



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

# Research summary sheet

### **Context and Challenges (introduction of the Work Package)**

In the last years the interest towards bioactives (naturally-occurring compounds in dietary plants and animal products) and their use in the production of "bioactives enriched foods" (BEF) is growing more and more, due to their positive impact in human health, wellbeing, and risk reduction of diet-related diseases (DRDs). Many studies across the world are targeted on demonstrating their effectiveness, however, at present, scientific understanding of the role and mechanisms of dietary bioactives is still limited:

- research is often related more to the theoretical possibility of their effects on health improvement rather than on their real, practical utilization in everyday diets (which rapresents the main EFSA's requirement) → for this reason human intervention studies are mandatory for health claim approval.
- intervention studies demonstrating the effectiveness of specific bioactives or BEF are often designed for different purposes and do not consider measurable, physiologically relevant end-points (leading EFSA to issue a negative opinion)
- high costs of large intervention studies and frequent waste of resources, generated distrust in SMEs, reducing their ability to develop new food products and gain a significant share of the healthy food market.

PATHWAY-27 focuses on better understanding the beneficial effect of foods enriched with DHA, alone or in combination with BG and AC, on MS risk factors. For this purpose, the aim of our WP is to investigate the effect of the consumption of selected BEFs on lipid profile and other metabolic parameters, related to metabolic syndrome (in volunteers at risk or affected by the disease).

The collected informations will be useful for the development of the PATHWAY-27 guidelines for scientific sector and food-industry.

## **Results and Applications**

In WP5 two clinical studies are included:

- PILOT STUDIES: About 210-300 volunteers are being recruited in 3 EU centres of human nutrition, to select the best combinations "bioactive-food matrix" (the BEF able to give the best results in lipid profile). Three food matrices (dairy products, egg-based products, bakey products) and 5 enrichments (DHA, BG, or AC alone or DHA+BG, or DHA+AC) have been previously selected for the trial. In each pilot, BEFs belonging to a specific food matrix are being studied: according to the results of pilot studies, the PATHWAY-27 BEF within each matrix exhibiting the most significant positive modification of the selected end points will be used in the larger intervention study.
- LARGE INTERVENTION STUDY: 800 volunteers will be recruited within 4 different countries (with the same criteria used for pilot studies) to investigate the effect of the consumption of selected BEFs for 12 weeks. Volunteers will be randomly divided into 4 groups of 200 volunteers, each receiving: 1. bakery BEF + placebo dairy and placebo egg-based foods (without bioactives); 2. dairy BEF + placebo bakery and placebo egg-based foods (without bioactives); 3. egg-based BEF + placebo bakery and placebo dairy foods (without bioactives); 4. all placebos (bakery + dairy + egg-based foods without bioactives). The main objective is related to the modifications





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of lipid profile, secondary aims involve body weight, blood pressure, glucose levels and insulin-resistance, waist circumferences. Furthermore biological samples will be collected for metabonomic and epigenetic analyses (to better understand the mechanism/s of action of the selected BEF) and to assess the bioavailability of bioactives in the BEF.

#### Results achieved

Pilot studies are still ongoing and the large intervention study will start further, therefore results are not yet available.

Main general difficulties (at present):

- Coordinate the approval procedures of local Ethics Committees
- Harmonize the operating procedures for the collection and the storage of biological samples
- Recruitment of volunteers (due to the restrictions of inclusion/exclusion criteria)
- Poor liking (unexpected) and difficult handling of some BEFs (in particular frozen ones)

### Breakthroughs, benefits and added value

(At the end of the sudy)