COMMITTEE PAPER FOR DISCUSSION **ACNFP/130/05**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

VIVINAL® GOS PT FROM FRIESLANDCAMPINA

Issue

The Committee is asked to consider information provided by FrieslandCampina, who have requested the opinion of the UK Competent Authority. An opinion is sought on whether their product Vivinal® GOS PT should be considered substantially equivalent with Vivinal® GOS already on the EU market. The Committee is asked if it agrees that substantial equivalence has been demonstrated.

Background

1. Galacto-oligosaccharide (GOS) is used to describe a group of carbohydrates composed of oligo-galactose with some lactose and glucose molecules. GOS is a prebiotic produced commercially from lactose by β-galactosidase. Oligosaccharides resembling GOS occur naturally in human milk and may be one of the factors that protect human infants from gastrointestinal pathogenic bacteria. GOS is typically added to infant formula powder to emulate human breast milk[1].

2. There have been several Novel Food Applications for GOS submitted under Regulation No 258/97 in the European Union (EC, 1997). These applications filed by several companies, related to notifications of substantial equivalence in which the comparator product was FrieslandCampina's Vivinal® GOS. Vivinal® GOS by FrieslandCampina was already marketed in the EU prior to 15 May 1997 and is therefore outside the scope of the novel food Regulation.

3. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has notified the Commission. In most cases, the Commission

[1] https://dx.doi.org/10.1080%2F17482970701414596

requires that the applicant first obtain an opinion on equivalence from a Member State. FrieslandCampina is requesting such an opinion from the UK Competent Authority for a new GOS product that they have developed, Vivinal GOS PT.

4. According to Article 3(4) of (EC) 258/97, the notification procedures applies to "foods or food ingredients…which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies…are substantially equivalent to existing foods or food ingredients as regards to their:
   - Composition
   - Nutritional value
   - Metabolism
   - Intended use, and
   - Level of undesirable substances contained therein."

5. FrieslandCampina has provided information to support the claim that their new product Vivinal® GOS PT is substantially equivalent to an existing product Vivinal® GOS. FrieslandCampina seeks equivalence to use the new product in the same way as other permitted GOS products already on the market, in particular Vivinal® GOS. The application dossier is attached as **Annex A** and appendices are attached at **Appendices.** Also attached at **Annex B** is a response to questions raised by the FSA and the associated appendices. Both annexes contain confidential information.

Evaluation

a) Composition

The dossier states that Vivinal® GOS PT and Vivinal® GOS have an equivalent production process chain. The only way in which they differ is the source of the β-galactosidase in the production process, Vivinal® GOS is obtained from *Bacillus circulans* and Vivinal® GOS PT is from *Papiliotrema terrestris.* The same raw material, equipment and production plant are used for both with only minor differences in some operating conditions.

In all of the analyses, the applicant's data have been compared. The applicant in each analysis had compared four batches of Vivinal® GOS PT to one batch of Vivinal® GOS.

The applicant explains that GOS PT Syrup is the starting material for Vivinal® GOS PT Easy Drying Syrup and Vivinal® GOS PT Powder and therefore concludes that the latter two products are substantially equivalent also. The applicant has not provided further analysis of the Vivinal® GOS PT Easy Drying Syrup and Vivinal® GOS PT Powder products.

The applicant has compared the Proximate analysis of Vivinal® GOS PT to Vivinal® GOS. This is summarised in the table below:

Test Parameter	**Vivinal® GOS Specification**	**Vivinal® GOS PT** 731	**Vivinal® GOS PT** 741	**Vivinal® GOS PT** 631	**Vivinal® GOS PT** 431	**Vivinal® GOS 704212**
	Comparator product?	**Novel Ingredient**				**Comparator product**
Dry matter	74 - 76 %	76,08	75,09	76,39	76,79	74.26
Galacto-oligosaccharides	Min. 57% on DM	62,2	63,14	63,8	64,82	58.14
Nitrogen	Max. 0.032% on DM	0,0016	<0,0016	<0,0016	<0,0016	0,0016
Protein		<0,01	<0,01	<0,01	<0,01	0,01
Sulphated Ash	Max.0,3% on DM	< 0,01	0,02	0,02	0,02	0.01
Lactose	Max.23% on DM	18,3	17,6	16,62	17,07	20,04
Glucose	Max.22% on DM	18,4	18,16	18,39	17,24	20,36
Galactose	Min.0.8% on DM	1,03	1,1	1,19	0,88	1.46
Nitrite	Max. 2 ppm on DM	0,08	0,07	0,07	0,07	0.02
pH	2,8 – 3,8	3,34	3,24	3,08	3,2	2,9

Small variations can be seen in the levels of Galacto-oligosaccharides, Lactose, and Glucose but the applicant does not regard these to be significant.

The applicant has compared the mineral content of Vivinal® GOS PT to Vivinal® GOS. This is summarised in the table below.

Minerals (µg/g)	**Vivinal® GOS PT 731**	**Vivinal® GOS PT 741**	**Vivinal® GOS PT 631**	**Vivinal® GOS PT 431**	**Vivinal® GOS 704212**
	Novel product				**Comparator product**
Sodium(mg/kg)	<20	<20	<20	<20	<20
Potassium(mg/kg)	<25	<25	<25	<25	<25
Calcium (mg/kg)	<10	<10	<10	<10	<10
Chloride (%)	<0.01	<0.01	<0.01	<0.01	<0.01
Phosphorus (mg/kg)	<10	<10	<10	<10	<10
Magnesium (mg/kg)	<1	<1	<1	<1	<1

The applicant has compared the Comparison of degree of polymerization of Vivinal® GOS PT Syrup Vivinal® GOS Syrup. The applicant states that whilst there are some differences in DP2, DP3 and DP4 these are slight differences and considers that the two products are substantially equivalent. This is summarised in Table 4.2 of **Annex A**.

b) Nutritional Value and Metabolism

The applicant has compared the total energy of Vivinal® GOS PT to Vivinal® GOS and considers them to be substantially equivalent. The applicant's explains that small variations seen in GOS, lactose, glucose and galactose when comparing Vivinal® GOS PT to Vivinal® GOS are not significant and will not have a significant impact on the nutritional value and metabolism Vivinal® GOS PT.

c) Intended Use

The applicant intends to market Vivinal® GOS PT, for exactly the same purposes and at the same levels as Vivinal® GOS. The novel ingredient is intended for use in a variety of food products including milk drinks, juices, yoghurts, food supplements, cereals and infant and follow-on formulae. The applicants intended uses and use levels are detailed in full in Table 4.6 of **Annex A**.

d) Level of undesirable substances

Chemical and Microbial Content

Chemical Contamination

The applicant provided results of heavy metals analyses (arsenic, cadmium and lead) for four separate batches of its Vivinal® GOS PT and has compared these with data obtained Vivinal® GOS on the market (Table 4.4 of **Annex A**).

Microbial Contamination

The applicant presented a summary microbiological data in Table 4.5 of **Annex A** and provided analyses of three separate batches of its Vivinal® GOS PT compared to its Vivinal® GOS on the market product. Data relating to yeasts and moulds, *E.coli*, *Salmonella*, coagulase positive Staphylococci, *Bacillus cereus,* Coliforms and Enterobacteriaceae were presented. No concerns were identified and FrieslandCampina's Vivinal® GOS PT results are comparable to its Vivinal® GOS product.

Committee Action Required

- The Committee is asked whether it agrees that substantial equivalence has been established between FrieslandCampina's Vivinal® GOS PT and an existing product on the market, Vivinal® GOS, also produced by FrieslandCampina, in accordance with Article 3(4) of Regulation (EC) 258/97.
- If so, the Secretariat proposes to draft an opinion incorporating the ACNFP's comments on this application which will be presented along with the results of the public consultation at the next meeting in November.

- If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

Secretariat

September 2017

Annexes attached:

Annex A - Application Dossier (Official sensitive)

Appendices - Certificates of analysis (Official sensitive)

Annex B - Response to comments by the FSA and associated appendices. (Official sensitive).