

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

VIVINAL® GOS PT

Issue The Committee reviewed this application for the first time at the last meeting in September. Queries were raised in a number of areas relating to the product. The applicant has now provided further information for the Committee's consideration. Members are invited to consider the response from the applicant and whether this addresses the questions raised in September. The Committee is asked to consider whether it recommends authorisation of the product. An opinion has also been provided for the Committee's consideration.

Background

1. This application from by FrieslandCampina is for authorisation of Vivinal® GOS PT (Galacto-oligosaccharide (GOS)) as a novel food ingredient under 258/97. At the September meeting the Committee requested further information in two key areas:
 - a) Composition
 - b) Undesirable substances
2. A letter was sent to the applicant communicating the Committee's points (**Annex A**). The applicant has now provided a response to the Committee's questions (**Annex B**) and provided accompanying documents (**Annex C**).

Public comments

3. In line with the Agency's openness policy, the application dossier was published on the Committee's website for a twenty one day public consultation. The public comments received have been summarised in **Annex D** for the Committee's consideration.

a) Composition

4. At the last meeting the Committee requested confirmation that the batches of analysed had been produced using the same process that would be used in future production. The Committee also requested evidence that the β -galactosidase enzyme is removed from final product.
5. The applicant has provided information confirming that the same process will be used in the future production of the product. Confirmation of the absence

of β -galactosidase enzyme in the final product is contained in the applicant's response (**Annex B and C**).

b) Undesirable substances

6. The Committee previously requested that the applicant revise the analysis summary tables for minerals and heavy metals and report absolute values.
7. The applicant has revised the tables and provided details on the limits of detection used for each analysis in an accompanying footnote.

Committee Action Sought

- a) The Committee is asked whether the response from the applicant is sufficient to address the questions raised in September 2017.
- b) The Committee is asked whether it agrees that substantial equivalence has been established between Vivinal® GOS PT and an existing product already on the market, in accordance with Article 3(4) of Regulation (EC) 258/97. A draft opinion is provided at **Annex E** for consideration.
- c) If not, the Committee is asked to indicate what feedback should be given to the applicant.

**Secretariat
November 2017**

Annexes and Appendices attached

Annex A- Letter sent to applicant following September 2017 meeting

Annex B- Applicant's response

Annex C- Analysis of activity of β -galactosidase

Annex D- Comments summary from public consultation of Vivinal® GOS PT dossier.

Annex E- Draft opinion of Vivinal® GOS PT dossier

Annex F- Secretariat summary of GOS data