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 the European scientific community

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). However, further guidance for stakeholders more specifically interested in claims relating to bioactive compounds and bioactive-enriched foods would be helpful.

For a health claim to be authorized by the European Commission, the specific relationship between the food/food constituent and the claimed effect has to be established, based on all robust and scientifically valid data existing. If no or insufficient data are available, it is essential to run well-designed, high-quality dietary interventions that can contribute to the evidence base. Even if data are available, it is important to be able to judge their reliability, i.e. do they come from well-designed controlled trials, and can they thus be used to substantiate a health claim dossier?

The present guidance document was developed within the framework of the EU-funded project PATHWAY-27 and describes guidelines and best practices for planning (and recognizing) well-designed dietary interventions, which can contribute to demonstrating the putative beneficial effect(s) of a specific food or food compound (e.g. a bioactive).

In these guidelines, we remind the reader that a dietary intervention will only be as good as the research question it aims to answer. A clear working hypothesis must be defined a priori which can subsequently be tested in a well-designed study. We focus on randomized controlled trials as they are the most rigorous way of investigating a claimed health effect of a specific food, and discuss the critical aspects of randomization, blinding and control, with hands-on examples from the PATHWAY-27 project on the issues that can be encountered when dealing with bioactive compounds and how to solve them. Furthermore, we give sample size and data analysis some considerations, emphasizing the need to involve an experienced biostatistician from the outset, and we discuss the issue of the study duration and (non-)compliance. Recruitment of study participants can often be a major bottleneck, and, therefore, various recruitment strategies are evoked here. This guidance document also refers to successfully submitted dossiers and other publically available relevant resources, which, together with the present document, will help with the appropriate scientific substantiation of health claim dossiers. In parallel, the reader is strongly encouraged to consult the second guidance document developed within the PATHWAY-27 project: a set of integrated guidelines for the food industry and small and medium enterprises.

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

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PATHWAY (FP7-KBBE-2012-6-singlestage) is a collaborative project targeted to SMEs and financed by the EC under the FP7, contract number 311876.