PIVOTAL ASSESSMENT OF THE EFFECTS OF BIOACTIVES ON HEALTH AND WELLBEING. FROM HUMAN GENOMA TO FOOD INDUSTRY

Introduction to the PATHWAY-27 integrated Guidelines for food industry/SMEs

Health claims can be important drivers of product development and they can have an impact on which food products consumers will choose.

Products with this 'added value' can be attractive to consumers who see them as healthier, and their novelty allows manufacturers to gain a greater profit margin than from a 'commodity' product.

The question for food businesses is: Why is a product intended to bear a health claim worth developing? This question should be answered at all steps of product development, i.e. from idea generation to market launch, while bearing in mind the EU regulatory requirements.

The Panel on Dietetic Products, Nutrition and Allergies of the European Food Safety Authority has published a number of documents in relation to health claims, including a scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (Article 13.5 or 14). Despite the availability of the guidance documents on how to prepare a health claim dossier, limited information is available on good practices specific to the manufacture of products with health claims and typical pitfalls to avoid.

The proposed integrated Guidelines for food industry/small and medium-sized enterprises (SMEs) offer a structured product development approach addressing all aspects that SMEs and their suppliers of material, knowledge and related services should consider when designing products for health claim application in Europe. The Guidelines cover:

- detailed description on the development process of products for health claim application highlighting the importance of standardized composition and low variability of each product parameter (particularly the concentration of the food constituent);
- the aspects of the characterisation of the food/constituent;
- food safety assessments of the product for health claim application;
- manufacturing ability;
- financial feasibility;
- sensory analysis methods for product acceptability testing;
- selection and verification of health claims to prepare scientific substantiation;
- dossier development;
- intellectual property rights in health claims;
- market and product launch concepts.

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PATHWAY-27 has produced complementary guidelines targeted at the scientific community (Scientific Guidelines), which highlight best practices for designing and running randomised controlled intervention trials, which aim to demonstrate the claimed beneficial effect and are a requirement of health claim dossiers.



The PATHWAY-27 Guidelines are available on the website of PATHWAY-27 (http://pathway27.eu/).

Further information: http://www.pathway27.eu/

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