

## Position Paper

# Inulin and oligofructose regarding enhanced calcium absorption in the context of the European Nutrition and Health Claim Regulation (NHCR)

BENE<sup>®</sup>O's claim entry related to enhanced calcium absorption and increased bone mineral density for Orafit<sup>®</sup>Synergy1 (ID 771 & 772) was rejected by EFSA in the 5<sup>th</sup> batch published on June 30, 2011<sup>1</sup>. The reason given for the negative opinion was "insufficient characterisation of the ingredient" and consequently no evaluation of the science was conducted (see text box below).

BENE<sup>®</sup>O would like to comment on the situation as follows:

### Claims ID 771 covering:

Oligofructose-enriched inulin (specific selection of long and short chains) from chicory

**Example of wording:** increases / promotes / enhances calcium absorption

### Claims ID 772 covering:

Oligofructose-enriched inulin (specific selection of long and short chains) from chicory

**Example of wording:** increased bone mineral density  
Increased bone strength

### EFSA response (ON 2244): Rejection due to insufficient characterisation

*"The Panel notes that the food constituents described in relation to the health claims, and the food constituents used in the references provided for scientific substantiation, include a wide variety of inulin-type fructans with variable degrees of polymerisation, which could have an impact on the claimed effects.*

*The Panel considers that the food constituents, inulin-type fructans, which are the subject of the health claims, are not sufficiently characterised in relation to the claimed effects considered in this section.*

*The Panel concludes that a cause and effect relationship cannot be established between the consumption of inulin-type fructans and the claimed effects considered in this section."*

### **BENEO position concerning the rejection of ID 771 and 772 because of “insufficient characterisation” of the ingredient**

- It is hard to understand why EFSA rejected this claim because of “insufficient characterisation”. In particular as EFSA defined Orafti<sup>®</sup>Synergy 1 (generic description “oligofructose-enriched inulin”) as a mixture of “low and high molecular weight compounds”.
- The industry was requested to use general sales designations (like “oligofructose-enriched inulin”, not brand specific) and there was no request for specific “identity documentation” other than that is used in scientific literature and food labelling.
- The current system foresees a “further clarification procedure” only in the case of probiotics which were also rejected due to insufficient characterisation. Although requested by industry, the Commission explicitly did not offer that option for other types of “insufficiently characterised” ingredients.

### **Next steps by BENEEO**

- EFSA did not address the scientific background at all in their opinion ON 2244.
- As there is no further clarification procedure possible for “insufficiently characterised” food, BENEEO cannot clarify with EFSA that e.g. the submitted key human intervention study (Abrams et al.) is only valid for Orafti<sup>®</sup>Synergy 1.
- Most probably the only option is to submit an Art 13(5) dossier.

### **Time lines and transition periods for Art 13(1) claims in the context of the NHCR**

- Authorities are currently working on the finalisation of the Art 13(1) list. It is assumed that the new list will be in place and in force from mid 2012 onwards. The transition period will end six months later. This means, the end of the phase out period for products not complying with the Art 13(1) list is estimated to be end of 2012.

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<sup>i</sup> EFSA Journal 2011;9(6):2244