

Position Paper

The prebiotic claim in the context of the European Nutrition and Health Claim Regulation (NHCR)

In several claims entries, including the entry filed by BENEEO (ID 766) EFSA decided negatively with respect to a prebiotic claim as a stand-alone health claim. The rejection was made based on “insufficient characterisation of the ingredient” and consequently no evaluation of the science was conducted (see textbox 1).

BENEEO would like to comment on the situation as follows:

Claims ID 766 covering:

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

Example wording:

- Stimulates the growth of bifidobacteria in the colon
- Beneficially affects the intestinal flora
- Promotes healthy / balanced / good bacteria

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 766 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 general sales designations (not brand specific) and there was no request for specific “identity documentation” at that time other than what is used in scientific literature and food labelling.
- The current system foresees a “further clarification procedure” only in the case of probiotics which were rejected due to insufficient characterisation. Although requested by industry, the Commission explicitly did not offer that option for other types of “insufficiently characterised” ingredients.

The prebiotic claim in the context of the European health claim system

- Art. 5(a) of the NHCR requires a beneficial nutritional or physiological effect related to the nutrient and claim – as established by generally accepted scientific evidence. The prebiotic concept is a nutritional concept related to the support of gut health and a healthy gut flora that was developed by academia (mainly European researchers) over the past 20 years. Numerous publications in peer reviewed journals and text books reflect this work. The basic principle of this concept is that the selective stimulation of the growth of those bacteria known to be “good”, rather than those with pathogenic or toxic potential, is beneficial to the body. Inulin and oligofructose are proven prebiotics. The list of scientific references that was provided by BENEEO to EFSA for this claim in 2007 is available on request. The NDA Panel however did not consider the prebiotic effect as being “beneficial to health” in the context of the NHCR.
- As a result of not being regarded as “beneficial to health” by the NDA Panel, the criteria for granting a health claim in the context of the European NHCR are not fulfilled and consequently, the claim can no longer be used as a stand-alone claim once the transition period is over.
- It needs to be pointed out that the prebiotic concept as such is accepted by a large scientific community and supported by abundant peer reviewed literature.
- The pre- and probiotic concepts, developed to support consumer gut health (not to treat illnesses), do not fit into the approach taken by the regulators when establishing the European Health Claim Regulation.
- BENEEO regards this as a tremendous drawback for the European consumer because information on food with highly probable positive effects for the consumer will not reach the consumer’s attention.

In more detail:

The specific confines of the NHCR – hard to understand and accept for ‘non-insiders’

- Due to the approach EFSA has taken, the whole prebiotic concept (more than 20 years of international research work!) has been rejected: textbook knowledge, national nutrition society conclusions and recommendations, national authorities approvals – all these do not seem to play a role when evaluating data in the specific context of the NHCR.

- During the public EFSA hearing on gut health and immunity in Amsterdam, Dec 2, 2010, Prof. Markwart Kunz, Member of the board of SÜDZUCKER, at that time in his role as President of ELC (the European voice of the European speciality ingredient manufacturers), asked EFSA to clearly communicate “...that their conclusions need to be seen in a very specific and narrow way of the specific claim assessed in the context of the Regulation, because there’s a high risk that the outcome [...] is perceived as the only and the common understanding of state of the art science.....” Prof. Albert Flynn (Chairman of EFSA’s NDA Panel) replied to that: “... indeed it’s correct that the scientific assessments carried out by the panel are done within the strict legal confines of the Regulation and they have to be seen in that light.....” (see textbox 2)





- Prof. Albert Flynn (chairman of EFSA’s NDA Panel) replied that:
- “... indeed it’s correct that the scientific assessments carried out by the panel are done within the strict legal confines of the Regulation and they have to be seen in that light.....”

“...EFSA should clearly communicate that their conclusions need to be seen in a very specific and narrow way of the specific claim assessed in the context of the Regulation, because there’s a high risk that the outcome of this event is perceived as the only and the common understanding of state of the art science.....it is a specific outcome under the Regulation of the European Commission and not the general scientific outcome.”

Reactions of the scientific and academic expert community

- There is extensive protest from academia about the approach EFSA has taken (written reaction to specific opinions, editorials, open letters, and speeches). This is reflected at e.g. <http://www.gut-health.eu>

- Experts in the field recently expressed their concern also in an open letter in the British Journal of Nutrition, that “*those who are not aware of either the research supporting specific probiotics and prebiotics or the NDA review process may come to the fallacious conclusion that probiotics or prebiotics have not been shown to have health benefits*”
Reference: F. Guarner et al., Probiotic and prebiotic claims in Europe: seeking a clear roadmap. British Journal of Nutrition, Nutr. 2011, 1-3, abstract is available here:
http://journals.cambridge.org/abstract_S0007114511002248
- It is not clear how ‘health’ and a healthy gut flora can be defined and how the support of a healthy gut flora can be measured in a way to comply with EFSA criteria. In the context of the NHCR, this issue will not be solved quickly.
- A recent review paper, developed as an initiative of ILSI Europe, addresses the research and the gaps related to the metabolic and health benefits of the prebiotic concept and is published in the British Journal of Nutrition.
Reference: M. Roberfroid et al., Prebiotic Effects: Metabolic and Health Benefits, British Journal of Nutrition 2010; 104 (Suppl.2): S1-S63, full article is available at:
http://journals.cambridge.org/abstract_S0007114510003363
- Another review paper on Dietary Prebiotics by Gibson et al., co-authored by the working group of ISAPP scientist, was published in Food Science and Technology Bulletin mid 2010.
Reference: G. Gibson et al., Dietary prebiotics: current status and new definition. Food Science and Technology Bulletin: Functional Foods 7, (1), 1-19, abstract is available at:
<http://www.foodsciencecentral.com/fsc/ixid15880>
- BENEEO initiated a scientific debate with a group of leading scientists in the field of prebiotics to develop a refined prebiotic concept: the healthy flora concept (more information for our customers and interested health professionals can be found in BENEEO’s Window to Science Dec 2010)

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 which do not comply with the Art 13(1) list is estimated to be end of 2012.

CONCLUSION:

- The European consumer, more so than the consumer outside the EU, will have very limited access to foods stating information related to the support of a healthy gut flora and the well-established prebiotic effect of inulin and oligofructose.
- Due to the restriction on target-specific effects in the context of the NHCR an expansion to broader health-supporting concepts like the pre- and probiotic concepts will require long-term mutual exchange among all stakeholders for a consensus on applicable and acceptable criteria.
- Further research in the area of gut health and gut flora is on-going, in Europe and outside Europe, supported by BENEEO and other interested parties of industry and academia.