The certificates of analysis can be found in Annex B: Annex_1_3_1_1_CoAs (p18 – 20).

Table 9. The average content of amino from three batches of CPI and CPC

Amino acid	Reference values for IAA (g/100g) *	CPI (g/100g)	CPI (standard deviation)	CPC (g/100g)	CPC (standard deviation)
Alanine		8.47	0.01	8.53	0.01

Arginine		2.99	0.01	3.00	0.01
Aspartic Acid		5.65	0.01	5.73	0.08
Cysteine	**	1.75	0.01	1.75	0.02
Glutamic Acid		21.16	0.02	21.28	0.04
Glycine		2.58	0.00	2.64	0.03
Histidine	1.5 – 2.0	1.92	0.02	1.93	0.02
Isoleucine	3.0 – 3.2	4.18	0.10	4.24	0.01
Leucine	5.9 – 6.6	16.03	0.06	16.06	0.11
Lysine	4.5 – 5.7	1.64	0.01	1.72	0.01
Methionine	**	2.53	0.01	2.63	0.06
Phenylalanine	***	6.12	0.05	6.09	0.04
Proline		8.19	0.01	7.96	0.09
Serine		4.16	0.21	3.98	0.07
Threonine	2.3 – 3.1	3.07	0.05	3.08	0.02
Tryptophan	0.6 – 0.85	0.41	0.03	0.48	0.01
Tyrosine	***	4.59	0.07	4.29	0.03

Valine	3.9 – 4.3	4.56	0.07	4.60	0.01

IAA – indispensable amino acids (quoted as range to include infants, children, adolescents and adults)

* EFSA (2012) Scientific Opinion on Dietary Reference Values for protein [p22 – 23]

** reference value for cysteine + methionine is 2.2 – 2.8 g/100g

*** reference value for phenylalanine + tyrosine is 3.8 – 5.2 g/100g

36. The applicant states that CPC is rich in leucine and sulphur containing amino acids, but poor in lysine compared to soy (Annex A: p19 dossier and Annex B: Table 5, p7 in Annex_1_5_1).

Toxicological Information

37. The applicant has provided copies of the final reports for the in vitro micronucleus test and the Ames test for CPC (Annex B: Annex _1_9_1_1 _CPC [**confidential**] and Annex _1_9_1_3 _CPC [**confidential**]). The results indicate that CPC is not genotoxic at up to 100 ug/ml and 1000 ug/plate respectively.

38. The applicant has provided copies of the final reports for the in vitro micronucleus test and the Ames test for CPI (Annex B: Annex _1_9_1_2 _CPI [**confidential**] and Annex _1_9_1_4 _CPI [**confidential**]). The results indicate that CPI is not genotoxic at up to 100 ug/ml and 1000 ug/plate respectively.

39. The applicant states that no feeding studies were completed on CPC or CPI because of the history of use of corn as a food, the characterisation of the novel food and the results from literature search (Annex A: p20 dossier).

Allergenicity

40. The applicant remarks that corn is not listed as one of the major allergens listed in Annex II of 1169/2011 (Annex A: p21 dossier).

41. The applicant has conducted a literature review and concludes that allergic reactions to corn proteins are rare. Further, LTP is responsible for these reported

allergic reactions, and since this protein demonstrates thermal stability, the potential for allergenicity from consuming the novel food ingredient cannot be excluded (Annex A: p21 dossier).

42. The applicant states that the novel food ingredient contains more than 10ppm sulphites and sulphur dioxide which should be declared as per Regulation (EU) 1169/2011 (Annex A: p21 dossier).

Committee Action Required

- The Committee is asked whether the available data provide a satisfactory basis for evaluating the safety of this novel food.
- If so the Committee is asked whether it is content to recommend approval of the novel food as an ingredient to be added to the range of foods specified.
- If not, the Committee is asked to indicate what additional data would be required.

ACNFP Secretariat December 2022

Annexes

ACNFP-157-06-Annex A – Dossier [Confidential]

ACNFP-157-06-Annex B – Annexes and References [Confidential] ACNFP-157-06-Annex C – Request For Information

ACNFP-157-06-Annex D – Applicant’s Response to Request For Information

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