



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

PATHWAY-27- INDUSTRY GUIDELINES ON DEVELOPMENT OF PRODUCTS WITH HEALTH CLAIMS

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The development of products with health claim

- is a more complex process than the development of conventional products
- requires high level of collaboration and harmonized interaction of several disciplines and independent partners.
- Independent **EFSA** laboratory Suppliers Customer Consumer Focal company Statistician Recruiting centres/clinics
- includes costly tests and analysis for provision of appropriate samples for scientific substantiation
 - ✓ Shelf-life tests: microbiological, chemical and sensory tests
 - ✓ Characterization of the constituent
 - ✓ Production trials and monitoring the uniformity of the concentration and stability of the constituent within batches and between batches during the whole shelf-life
 - ✓ In vivo and in vitro tests to validate the constituent-effect relationship
 - ✓ Absorption studies
 - ✓ Human intervention studies: complexity of selection of volunteers, drop-outs

Analysis are interrelated to and build on each other Providing samples



in the RIGHT QUANTITY in the RIGHT PLACE at the RIGHT TIME

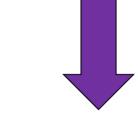
for all analysis and human intervention studies

Number of changes should be kept to the minimum and necessary changes should be identified as early as possible.

Changes in composition, packaging, storage conditions

Influence the stability and uniform distribution of the constituent

> Shelf-life test has to be repeated and HACCP plan has to be revised



Delay in further activities; increasing cost

Understanding the fact that any change in the process requires repeated tests

Careful planning and design

Tools to help in planning and organizing the activities:

- Product development brief
- Clear specifications for products, ingredients and packaging
- Early design of the required outputs
- Estimation of the amount of samples
- Careful planning- Gantt chart
- Reproducibility needs
- Set of integrated Guidelines for food industry/SMEs

The draft guidelines are available for public discussion.

Input needs Process step Output information Need to repeat the test, study Step 2 Step 3 Need to repeat the test, study

FURTHER INFORMATION



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