

Position Paper

Inulin and oligofructose for bowel function in the context of the European Nutrition and Health Claim Regulation (NHCR)

BENEEO's claim entry related to the support of inulin and oligofructose on digestive function/bowel function (ID 769) was rejected by EFSA in the 5th batch published on June 30, 2011¹. The negative outcome was based on "insufficient characterisation of the ingredient" and consequently no evaluation of the science was conducted (see text box below).

BENEEO would like to comment on the situation as follows:

Claims ID 769 covering:

Inulin, oligofructose and oligofructose-enriched inulin (specific selection of long and short chains) from chicory

Example of wording:

- Promotes / supports digestive health
- Improves bowel regularity
- Improves digestive / bowel function

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."

¹ EFSA Journal 2011; 9(6) 2244

BENEO position concerning the rejection of ID 769 because of “insufficient characterisation” of the ingredient

- When the claims were submitted **in 2007**, inulin, oligofructose and oligofructose enriched inulin (Orafti®Synergy1) were grouped together in one claim entry because the scientific basis is relevant for all these inulin-type fructans and these claims are used on the market.
- Industry was requested to use generic sales designations (not brand specific) and there was no request for specific “identity documentation” at that time, 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 in their opinion ON 2244 at all.
- Nevertheless EFSA regards the improvement in bowel motor function within the normal range as beneficial to human health. This means that the claim as such is possible, assuming a cause and effect relationship can be established on generally accepted scientific evidence.
- Scientific work by the BENEEO-Institute is on-going to strengthen the scientific basis for fructan-type inulin.
- The BENEEO-Institute will prepare an Art 13(5) dossier based on current data and new research once sufficient additional data are available.

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.

CONCLUSION:

- The important role of dietary fibres in bowel function is scientifically well-accepted by academia on a global basis. Inulin and oligofructose are dietary fibres.
- The claim for inulin and oligofructose was rejected due to the specifics in applying the European NHCR and not due to a scientific evaluation of the data.
- As a consequence, the European consumer, more so than the consumer outside the EU, will have limited access to information on products related to the support of bowel function by these fibres for some time.
- Further research in the area of gut health and bowel function is on-going and supported by BENEEO. This will result in an Art 13(5) application.