

European Functional Foods Highlights



THE BECEL PRO ACTIV CASE

the first authorised European functional food cleared through the Codes of Conduct as well as through the Novel Foods Legislation.
Launched in the EU in August 2000

Source:

The Functional Foods Dossier: BUILDING SOLID HEALTH CLAIMS

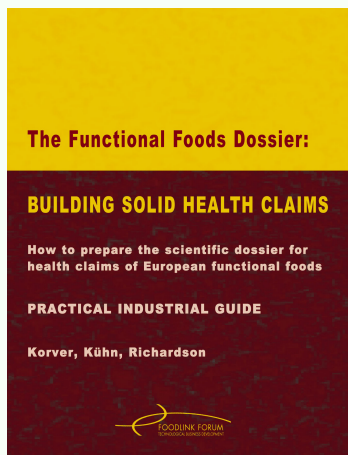
- How to prepare the scientific dossier for health claims of European functional foods -
PRACTICAL INDUSTRIAL GUIDE

Authors: Dr. O. Korver, Dr. M.C. Kühn
& Prof. Dr. D. Richardson

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Becel *pro-activ* is a fat-spread (margarine) containing phytosterols specifically targeted to help people with a high cholesterol level. It has been developed and is marketed by Unilever.

The safety clearance

The functional ingredients in Becel *pro-activ* are soybean phytosterols that are normally present in the food chain. For this reason it could have been argued that the product introduction in the market did not require a special safety testing. It was estimated though that consumption of a realistic amount of the spread would significantly increase the consumption level of the phytosterols. Therefore Unilever decided to pass Becel *pro-activ* through the EU novel food regulation to prevent a later debate about its safety. By clearing safety through the Novel Foods Law, the safety aspects were dealt with for all EU countries.

Becel *pro-activ* was the first functional food passing through the EU Novel Foods Regulation. It turned out to be a lengthy process (more than 2 years; from May 1998 to July 2000) because it was actually a learning process for the evaluators who were confronted with the individual nationalistic approaches of some national authorities. The position of one of the member countries was particularly hindering and prolonged the process considerably: it debated whether this functional margarine was “drug or food”. This changed the focus from the scientific debate into a more involved and prolonged political one.

The health claim clearance

With regards to the health claim of the product and since no EU legislation existed, Unilever decided to pass the product through one of the existing voluntary Codes of Conduct for health claims; this was done in The Netherlands, the country in which the product was introduced into the EU market.

The process via the Codes of Conduct went more smoothly than the novel foods clearance. Reasons for this are that the codes of conduct were well-defined and the discussion retained its scientific focus all through the process. It also helped that a similar product, having a related active ingredient, was already known in the market for the same target group: Benecol of the Raisio Group (Finland). This product had actually been consumed even before 1994 when the novel food regulation was introduced.

Overall

The work and time needed to pass these procedures were not totally wasted. The resulting dossier was also used to proceed with the necessary communication of the scientific basis to health opinion leaders throughout Europe.