Meeting

Isomalto-Oligosaccharides (IMOs) Discussion Paper

Committee Paper for Discussion - ACNFP/157/05

Advisory Committee for Novel Foods and Processes

Application for the extension of use as a Novel Food for Isomalto-Oligosaccharides (IMOs)

Application number RP1033

Issue

An application has been received under the novel food authorisation process (regulation 2015/2283 as repatriated) for the extension of use for isomalto-oligosaccharides as a food ingredient.

1. The Committee is asked to advise on whether the available data provides an adequate basis for a risk assessment, and whether the novel food as changed by the extension of use application is safe and not nutritionally disadvantageous under the additional proposed uses and use levels. Members are asked to focus on the changes sought to the current authorisation and the additional evidence available in their review.

Background

2. On the 16th April 2021, the FSA received a request for the extension of use for isomalto-oligosaccharides (IMOs) as a food ingredient authorised as a novel food, from Bioneutra North America, Inc.

3. The novel food ingredient is made by the hydrolysis of starch using an enzyme catalysis reaction, followed by filtration and purification steps to generate either a powder or liquid (syrup) form of the product. The applicant wishes to extend the

current list of approved food uses to include ice cream and dairy desserts, instant coffee and tea, table-top sweeteners, cakes, muffins, pies, pastries, breakfast cereals, condiments/relishes, gravies and sauces, gelatines, puddings, fillings, jams and jellies, yoghurts, milk-based drinks, snack foods, and sweet sauces, toppings and syrups, and food supplements.

4. The application dossier is attached as Annex A and the annex to the dossier is attached as Annex B. This contains confidential information.

This application

Identification

5. The novel food corresponds to a mixture of oligosaccharides consisting of 3 to 6 monosaccharide units linked together; however, disaccharides and longer polysaccharides, with up to 9 units, are also present – see Annex A: Table 2.a.1-2, p3 dossier [**confidential**].

6. Compositional analysis reports that IMOs are approximately 30% of mono- and disaccharides, and 70% of oligosaccharides characterised by 3 or more degrees of polymerisation. The majority of the syrup and powder products are composed of isomaltose and oligosaccharides with 3 or more degrees of polymerisation, while less than 10% of the syrup and powder products are composed of sugar as glucose and maltose. See Annex A: Table 2.a.1-3, p4 – 5 dossier [**confidential**].

7. The oligosaccharides are linked together by α-(1,6)-bonds which prevent digestion by enzymes in the gastrointestinal tract (Annex A: p3 dossier).

8. The original novel food application was submitted to the FSA for review in 2008; the initial opinion was drafted in 2012; and the EU authorised IMO as a food ingredient in 2013 (see Annex B: [Annex F] – initial opinion letter, 2012; IMO as novel food ingredient, 2013; amend labelling, 2016). The current approved uses for IMOs are listed in Table 1 of the Annex in (EU) Regulation 2017/2470.

Production Process

9. The applicant states that the production process which was considered and approved in the original submission will not be amended. The detailed production process, raw materials and processing aids are outlined in Annex B [Annex B: p16 – 23 dossier – **confidential**]

10. IMO is produced in accordance with current Good Manufacturing Practice (cGMP) *via* enzyme-catalysed hydrolysis of starch from different sources of plant-based crops (e.g., cereals, legumes, and roots). All starting materials and processing chemicals are appropriate for use in food and meet the specifications of the Food Chemicals Codex, 5th edition (FCC, 2003). The specifications for the different enzyme and fermentation organism preparations used during the production of IMO are consistent with those of the Joint FAO/WHO Committee on Food Additives (JECFA, 1991) and/or FCC (2003) – see Annex A: p6 dossier.

11. The original application referred to potato and wheat as the sources of starch. This extension of use application refers to other sources of starch (cereals, legumes and roots – Annex B [Annex C: p6 dossier]) for which specification sheets can be found in Annex B [Annex B – raw materials specifications].

Composition

12. The applicant has reported analytical data for five batches of IMO syrup and five batches of IMO powder. Analytical data is presented for physicochemical properties, carbohydrate contents, heavy metals and microbiology – see Tables

1 and 2 (Annex A: Table 2.c.1.1-1, p 8 – 9 dossier) meets the proposed specification limits.

Table 1. Product Analysis Results for IMO Syrup Products

Test Parameter	Specification	Method	Batch 1S	Batch 2S	Batch 3S	Bat
Physiochemical Properties						
Appearance	Transparent sticky syrup with light yellow colour	Visual, spectrometer (liquid only)	Transparent sticky syrup; light yellow colour	Transparent sticky syrup; light yellow colour	Transparent sticky syrup; light yellow colour	Tra stic syru yell colo

Taste	Light-sweet t aste	Organoleptic	Mildly sweet	Mildly sweet	Mildly sweet	Mild swe
Viscosity (mPas/cP)	3,000 to 7,000	USP 912>	4,025	4,025	4,300	4,3
Solid content (g/100 g)	>75	USP 831>	75.8	76.2	76.1	76
Water activity (aw)	≤0.8	USP 1112>	0.8	0.8	0.8	0.8
Moisture (%)	≤4.0	AOAC 972.20	-	-	-	-
pH	4 to 6	USP 791>	4.8	4.4	4.6	4.5
Sulphated ash (g/100 g)	≤0.3	USP 281>	0.219	0	0.044	0.0
Carbohydrate Contents						
Glucose (% dry basis)	≤5.0	HPLC-RI	0.86	0.78	0.81	1.4
Isomaltose + DP3 to DP9 (% dry basis)	≥90	HPLC-RI	90.10	90.20	90.22	90.
Heavy Metals						

Lead (mg/kg)	≤0.1	USP 233>, ICP-MS	0.02	0.02	0.02	0.0
Arsenic (mg/kg)	≤0.1	USP 233>, ICP-MS	0.03	0.03	0.03	0.0
Cadmium (mg/kg)	≤0.1	USP 233>, ICP-MS	0.02	0.02	0.02	0.0
Mercury (mg/kg)	≤0.1	USP 233>, ICP-MS	0.02	0.02	0.02	0.0
Microbial Content						
Total aerobic count (CFU/g)	1,000	USP 2021/2022>	10	10	10	10
Yeast and mould (CFU/g)	100	USP 2021/2022>	10	10	10	10
Escherichia coli	Absent/10 g	USP 2021/2022>	Absent	Absent	Absent	Abs
Salmonella	Absent/375 g	USP 2021/2022>	Absent	Absent	Absent	Abs

Staphylococcus aureus	Absent/25 g	USP 2021/2022>	Absent	Absent	Absent	Abs
Coliform (CFU/g)	10	MFHPB-34	10	10	10	10
Enterobacteriaceae (CFU/g)	10	USP 2021/2022>	10	10	10	10

“-“ = not applicable; CFU = colony forming units; DP = degree of polymerisation; HPLC-RI = high- performance liquid chromatography refractive index; ICP-MS = inductively coupled plasma mass spectrometry; USP = United States Pharmacopeia

Table 2. Product Analysis Results for IMO Powder Products

Test Parameter	**Specification**	**Method**	**Batch 1P**	**Batch 2P**	**Batch 3P**	**Batch 4P**	**Batc 5P**
Physiochemical Properties							
Appearance	Transparent sticky syrup with light yellow colour	Visual, spectrometer (liquid only)	Fine white powder, no visible particles	Fine white powder, no visible particles	Fine white powder, no visible particles	Fine white powder, no visible particles	Fine white powd no visibl partic
Taste	Light-sweet taste	Organoleptic	Light-sweet taste	Light-sweet taste	Light-sweet taste	Light-sweet taste	Light- swee taste

Viscosity (mPas/cP)	3,000 to 7,000	USP 912>	-	-	-	-	-
Solid content (g/100 g)	>75	USP 831>	-	-	-	-	-
Water activity (aw)	≤0.8	USP 1112>	-	-	-	-	-
Moisture (%)	≤4.0	AOAC 972.20	3.70	2.92	2.63	2.48	3.34
pH	4 to 6	USP 791>	4.8	4.7	5.8	4.7	5.8
Sulphated ash (g/100 g)	≤0.3	USP 281>	0.195	0.215	0.045	0.081	0.117
Carbohydrate Contents							
Glucose (% dry basis)	≤5.0	HPLC-RI	0.25	0.47	1.26	0.92	0.68
Isomaltose + DP3 to DP9 (% dry basis)	≥90	HPLC-RI	90.96	92.34	89.88	90.08	90.73
Heavy Metals							
Lead (mg/kg)	≤0.1	USP 233>, ICP-MS	0.004	0.02	0.02	0.003	0.010

Arsenic (mg/kg)	≤0.1	USP 233>, ICP-MS	0.015	0.03	0.03	0.005	0.05
Cadmium (mg/kg)	≤0.1	USP 233>, ICP-MS	0.004	0.02	0.02	0.003	0.005
Mercury (mg/kg)	≤0.1	USP 233>, ICP-MS	0.004	0.02	0.02	0.003	0.002
Microbial Content							
Total aerobic count (CFU/g)	1,000	USP 2021/2022>	10	130	10	10	10
Yeast and mould (CFU/g)	100	USP 2021/2022>	10	40	10	10	10
Escherichia coli	Absent/10 g	USP 2021/2022>	Absent	Absent	Absent	Absent	Abse
Salmonella	Absent/375 g	USP 2021/2022>	Absent	Absent	Absent	Absent	Abse
Staphylococcus aureus	Absent/25 g	USP 2021/2022>	Absent	Absent	Absent	Absent	Abse
Coliform (CFU/g)	10	MFHPB-34	10	10	10	10	10

Enterobacteriaceae (CFU/g)	10	USP 2021/2022>	10	10	10	10

13. Certificates of analysis, analytical methods and laboratory accreditations can be found in Annex B [Annex B – **confidential**; Annex C – **confidential**; Annex D respectively].

Stability

14. The applicant relies on the stability data submitted with the original novel food application found in Annex B [Annex A: p23 – 24 original NF dossier] which states that the IMOs are > 99% stable at room temperature (25 ºC), at refrigerator temperature (4 ºC), and at high temperature (45 ºC).

Specification

15. The applicant reports that the chemical, physical and microbiological specification for IMO powder and IMO syrup will not be amended from the original application. See Annex B [Annex A: p54 – 56 original NF dossier].

16. The specification parameters for the novel food were assessed using internationally recognised methods or are otherwise determined using internally developed and validated methods – see Tables 3 and 4 below (Annex A: Tables 2.d.1-1 and 2.d.2-1, p11 dossier).

Table 3. Physical and Chemical Specifications for Isomalto-Oligosaccharide from the Union List of Novel Foods

Specification Parameter	Syrup	Powder
Solubility (water) (%)	NA	≥99
Dried solids (g/100 g)	>75	NA

Glucose (% dry basis)	≤5	≤5
Isomaltose + DP3 to DP9 (% dry basis)	≥90	≥90
Moisture (%)	NA	≤4
pH	4 to 6	NA
Sulphated ash (g/100 g)	≤0.3	≤0.3
Heavy Metals		
Lead (mg/kg)	≤0.5	≤0.5
Arsenic (mg/kg)	≤0.5	≤0.5

DP = degree of polymerisation; NA = not applicable.

Table 4. Microbiological Specifications for VitaFiber® (IMO-syrup and IMO-powder)

Specification Parameter	Syrup	Powder	Analytical Method
Total Aerobic Plate Count (CFU/g)	1,000	1,000	USP 2021/2022>
Yeast and mould (CFU/g)	100	100	USP 2021/2022>
Escherichia coli	Absent/10 g	Absent/10 g	USP 2021/2022>

Salmonella	Absent/375 g	Absent/375 g	USP 2021/2022>
Staphylococcus aureus	Absent/25 g	Absent/25 g	USP 2021/2022>
Coliform (CFU/g)	10	10	MFHPB-34
Enterobacteriaceae (CFU/g)	10	10	USP 2021/2022>

CFU = colony forming units; IMO = isomalto-oligosaccharides; MFHPB = Microbial Analysis of Food Health Protection Branch; USP = United States Pharmacopeia.

History of Use

17. The novel food is already authorised as a food ingredient in the EU (Table 1 of the Annex in (EU) Regulation 2017/2470).

18. The applicant states that all raw materials used in the production of the novel food are common substances used in standard food production practices. (Annex A: p12 dossier).

19. The applicant reports that the isomalto-oligosaccharides are approved for use as a food ingredient and consumed in Australia/New Zealand, Canada, China, India, Israel, Japan, Korea, and the USA (Annex A: p1 – 2, and p12 dossier).

20. The applicant reports that proposed extension of use is similar to the conditions of use for isomalto-oligosaccharides in the U.S. for the proposed food categories (GRN 246 – U.S. FDA 2009; GRN 674 – U.S. FDA 2017; GRN 779

– U.S. FDA, 2018) – see Annex A: p12 – 13 dossier.

Proposed Use and Intake

21. The extension of use for the novel food will increase the number of permitted food groups by fourteen (Table 5) to twenty-six in total (Annex A: p14 – 15 dossier). Additional proposed food uses are listed below in bold.

Table 5. Permitted and Proposed Food Uses and Use Levels of IMO

Specified Food Category	Maximum Levels
Energy-Reduced Soft Drinks	6.5%
Energy Drinks	5.0%
Foods intended to meet the expenditure of intense muscular efforts, especially for sportsmen (including isotonic drinks)	6.5%
Fruit Juices	5.0%
Processed Vegetables and Vegetable Juices	5.0%
Other Soft Drinks	5.0%
Cereals Bars	10%
Cookies, Biscuits	20%
Breakfast Cereal Bars	25%
Hard Candies	97%
Soft Candies/Chocolate Bars	25%
Meal replacement for weight control (as bars or milk based)	20%
Ice Cream and Dairy Desserts	**8%**

Instant Coffee and Tea	**10%**
Table-Top Sweeteners	**100%**
Cakes, Muffins, Pies	**20%**
Pastries	**15%**
Breakfast Cereals	**10%**
Condiments/Relishes; Gravies and Sauces	**10%**
Gelatines, Puddings, Fillings	**15%**
Jams and Jellies	**50%**
Yoghurts	**2.5%**
Milk Based Drinks	**5%**
Snack Foods	**5%**
Sweet Sauces, Toppings and Syrups	**50%**
Food Supplements as defined in Directive 2002/46/EC	**30 g/day for the general population older than 10 years**

Additional Specific Labelling Requirements:

1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “Isomalto- oligosaccharide”.

2. Foods containing the novel ingredient must be labelled as ‘a source of glucose’.
3. Food supplements containing isomalto-oligosaccharide shall bear a statement that the food supplement should not be used if other foods with added isomalto-oligosaccharide are consumed the same day.

22. A summary of the intake calculations with listings for top contributing categories per population group is provided – the appendix showing exposure determinations for each EU country can found in Annex B [Annex E – **confidential**].

23. The applicant estimated the daily intakes of IMO by matching the FoodEx2 code for food products with the summary statistics of food consumption from the EFSA Comprehensive Database for permitted food uses. Table 6 shows the mean and high intakes for the permitted food uses of IMO (columns 2 and 3), and the mean and high intakes for the permitted plus proposed food uses of IMO (columns 4 and 5).

Table 6: Estimated absolute intake levels for the permitted food uses (columns 2 and 3), and the permitted plus proposed food uses of IMO (columns 4 and 5)

Population Group	Mean intake levels for IMO (g/day)	High intake levels for IMO (g/day)	Mean intake levels for IMO (g/day)	High intake levels for IMO (g/day)
Infants	1 – 3	1 – 13	1 – 8	5 – 27
Toddlers	2 – 19	8 – 40	7 – 37	12 – 49
Other children	8 – 23	18 – 46	16 – 37	28 – 66
Adolescents	7 – 32	22 – 91	14 – 48	29 – 98
Adults	6 – 24	16 – 94	10 – 42	32 – 113

Pregnant and lactating women	8 – 13	17 – 33	17 – 31	28 – 58
Elderly	3 – 13	4 – 52	5 – 34	16 – 83
Very elderly	4 – 10	9 – 44	10 – 34	15 – 88

Infants ≤ 11m; toddlers 12 – 35m; other children 3 – 9y; adolescents 10 – 17y; adults 18 – 64y; elderly 65 – 74y; very elderly ≥ 75y

24. The applicant states that the data shows adults are expected to have the highest high level intake of the novel food from the current permitted food uses. The addition of the proposed food uses increases the high-level estimated daily intake in adults by 19 g/person/day, from 94 g/person/day to a maximum of 113 g/person/day (Annex A: p20 dossier).

25. The applicant states that the largest increase in the estimated mean and high level intakes of the novel food was seen in the very elderly with the IMO intake levels increasing by an additional 24 g/day (from 10 to 34 g/day) and 44 g/day (from 44 to 88 g/day), respectively.

26. Table 8 shows the mean and high intakes for the permitted food uses of IMO (columns 2 and 3), and the mean and high intakes for the permitted food uses plus proposed food uses of IMO (columns 4 and 5) on a body weight basis.

Table 7: Estimated intake levels for the permitted food uses (columns 2 and 3), and the permitted plus proposed food uses of IMO (columns 4 and 5) on a body weight basis

Population Group	**Mean intake levels for IMO (g/kg bw/day)**	**High intake levels for IMO (g/kg bw/day)**	**Mean intake levels for IMO (g/kg bw/day)**	**High intake levels for IMO (g/kg bw/day)**
Infants	0.1 – 0.4	0.1 – 1.6	0.1 – 0.9	0.6 – 2.8

Toddlers	0.2 – 1.4	0.7 – 3.3	0.5 – 2.7	1.0 – 4.2
Other children	0.3 – 1.1	0.8 – 2.4	0.6 – 1.9	1.1 – 3.0
Adolescents	0.1 – 0.7	0.4 – 1.6	0.3 – 1.0	0.6 – 1.7
Adults	0.1 – 0.3	0.2 – 1.3	0.1 – 0.5	0.4 – 1.5
Pregnant and lactating women	0.1 – 0.2	0.2 – 0.6	0.3 – 0.4	0.4 – 0.9
Elderly	0.1 – 0.2	0.1 – 0.7	0.1 – 0.4	0.1 – 1.0
Very elderly	0.1 – 0.1	0.1 – 0.6	0.1 – 0.5	0.2 – 1.1

Infants ≤ 11m; toddlers 12 – 35m; other children 3 – 9y; adolescents 10 – 17y; adults 18 – 64y; elderly 65 – 74y; very elderly ≥ 75y

27. The applicant states that on a body weight basis, the highest intakes of IMO from permitted plus proposed food uses were observed in toddlers, up to 2.7 and 4.2 g/kg body weigh/day at the mean and high-level, respectively. In the remaining population groups, mean intakes remained below 1.9 g/kg body weight/day, while high-level intakes remained below 3.0 g/kg body weight/day.

28. The applicant proposes that IMO in food supplements, for consumers > 10 years old, will be used as an alternative to consuming conventional foods containing the novel food, at a maximum of 30 g/day. This is equivalent to 0.43 – 0.69 g/kg body weight/day.

29. IMO in foods and food supplements are not intended to be consumed on the same day. The applicant proposes a labelling statement to address this issue (Annex A: p14 dossier).

Absorption, Distribution, Metabolism and Excretion (ADME)

30. The applicant states that malto-oligomers (1→4) and smaller isomalto-oligomers (1→6), e.g. isomaltose, are digested by intestinal enzymes to glucose. The larger IMOs pass essentially undigested through the gastrointestinal (GI) tract because they resistant to enzymatic hydrolysis (Annex A: p23 dossier).

31. The applicant states that *in vitro*, and *in vivo* animal and human studies demonstrate that larger IMOs are resistant to enzymatic hydrolysis in the upper GI tract and remain unabsorbed (Kaneko *et al*., 1992; Oku and

Nakamura, 2003). These IMOs can be used as a source of energy by bacteria in the lower GI tract where they undergo fermentation. This results in the production of short-chain fatty acids (SCFAs) which are absorbed and utilised in well characterised biochemical pathways (Oku and Nakamura, 2002, 2003; Goffin *et al* ., 2011) (Annex A: p23 dossier).

32. The applicant refers to published *in vitro* studies using pancreatic amylase and amyloglucosidase or brush border enzymes (Hu *et al*., 2017, 2020). In these experiments, glucose release from IMOs was lower than maltose (digestible control), and higher than resistant maltodextrin (non-digestible control). The applicant concludes that these results show that the novel food is only partly digestible (Annex A: p23 dossier).

33. The applicant reports that the digestibility of IMOs have been evaluated *in vivo* in ileal-cannulated pigs (Hu *et al.*, 2020). The results indicate that the novel food which has a higher proportion of α-(1,6)-linkages has a lower digestibility than IMO’s with a higher proportion of α-(1,4)-linkages (Annex A: p23 – 24 dossier). The applicant concludes that this supports the findings in human studies for a lack of absorption of isomalto-oligomers (1→6) from IMO.

Nutritional Information

34. The applicant relies on the nutritional profile data submitted with the original novel food application found in Annex B [Annex A: p36 – 58 original NF dossier]. Further comments from the ACNFP during the original review process can be found in Annex B [Annex F: p6 – 9, FSA IMO initial opinion 2012].

Toxicological Information

35. The applicant reports that no new genotoxicity studies have been conducted on isomalto-oligosaccharides (Annex A: p26 dossier). The applicant refers to the studies in Kaneko *et al* (1990) which reports that IMO’s are not mutagenic (Ames

test – standard battery) or clastogenic in Chinese hamster lung cells.

36. The applicant reports that no new feeding studies have been conducted on IMOs (Annex A: p27 – 28 dossier). A summary of the studies reported in the initial novel food dossier, not conducted to OECD standards, are presented in Table 8.

Table 8. Summary of published studies from original dossier to support safety of novel food

Authors	Study	Observations
Kaneko *et al* (1992)	35 day feeding study in male SD rats – 20 g/kg bw/day only	No statistical difference in final body weight, body weight gain, food intake or relative organ weights. Group mean serum triglyceride level significantly lower than control, but other lipid classes comparable to control.
Day and Chung (2004)	6 week feeding study in male SD rats – 0, 5, 10 and 20 g/kg bw/day	Weight gain, food intake and organ weights comparable in all groups. Increase in caecum weight at 10 and 20 g/kg bw/day. Dose dependent reduction in abdominal fat.
Kaneko *et al* (1990)	1 year chronic study in male Wistar rats – 3% IMO in drinking water (3 – 5 g/kg bw/day)	Significant decrease in haemoglobin, haematocrit, and ALT levels. No abnormalities noted in histopathology or gross necropsy.
Ly *et al* (1999) Chai and Ree (2000) Sung *et al* (2004)	3 x 30 day studies in normal and diabetic SD rats – 3 to 10 g/kg bw/day	No reported significant differences in body weight, weight gain, food intake or liver weights. Increased weight in caecum or caecal contents.

37. The applicant provides a review of human safety/tolerance studies that were evaluated during the assessment of the original dossier (Annex A: p31 – 32 dossier). These studies confirm that IMOs are usually well tolerated. The threshold dose for transient diarrhoea in consumers of IMOs is reported as 1.5 g/kg body weight or greater.

38. The applicant states that five new studies using human subjects have been conducted since the original novel food authorisation – one concerning prebiotic activity and four other studies relating to the glycaemic response. A summary of the four published studies are presented in Table 9 Annex B [References – published]. One study remains unpublished and can be found in Annex B [References – Unpublished].

Table 9: Summary of studies on safety and tolerability of IMO's

Authors	Study	Observations
Yen et al (2011)	Double-blind, random, diet controlled study; 13 elderly M/F subjects; IMO dose increased to 10 g/day for 4 weeks	No significant differences in body weight, albumin, glucose, triglyceride, HDL- cholesterol, urea nitrogen, creatinine, or ALT were reported. Significant increase in spontaneous defecation, stool output and dry faecal mass.
Gourineni *et al* . (2018) Source of IMO is Bioligo™ IL5040 and Bioligo™ IL7010	Single dose cross- over trial; 26 healthy M/F, age 18 – 75 (1st trial) and 10 healthy M/F, age 34 +/- 11 years (2nd trial), dextrose or IMO equivalent to 50g carbohydrate	No significant differences in postprandial glucose or insulin responses after consumption of a single administration of IMO or glucose control. No significant differences in postprandial breath hydrogen between conditions. No significant differences in composite or individual GI tolerability scores were reported.

Lowery *et al.* (2018) Source of IMO from Tate and Lyle, PLC	Randomised, double blind cross over trial; 10 adults (age 27.1 +/- 2.1 years) – 25g IMO syrup	No significant difference in breath hydrogen levels between IMO and placebo control. Blood glucose and insulin levels were significantly higher 30 minutes after the consumption of IMO compared to other groups. Evaluation of adverse effects not stated.
Grubic *et al.* (2018) Source of IMO is Bioneutra's Vitafiber^{T}	Randomised, cross - over trial; 20 (1st trial) and 10 (2nd trial) healthy adults (age 18 – 35 years) with BMI 25 – 25g IMO in food bar; 20g IMO in beverage	IMO in a food bar significantly lowered the glycaemic response compared to control. No significant treatment effects were observed in either trial. IMO in beverage produced similar post-prandial changes in plasma glucose and insulin as control. Well tolerated, with no adverse GI effects.

Allergenicity

39. The applicant states that IMOs must be used in accordance with requirements on food allergens, if it is derived from one of the allergenic crops identified in EU labelling legislation – compositional analysis shows that starch can be derived from tapioca, corn or pea (Annex A: p37 dossier).

40. The applicant reports that purification of the IMOs using ion exchange columns ensure that there is no protein present – see Annex B [Annex A: p23 original NF dossier].

Committee Action Required

- The Committee is asked whether the available data provide a satisfactory basis for evaluating the safety of the extension of uses for the 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-157-05-Annex A – Dossier and References [Confidential] ACNFP-157-05-Annex B – Annexes [Confidential]

ACNFP-157-05-Annex C – Request For Information

ACNFP-157-05-Annex D – Applicant’s Response to Request For Information