PATHWAY-27

INDUSTRY GUIDELINES AND RECOMMENDATIONS FOR DEVELOPING PRODUCTS WITH HEALTH CLAIMS

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Industry Guidelines and Recommendations for developing products with health claims

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The PATHWAY-27 project officially started on February 1, 2013 but it began earlier in the mind of researchers who contributed to the proposal. I hope PATHWAY-27 will live longer than the scheduled five years through the PATHWAY-27 Guidelines. The Guidelines are based on the activities performed during the project, and they represent the summation and integration of expertise and knowledge generated from a five-year collaboration. We have high hopes they will help scientists and companies, making our efforts not limited to the achievement of scientific results but representing a real path to be followed in the future.

I gratefully thank all Members of the PATHWAY-27 Consortium, who worked hard to manage and overcome difficulties.

Alessandra

The elaboration of the Industry Guidelines and Recommendations for developing products with health claims was based on the activities and experiences of the PATHWAY-27 FP7 project. The members of the working group welcome the opportunity to thank all the project partners, the EC Project Officers, the organizations and individuals who contributed. They are listed in Appendix I, although it is inevitably incomplete and cannot include the numerous verbal comments received. However, we wish to thank all who were conducive to the Guidelines.

András and Alessandra on behalf of the Working Group

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Preface

Why develop products with a health claim

The role of food has changed from the essentiality to optimality, whereby foods do not simply serve as a source of nutrition for metabolism and the prevention of deficiencies. Food in itself represents pleasure and diet derived components can support optimal physical and psychological well-being, disease risk reduction and overall resilience to internal and external 'stressors'.

Strategic Research Priorities of FoodDrinkEurope for the European Food and Drink Industry (2015) identified health and nutrition as a main strategic priority for innovation and stated that "the prevention of the rise in non-communicable diseases, focusing on nutrition and behaviour changes" should be what the whole food and drink industry pursues to achieve through research. Figure 1. shows the results of the trend analysis on the drivers of innovation regarding new product development. Food innovation can be divided into 15 trends, grouped along five axes, corresponding to general consumer expectations: pleasure, health, physical, convenience and ethics (FoodDrinkEurope Data & Trends 2017).

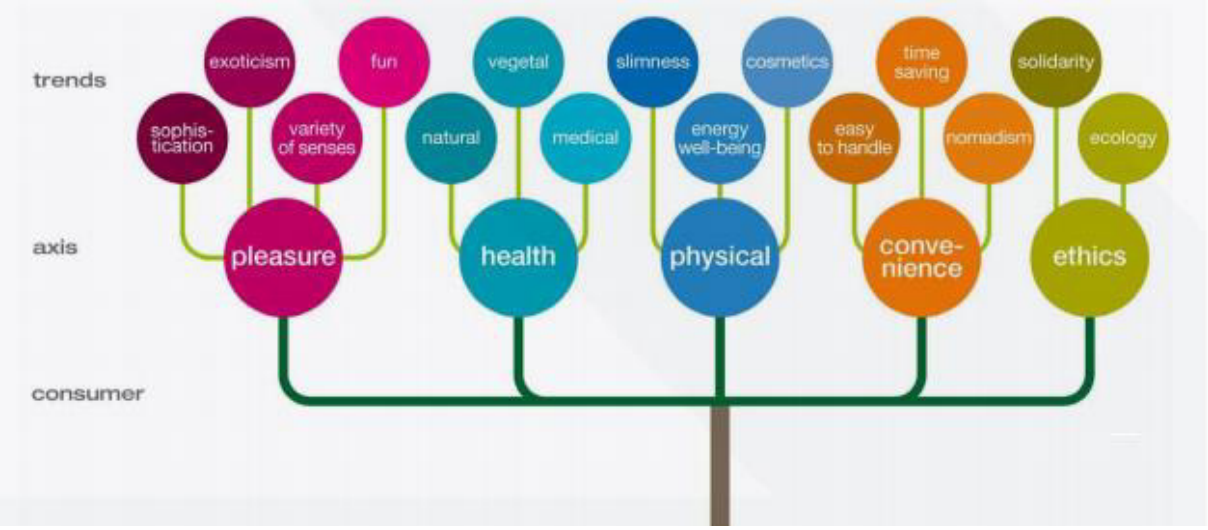

Figure 1. Trends of food innovation in Europe (FoodDrinkEurope Data & Trends, 2013-2014)

According to the cited source the health and convenience trends are the second biggest drivers after pleasure and closely linked to the new motivators of product development with health claim.

The use of health claims on food and drink packaging, or in any advertising of food and drink products, has received a great deal of attention in recent years. Campden BRI, UK has carried out a survey on industry needs involving their members (13 Member Interest Groups (which have a collective membership of over 3,000 industrialists) via an online survey (2,400 companies in 75 countries) and consultancy, through extensive day-to-day discussions.

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According to this survey one of the primary drivers of innovation is nutrition, health and well-being and these drivers are relevant for all steps of the whole food supply chain from primary production through manufacturing and supply of the product and packaging to food, drink and the consumer. At primary production the objective relevant to products with health claim is enhancing nutritional potential through the use of varieties and raw materials, which offer health benefits. At the manufacturing and supply stage the objective is preserving and enhancing health benefits during processing, distribution and sale. This is achieved by optimising of existing and emerging processes to retain health beneficial properties through product shelf-life and by new technologies and processes to assist the development and production of products aimed specifically at maintaining and improving health. At the product and packaging stage the relevant objective is to deliver nutritious products that meet dietary needs with accompanied guidance, information and services for supporting health claims on products. These are based on better understanding of the underlying science and technologies available to support products targeted at specific health benefits on which to base health claims.

For the activities related to food, drink and the consumer the objective is to determine nutritional requirements leading to health benefits and dietary hurdles by defining ways to improve consumer's health and wellbeing through understanding of the relationship between diet and health for individuals, groups (e.g. age, health conditions, ethnicity) and populations, at the genomic to physiological levels; influencing purchasing decisions through better understanding of consumer perception of diet and health issues and associated behaviours; understanding the links between nutritional value, price, product quality, product claims, marketing information and other factors on consumer dietary choices (Campden, BRI UK 2014).

Strategic themes and the drivers for food industry needs related to nutrition, health and well-being are presented in Figure 2.

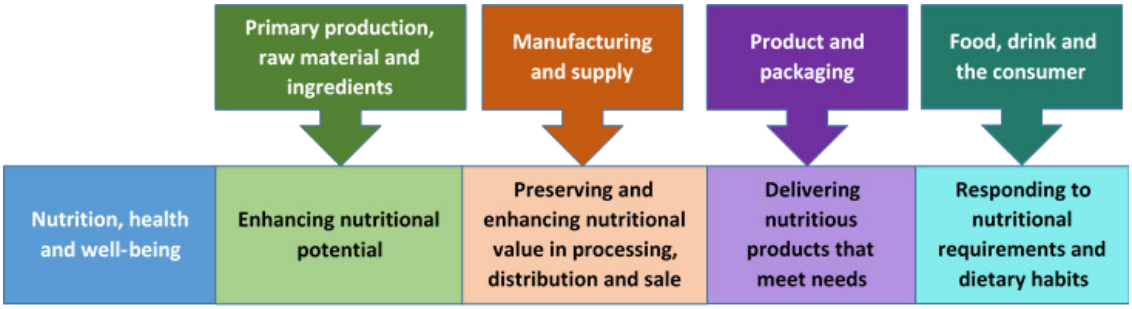

Figure 2. Roadmap showing industry needs for nutrition, health and well-being (Modified after: Campden, BRI UK 2014)

Mintel research shows that total sales of healthier eating options in some key food and drink categories are now worth (about €11bn) with some areas expanding at twice the rate of the market as a whole (Food and Drink Federation, 2014). Key target areas for foods with health claim include cardiovascular health (56%), bone health (15%), immune health (18%), and gut health (11%). Reformulation of the foods towards reductions of fat, salt and sugar is also popular, which complies with the aims of the *WHO European Food and Nutrition Action Plan 2015-*

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2020 to tackle excessive intake of energy, saturated fats and trans fats, sugar and salt (WHO Regional Office for Europe, 2014).

The document on Strategic Research Priorities of the FoodDrinkEurope for the European Food and Drink Industry (2015) also highlights the importance of understanding behaviour and defined it as one of the 5 core scientific platforms for R&D. "The challenge of better understanding the consumer and ensuring that new food related developments as part of balanced diets and active lifestyles are accepted by the consumer is daunting, but also crucial for the European food industry in order not to lose its innovation initiatives to other regions of the world." (European Food and Drink Industry, 2015).

A real potential exists to increase profit margins by developing a product, along with supporting evidence, for which a proprietary health claim can be made. Restricted use, if granted, expires after five years (article 13.5). This strategy requires greater investment and carries a higher risk; however, potential profits are also higher if a unique claim is authorised.

There is a wide range of determinants that can have an impact on consumers' reactions towards health claims. Food choice behaviour is driven by the optimisation of both nutrition and enjoyment derived from food.

A consumer survey was carried out in the PATHWAY-27 project in which the behaviour of the consumers and reasons for purchasing functional foods were measured. 360 consumers were involved in the survey in Hungary. The consumers were divided into three clusters based on questions on attitude and the behaviour towards health and diet.

Respondents in Cluster 1 can be described as 'extremely health conscious consumers'. Their health is an important focal point of their life, they regularly monitor their health status, frequently themselves and with the help of their doctors. Notwithstanding, they do not consider the composition of their food as very important: higher vitamin and mineral content, additives and artificial flavourings had only a slight impact on their food choices.
Cluster 2 included consumers who pay attention to their health and diet, however they strive for delicious food consumption. Furthermore, they are more interested in the composition of the food. They prefer meals with high vitamin, mineral content and low cholesterol/fat level and try to avoid additives in their food.
Cluster 3 is a transition between Cluster 1 and 2. These consumers are also health conscious, they try to follow healthy diets, and although they prioritise the composition of the food, the enjoyment of food also has an impact on their food choices. They prefer it if their food contains high quantity of vitamins and minerals, and organically grown vegetables just as cluster 2. They try to avoid consuming processed food and food with additives.
Cluster 1 included 175 respondents (49%), Cluster 2 included 67 respondents (19%), and 118 respondents (33%) were in the third cluster.
The **key drivers** of purchasing products with health claims were "to stay healthy", followed by "to avoid medical treatment" and "good taste" in all the three clusters (Figure 3). This suggests that food with health claims has not only to be "functional", i.e. have an effect on the health and well-being of consumers, it has also to be "food" in that consumers expect it to taste good.

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The main results confirmed the conclusions reported in several studies such as Mintel in UK, 2013 and by the JRC Scientific and Technical Report, 2008. In the JRC study the reasons for not buying "functional" food were investigated and showed a very heterogeneous picture in the four EU countries examined (Spain, Germany, UK, Poland), including general concerns about novel food, bad taste, preference for organic food, focus on the present rather than on the future, absence of illness, fear of side effects, aversion towards artificial additives, distrust of effectiveness and price (Hegyi et al. 2016).

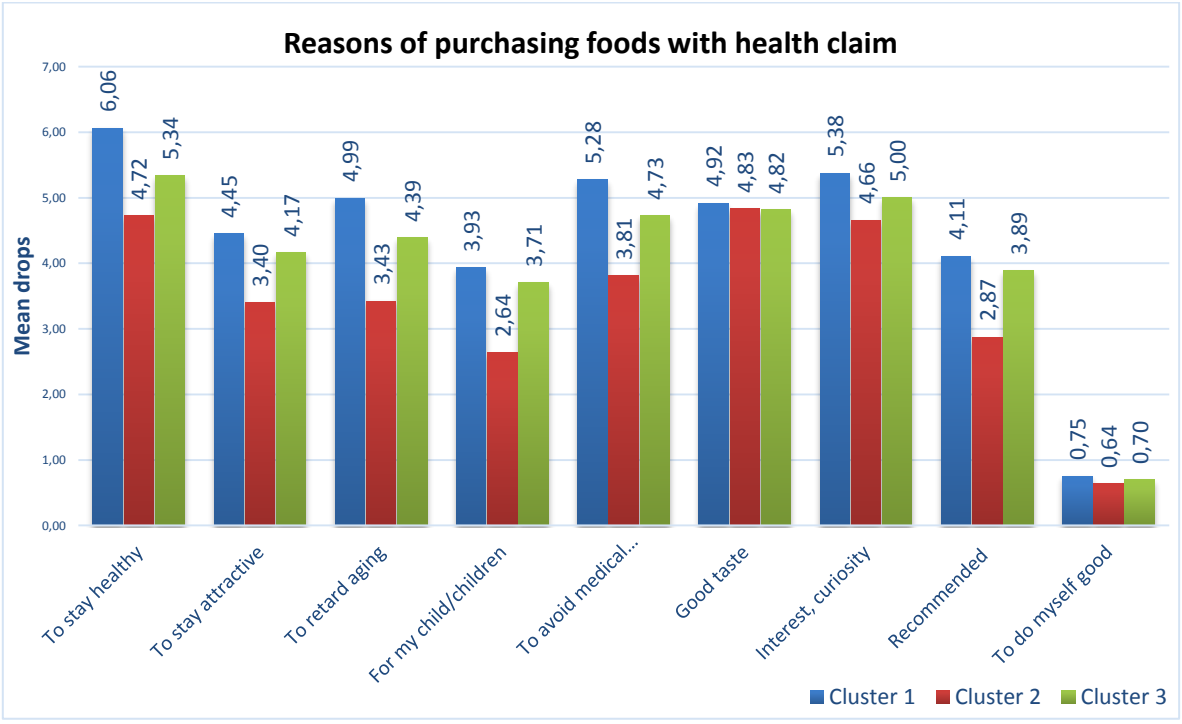

Figure 3. Reasons to purchase products with health claims (Hegyi et al. 2016)

Health claims can therefore be an important source of information, and became a vital marketing tool used by food business operators to attract consumer attention and to influence choice. The European food and drink industry is constantly responding to consumer demands by providing a wide range of nutritious, safe and enjoyable food products which differ in energy and nutrient content in the context of a balanced diet.

It's important for food businesses to ask the question, why a product with health claim is worth considering developing and this for should be answered at all steps of the product development process from the original idea generation to market launch.

Therefore the main drivers of developing, producing and selling products with health feature the following main benefits for food businesses:

- distinguishable product with high value for the consumer, which can result in premium pricing;
- following one of the key trends in consumer needs;

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- demonstrating competence to business partners and retailers;
- creating an image of professionalism and high quality for consumers;
- improving cooperation with knowledge providers.

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1. Introduction

1.1 Background and objective of the guidelines

Regulation (EC) No 1924/2006 describes the "specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer". The European Food Safety Authority (EFSA) is tasked with scientifically assessing health claim dossiers submitted by applicants. Despite the availability of some guidance documents on how to prepare a health claim dossier, limited information is available on good practice specific to the manufacture of products with health claims and typical pitfalls to avoid. The time- and cost-effective development and market release of such products is a complex task and more guidance is necessary to help SMEs to organise and implement the product development process.

Therefore, the aim of this document is to provide food businesses, in particular SMEs, and their suppliers (material, knowledge and related services) a practical and comprehensive guidance on the development of products with health claims in an efficient way. This guide takes a step-by-step approach to following the complex tasks of the product development process focusing on the specific challenges, good practices and the typical pitfalls for developing and placing products with health claims onto the market in Europe.

The content of the guideline is based on the results and experiences from the PATHWAY-27 project (http://www.pathway27.eu/) as well as relevant publications, guides and experience collected from industry practice.

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.

During the project, barriers of food businesses to meeting the requirements established by the European Union (EU) and national authorities for health claim substantiation were identified (Hegyi et al., 2015). These barriers can be divided into the following three categories in decreasing order of importance indicated by the businesses:

TECHNICAL/TECHNOLOGICAL BARRIERS:

- difficulties in appropriate characterisation of food/constituent;
- difficulties in establishing the relationship between the constituent and the claimed effect considering the target population;
- difficulties in communication with the national and/or EU authorities;
- lack of guidelines/supporting documents;
- difficulties in communication within the company;
- lack of knowledge (how best to conduct RCTs, statistics);
- Lack of specific technology to assess biomarkers.

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ECONOMIC BARRIERS:

- lack of specialised human resources for organizing and performing clinical tests;
- costs of human intervention studies (HIS);
- cost of the health claim dossier preparation;
- length of the process of authorisation increasing the time and cost of product development;
- uncertainty about the return on investment;
- high input costs;
- limited human and financial resources of the food businesses.

SCIENTIFIC BARRIERS:

- lack of appropriate biomarkers, to be used, accepted by EFSA;
- difficulties in establishing the relationship between the food/bioactive substance and the claimed effect;
- difficulties in setting up the experimental design and human intervention studies;
- limited availability of information on good practice and typical pitfalls of carrying out human intervention studies.

OTHER BARRIERS:

- The supply of samples for the human intervention studies (pilot and large human randomized controlled trials (RCTs)
- The content of this guidance has been reviewed by the project partners and external experts in the field of health claims.
- The focus of the guidance is on products enriched with bioactive compounds.

Practical examples are provided to support better understanding of the topics. Moreover, this guideline helps in developing test and control products with adequately low variability for the human intervention study (HIS) and in order to get them supplied in appropriate conditions at the right time.

Concerning applicability in global trade it is important to note that the regulations on health claims differ between the European Union and other parts of the world. For example, in the United States claims are regulated by the US Food and Drug Administration and in Japan by the Ministry of Health Labour and Welfare. The present guidelines pertain only to the EU, particularly foodstuffs governed by Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

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2. Procedures and general methods for developing products with health claims

2.1 What is a health claim?

Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods defines a health claim as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

The main categories of health claims are the following:

a) General function (article 13.1) health claims (e.g. vitamin C contributes to normal functioning of the nervous system), which are approved by the EC. There are 229 general function claims (other than botanicals), which have been approved by the EC and published on the Community Register. Only "references to the relevant scientific justification "are requested when suggesting such claims.
b) New science or proprietary data (article 13.5) health claims, which are based on newly developed scientific evidence and/or for which protection of proprietary data is requested.
c) Reduction of disease risk (article 14.1a) claims, which link the consumption of a food, or ingredient with a significant reduction in a risk factor in the development of a disease (e.g. oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease).
d) Children's development or health (article 14.1b) claims.

This Regulation states that nutrition and health claims must be reviewed by the EFSA Panel on Dietetic Products, Nutrition and Allergies. Only claims deemed to be scientifically substantiated and authorised by the European Commission (EC) may be permitted for use in the EU. A public EU Register of Nutrition and Health Claims lists all permitted nutrition claims and all authorised and non-authorised health claims (http://ec.europa.eu/nuhclaims/). It serves as a source of reference and ensures full transparency for both consumers and food business operators. Since 14 December 2012 any unauthorised health claims that are not listed in the EU register are no longer permitted for use on products sold in the EU. The EU register also includes the outcome of separate EC evaluations of health claims relating to new science or proprietary data, reduction of disease risk and children's development and health. These published lists offer opportunities for food and beverage manufacturers to use authorised claims on current products (providing the conditions of use are met) or to reformulate products in order to comply with the conditions. Furthermore, manufacturers can submit a dossier for review in relation to new science or proprietary data, reduction of disease risk and children's development and health claims.

All claims in the Article 13.1 list may be used without any further application or notification procedure, provided that the claim and the product comply with the Regulation and any conditions of use specified for the claim in question, including any nutrient profiles that maybe

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established. Article 13.5 and Article 14 claims (both 14.1a and 14.1.b) are reviewed on a case-by-case basis following the submission of a scientific dossier to EFSA (EC (2006)) (Figure 4).

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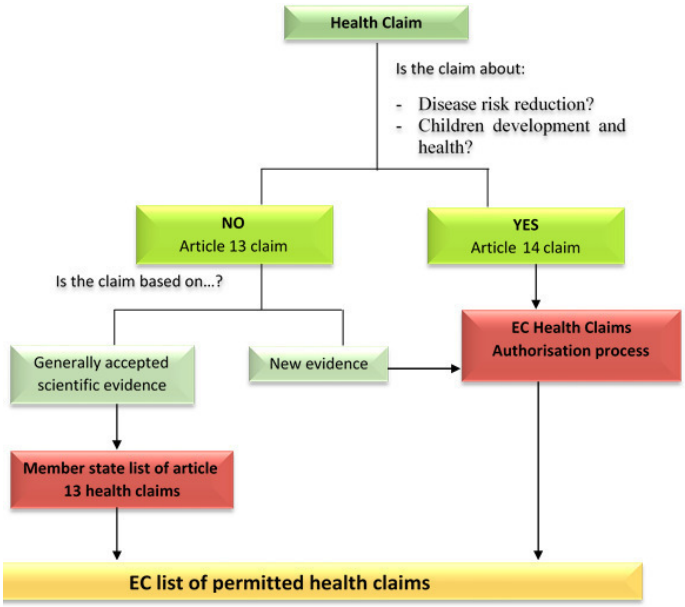

Figure 4. Main categories of health claims (adapted from ERNA Nutrition and Health Claims Guidance, 2012)

2.2 Stages of product development procedure

As mentioned before these guidelines are focused on products enriched with bioactive compounds. The development process for products with health claims is shown in Figure 5. Careful planning and regular reviewing of the process is crucial to manage and harmonize a wide range of closely related tasks:

- the selection of natural ingredients or product enrichment with an appropriate level of the bioactive compound;
- the sensory testing to ensure consumer appeal;
- the standardisation of the concentration of the bioactive compound over the shelf-life of the product and across batches;
- the production of a control product for the human intervention studies, which matches as closely as possible to the composition and sensory properties of the product with the health claim (test product) but does not contain the bioactive compound;
- the organisation of the human studies (including sample logistics).

All of the above make the whole process more complex than the development of an ordinary innovative product.

Developing products with a health claim usually requires more involvement of and collaboration with external knowledge and service (such as clinical studies, statistics, etc.) providers (such as researchers, statisticians, etc.).

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For the test and control products provided for human intervention studies standard properties and high reproducibility of the product composition is required, with specific focus on appeal and acceptability for regular consumption, energy content, physical properties, and low variability within and between batches during the whole shelf life.

Recruitment of volunteers for human studies and other preparation work is time consuming and once the dates of the human studies are fixed there is a very limited flexibility in time. The food samples for the volunteers for the human intervention studies and, for all analysis and testing must be in the right place, at the right time, in the right quantity. The lack of availability of the product will undoubtedly have cost implications associated with additional research staff time and clinical and laboratory facilities and the potential need to rescreen participants or extend recruitment to replace volunteers lost due to the trial delay. Furthermore, such delays can impact on the credibility and perceived professionalism of the staff involved. The implementation of any change necessary at this stage may take a long time because of the complexity of the interrelated tasks, which may have to be repeated. The cost of some of the repeated activities, such as laboratory tests, pilot scale production of the samples for the human studies, and particularly that of the human studies can be high.

In order to avoid unnecessary costs and delays, the careful, systematic design of the whole product development process, including the submission of the claim for EU approval is particularly important during the development stage of products with health claims. The number of changes to the process should be kept as low as possible and the need for any changes should be identified as early as possible in the product development process.

A systematic design of the development of the products with health claims can be based on considering the main tasks at the key steps of the process (see the planning tool in Figure 5). This planning tool shows also the inputs and outputs of the different steps and the consequences of results which are unsatisfactory leading to repeated tasks. Although the planning tool shows a linear approach for the sake of making easy to understand and overview the sequence of the necessary steps, in reality some of the steps can be carried out in parallel. This can be the case for the technical and consumer-marketing related processes, but also within one category of processes. The potential for carrying out parallel activities varies case by case. Project management techniques, such as PERT (Program Evaluation and Review Techniques) can be used to design the parallel processes and to reduce the total time necessary to complete the product development process for products with health claims and also to redesign the potential for parallel activities and deadlines after major delays, changes.

When already existing products with health claims are reformulated the same procedure has to be applied as for the design of a completely new product with health claims, but first it should be defined precisely, what is the objective of the reformulation, what has to be changed to achieve this change and what are the implications of these changes on the concentration, stability, bioavailability, bioaccessibility of the bioactive compounds and on the other properties of the product. On this basis it should be identified, which stages/steps need

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to be re-designed following this procedure and what are those steps, properties, which can be unchanged.

If a company wants to use an already approved claim a similar procedure has to be applied, but it is not necessary to carry out human intervention studies and dossier development. The composition of the new product and labelling of the packaging should meet the use of conditions and/or the restrictions of use described in the EU Register on nutrition and health claims.

These aspects should be included in the product development brief. From that point the process is not different from an innovative product development procedure and further notification, authorization is not required, but the company must ensure that its product contains the required amount of bioactive compound.

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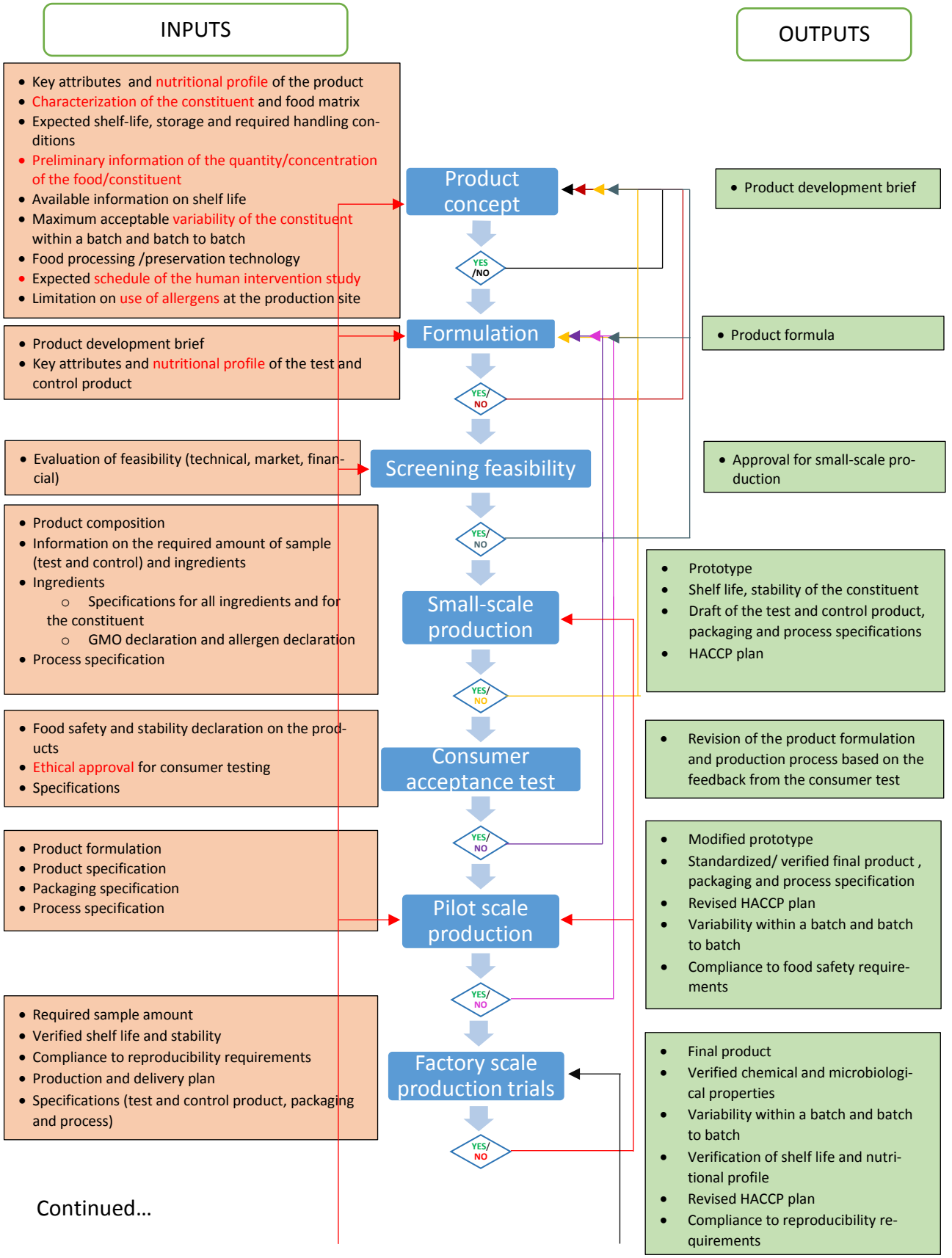

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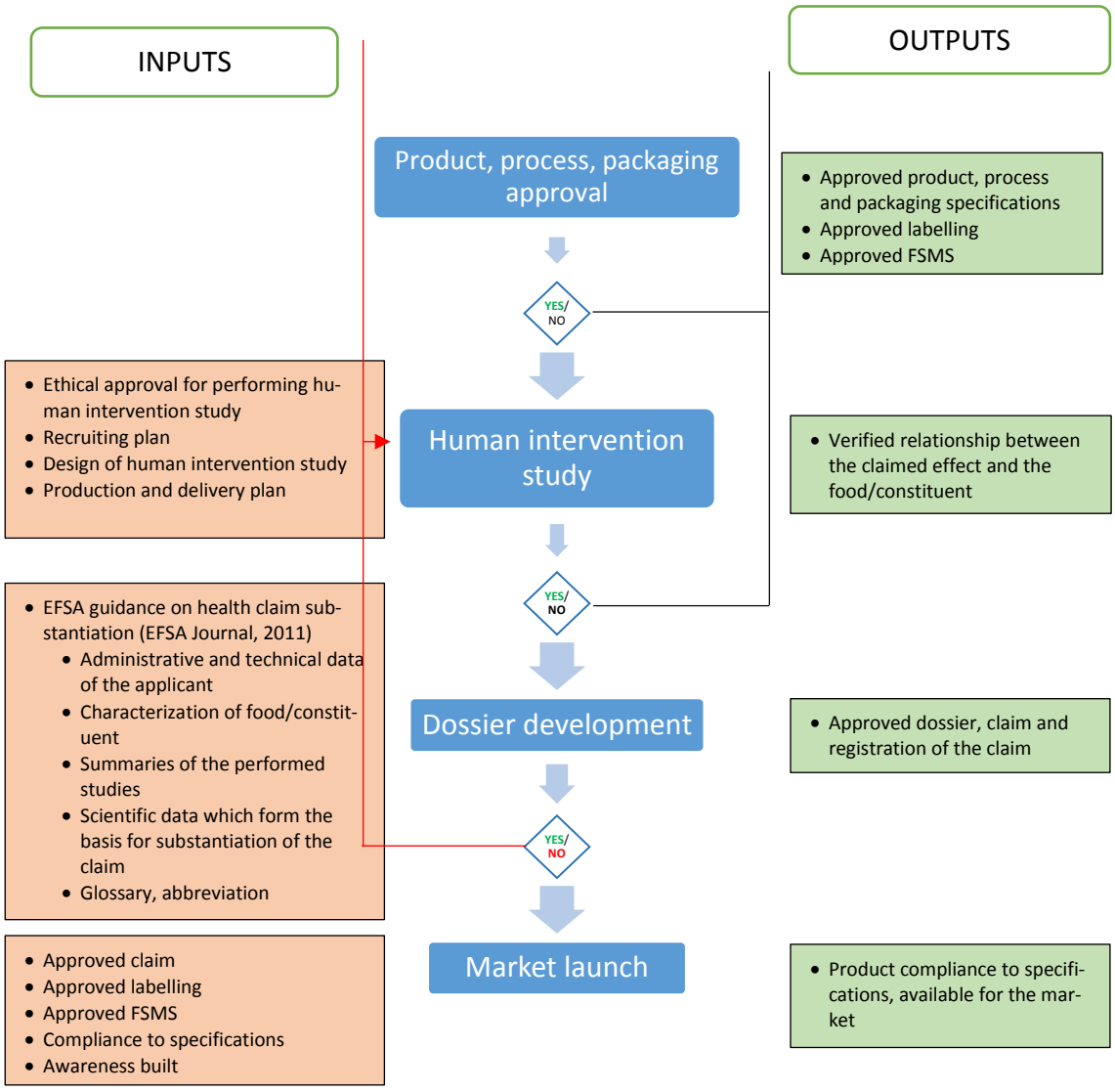

Figure 5. A planning tool for the development of products with health claim (Sebők et al. 2016).

YES: The relevant outputs are achieved if the task is completed successfully
NO: Return to a previous step indicated by the colour of the arrows

2.2.1 Idea generation, concept development

The aim of an idea generation session is to meet the requirements of the challenge or brief by gathering people from different disciplines of the company. Since for a new product with health claim the idea may come from academic research, representatives of external research groups may be involved in the idea generation and concept development.

There are several techniques for idea generation.

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At the stage of concept development of a product with health claim the food businesses can assess the feasibility and risks at minimal cost, i.e. before buying ingredients, running production trials or undertaking human intervention studies.

In addition to the usual questions of a product development process, the following specific questions should be answered for a product with health claim:

- What type of claim is the target?
- Could authorised health claims (article 13.1) be applied to the product?
- Would reformulation of an existing product result in the product meeting the conditions for an already authorised claim?
- If targeting an article 13.5 and article 14 claim, has a similar claim been previously rejected? If so, why was it rejected? What can be learnt from this?
- If targeting an article 13.5 and article 14 claim, has a similar claim been previously authorised? If so, why was it authorised? What can be learnt from this? Does a similar claim make sense?
- Has any previous work been carried out, which can support this claim (for example *in vitro* work in support of the mechanism of action)?
- Can the target claim be scientifically demonstrated?
- What is the target market (e.g. children and/or adults, healthy people and/or patients)?
- How can the stability of the bioactive compound and the attractive, appealing sensory properties be ensured?
- What products do the consumers eat at sufficient frequency and in sufficient quantity to ensure that the intake of the bioactive compound is at the level required to achieve the targeted effect?
- Are there any available production facilities in house for preparing the experimental samples and to carry out the production - considering that new ingredients and new products may represent a potential source of contamination, including allergens for the current scope of products in the targeted production facility? Is it possible to contract an external facility for large scale sample preparation and/or production?
- How can the availability of safe, appealing samples with appropriate concentration of the bioactive compound be ensured at the site(s) carrying out the human studies? Their storage, handling, food preparation capabilities and capacities and the logistics of quantities smaller than a whole truck should be considered particularly for chilled and frozen products.
- What is the feasible packaging size and packaging type?
- What is the value of the product for the company - considering the benefits and costs, including the costs of the substantiation as well?
- What price, turnover and profit can be achieved compared to the competitive products, the other alternatives, such as food supplements and to similar conventional products without health claims?

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The claim

Permitted claims listed in the EU Register of Nutrition and Health Claims may be used by any food business operator unless they are restricted for use by Article 21 of this Regulation (EC) No. 1924/2006. However, the food business operator is responsible to ensure that the food contains the bioactive compound on which the claim is made in the minimum required quantity and to inform the consumer about the minimum daily intake necessary to achieve the claimed beneficial health effect. Additionally, the general conditions of use of the claim have to be complied with (see in Chapter 2.2.8 and Annex 1).

If new claims are intended to be used based on new scientific evidence, the activities necessary for the scientific substantiation and by the authorisation by the EC should be included in the product development process. A more detailed description of the aspects to be considered and the tasks to be carried out for substantiation of health claims is provided in Chapter 3. Non-authorised health claims for foods must not be used.

If the subject of the claim is a food, the category of food for which the health claim is made should be described. Otherwise, a brief description of the food or food category, including characterization of the food matrix and the overall composition (including the nutrient content of the food) should be provided.

Answering these questions might narrow down the list of ideas which are applicable to be investigated further. Consumer research and qualitative discussion groups can be used to explore the possible consumers and determine the value that the new product might offer to the consumers (Campden & Chorleywood, 2007; adapted from Kuczora, 2014).

2.2.2 Setting the target- product development brief

After the concept development, a specific, focused and flexible, written product development brief has to be prepared.

Prior to the preparation of the product development brief a thorough background literature search has to be performed to collect all available scientific evidence for the relationship between the claimed effect and the food/constituent.

General information on the product development brief is provided in Annex 2.

A good brief for products with health claim includes the following specific information in addition to those necessary for all new products:

- Description of the new product:
  - product idea description (key attributes, main ingredients, strengths leading to competitive advantage);
  - clear definition of the food and the bioactive compound to be incorporated on which the health claim is made;
  - impact of food matrix on the activity and bioavailability of the food component;

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  - preliminary information on the sensitivity of the bioactive compound on food processing. Bioactive compounds are often sensitive to conditions encountered during food processing (e.g. temperature (vitamins); oxygen (antioxidants); light or acidic pH (probiotics); digestive enzymes (peptides); or presence of other nutrients). The food matrix in its raw state, after storage or preparation has an influence on the activity or release of the bioactives. Limitations related to food processing shall be identified;
  - target price, cost limitations due to competitors products and alternative products as food supplements.
- Definition of the basis of the claim (specific aspects for products with health claims), identification of the appropriate bioactive compound.
  - the description of the targeted cause-effect relationship to obtain the claimed effect. The claimed effect must be beneficial to human health;
  - the composition of the product, which ensures the availability of the bioactive compound in the required quantity for provision of the minimum effective dose of the bioactives;
  - identification of the providers of the bioactive compound or the ingredients containing the bioactive compound, clarification on commercial sources;
  - collation of existing research data on bioactive and health impact;
  - preliminary information of the quantity/concentration of the food/bioactive compound in a portion, relationship between the consumption of the food/constituent and the claimed effect (for the target group under proposed conditions of use), allowed limits of variability;
  - design of the human intervention studies: definition of the target population, the duration, external resources (e.g. external labour for statistical evaluation) possible costs (see Chapter 5);
  - preliminary description of the use of the product;
  - the properties and production of the test and control product for the human intervention studies focusing on volumes, timing, shipment and handling. Prediction on the estimated amount of test and control product for the HIS is manageable at bench, pilot or factory trial scale.
  - minimum quantity of the experimental samples and the control product necessary for different tests, such as human studies, bioavailability tests, etc.
- Labelling the claim.
- Targeted consumers, markets, intended use; the eating habits and consumer preferences should be considered, particularly for the targeted countries for sale. The product with the health claim should fit into the consumption pattern of the target population and satisfy the consumers' needs (in terms of the required frequency of consumption, portion size, required time to prepare the product and affordability). It is recommended that desk research should be carried out on the consumption

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frequency and willingness of consumption of the test product and the control product.

- The measures necessary to ensure the requested minimum quantity of the bioactive compound within a batch, between different batches, lots and through the whole shelf life of the food.

Additional aspects of information, which are necessary for the product development brief of all new products independent from health claims

- Handling and storage requirements of the product (e.g. chilled, frozen, ambient).
- Shelf-life at the specified storage and handling conditions (temperature, humidity, etc.).
- Target information on packaging, pack size and mode of distribution.
- Commercial unit size, distribution of the planned product.
- Compatibility to existing products of the facility, where the production of the test samples and the production itself is planned.
- Competitive products as benchmark(s).
- Target wholesale and/or retail price and its constraints represented by the competitors and pack size taking into consideration the necessary amount to produce the claimed impact; cost limitations.
- Capital necessary – availability.
- Time scale: targeted launch date and any other requirements.
- Other limitations.
    - the food safety of the product;
    - the sensory appeal of the product;
    - the manufacturing ability;
    - the financial feasibility.

A more detailed description is provided in Chapter 3 on the aspects to be considered and the tasks to be carried out for substantiation of health claims.

Considerations on the bioactive compound to enable scientific substantiation

The information necessary to characterise the bioactive compound and the nutrition profile shall be considered first during the preparation of the product development brief.
The bioactive compound, and/or the food containing the bioactive or the bioactive itself on which the beneficial effect is based, needs to be well characterized and defined.
The following aspects have to be considered and included into the dossier (EFSA, 2015), (González-Ferrer and Sáiz-Abaj, 2015):

- The source of the bioactive compound and its specification. For plant products the scientific (Latin) name (genus)/full systematic, species, name including botanical family, genus, species, variety; subspecies, and chemotype, where relevant, the part used for obtaining or extracting the active constituent (e.g. fruit, root, leaves, seed, whole), seasonality, harvest time, typical concentrations found in the plant. Conditions of transport and storage of raw materials before processing, the complete

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specification of the manufacturing process, and its standardization. For food ingredients or bioactive compounds from material extracts the species from which the bioactive compound came from should be defined. For food categories, the variability between individual foods regarding those characteristics, which may influence the specific claimed effect should be considered. For specific formulation of a fixed combination of bioactives, the studies and the combination for which the claim is related should be described. For microorganisms (e.g. bacteria and yeasts) the species, genetic type at strain level by international accepted molecular methods, the naming of the strain according to the International Code of Nomenclature should be specified. In the case of combination, the combination itself and each microorganism has to be characterised. Good examples are available such as the characterisation of lycopene-free and fat-free water soluble tomato concentrate (Duttaroy, 2014) and the arabinoxylan derived from wheat endosperm (EFSA, 2011a).

- The physical-chemical properties of the food ingredient and the bioactive must be determined; this is either an extract or an individual compound. Solid/liquid state, water activity and water content and physical properties (powder, colour, etc.) must be described. In case of powder materials, the particle size or range of particle size must be included in the specifications. Microbiological profile should be described, as necessary.
- The composition of the food ingredient containing the bioactive is one of the most important characteristics to be determined, including the concentration of the bioactive compound. When working with a mixture of compounds (extract) in which only some of them are active, the whole characterization of the extract must be provided including that of each compound or component up to 99.9% of the weight of the sample. Any stabilisation, encapsulation process applied should be described.
- Variability: from batch to batch and within a batch, factors affecting the variability (geographical locations, source, seasonality, process parameters, personnel, etc.), consistency of the finished product should be specified. The targeted/acceptable variability within a batch during the whole shelf-life and batch to batch should be defined.
- Analytical methods applied to ensure the quality and consistency of the data and their validation, reproducibility.
- Measurements should be performed in a competent laboratory that certifies the data. A quality system should be in place for control/documentation (GLP; ISO 17025). The particular system should be indicated.
- Short, but complete description of the manufacturing process of the constituent should be provided and if the production follows a quality system, it should also be indicated. The explanation how the product is standardised.
- Short overview of the results of stability studies if they were conducted should be given: together with the conditions, batches and analytical methods and as results storage condition and shelf life.

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- Bioavailability data: if it is applicable, e.g. absorption studies or data related to the bioactive compound. Nutritional properties of the bioactive/food containing the bioactive for which the claim is made, which reaches the target site should be provided together with any data regarding factors which have an influence on the absorption or utilisation of the bioactive compound.
- Contaminants: present in the food constituent, residual solvents, extract, other food, microbiological contaminants, residues (pesticides, heavy metals, and polycyclic aromatic hydrocarbons), mycotoxins, other residues (acrylamide) etc.
- Collation of the data for specification of the bioactive.

The company should have evidence that the food/bioactive/ingredient complies with the specifications given for the food/bioactive for which the claim is proposed. By the request of the food control authority the company should be able to verify that the food/bioactive which bears a claim is the same as that what was subject of the EC authorisation.

If the ingredient containing the bioactive compound, or if the bioactive compounds are derived from raw materials that have not been consumed to a significant degree by humans in the EU prior to May 1997 and have not been authorised as novel foods yet, they must be approved for use in compliance with the Regulation (EU) 2015/2283, of 25 November 2015 on novel foods. Novel food will only be approved for use in the EU if they do not present a risk to public health, are not nutritionally disadvantageous when replacing a similar food and are not misleading to the consumer. They must undergo a scientific assessment prior to authorisation to ensure their safety. The authorisation sets out the conditions for their use, their designation as a food/food ingredient and labelling requirements.

2.2.3 Nutrient profile

If there is an authorised health claim for the desired constituent and matrix as well, an important task is to check minimum qualification requirements for products that can bear claims; n.b., to date, no such minimum requirements or thresholds for nutrients have been established; in addition, Regulation EC (No) 1924/2006 is currently in the process of a Regulatory Fitness and Performance programme (REFIT) evaluation and the issue of nutrient profiles is a key aspect of this evaluation process. Therefore, the considerations in this subchapter may need to be adapted according to the outcome of this evaluation and the possible adaptation of this regulation. For more information see: https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en.

As EC Regulation 1924/2006 states: “The establishment of nutrient profiles should take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, trans-fatty acids, salt/ sodium and sugars, excessive intakes of which in the overall diet are not recommended, as well as poly- and mono-unsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre”.

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The different categories of foods and the place and role of these foods in the overall diet should be considered during setting up the nutritional profile. However, it is a risky practice to develop a food with a health claim which has a nutrient profile in conflict with the balanced diet recommendations. There is no applicable nutrient profile available.

Although at present there is no regulation on the nutrient profile.

2.2.4 Prerequisites for the human intervention studies (HIS)

To demonstrate the beneficial health effect in the human intervention studies a comparison of the effect of the food product with the bioactive (test product) and a control product without bioactive (control) is performed. Then, a proper characterisation of the bioactive will help for its quantification in the test products (in the different batches, different points of the shelf life...) and depending on the bioactive in monitoring its consumption by the volunteers. At present, proper markers of consumption are available for a limited number of bioactives.

The proper characterisation of the bioactive compound meeting the above listed requirements is necessary to carry out a human intervention study, which provides valid results for scientific substantiation of the claimed beneficial health effect. For the human intervention studies in addition to the experimental (test) product, a reference (control) product has to be provided.

A **test product** is a food under investigation, which contains the bioactive compound causing the beneficiary health effect. At the design of the study the intended use of the product (method and time of the preparation, typical eating occasion for the target consumer group) and the amount and the frequency of the required consumption of the product should be stipulated, which ensures the required level of intake of the bioactive constituent (e.g. its concentration in the food), on which the claimed effect is based. Ultimately, the amount and frequency at which an individual is required to consume the test product to have detectable health benefits should fit to the normal eating pattern of that individual.

A **control product** (or **placebo product**) is a product that does not provide the bioactive compound that is being tested (Welch et al. 2011), but matches to the composition and sensory properties of the test product as closely as possible. This is necessary for conducting blind intervention trials and eliminating the influence of differences in intake of other bioactives or their product attributes, on trial outcomes.

The control product should match the test product for nutrient content, energy content, sensory attributes (palatability, sensory appeal, appearance, taste, mouthfeel and breakdown characteristics in the mouth) and physical properties (gross morphology, volume and texture) as closely as possible. The appropriate matching has to be verified by sensory and other tests. The close matching of the test and control product ensures also, that the human intervention study can be conducted in a double-blind fashion thereby reducing the risk of bias and increasing trial validity.

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- Test and control products should have the attributes which meet the specific requirements, expectations of the consumer target group (e.g. ethical aspects-vegetarian diet; religious aspects (e.g. halal); sustainability aspects; health-conscious diet, as appropriate).

It is recommended that all of the requirements related to the test and control samples for the human intervention studies should be defined systematically in the product development brief. The product development team and the staff of the clinical centres have to work together on developing the brief.
The clinical centre(s) should provide the following information influencing the amount, the required stability of the test and control product, the size of the batches produced for the study, for this internal document:

- the duration of the overall human intervention studies;
- the duration of the human intervention period for each volunteer;
- the total number of volunteers involved in the trial;
- recruitment capacity of the clinical centre(s) during a set time;
- the required portions of test and control product per volunteer. For the test product the stability of the concentration of the constituent also should be addressed;
- sample storage capacity in each clinical centre- e.g. capacity of freezers, refrigerators;
- sample preparation facilities (equipment, capacity) at the clinical centre(s) or realistically available at the targeted consumer;
- the estimated amount of test and control products in total for each clinical centre.

The behaviour and eating habits of the volunteers participating in the human intervention studies should also be considered e.g. what the food products are that they are ready to eat during the human studies in the required amount and frequency during the set time.

Packaging for clinical trials vs. commercialised products

The packaging of the samples for the clinical trials should enable blind testing. There is no need for graphics. The label should provide at least the following information:

- Best before/use by date;
- Instruction for preparation/use;
- Storage conditions;
- Allergen information;
- Randomisation number if available

The labelling requirements are described in more details in Annex 1.

At the selection of the packaging material the functionality and usability are important aspects to be considered. Requirements of food contact materials are described in Annex 6.

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2.2.5 Screening feasibility

Screening feasibility is a complex process to assess the viability/applicability of an abstract idea.

It is particularly important to collect all available (public and internal) information on physico-chemical and microbiological properties of the ingredient containing the bioactive compound, its composition, stability and bioavailability. Thus, an extensive search of information is necessary to know the current state-of-the-art.

A preliminary composition of the product has to be designed which enables an evaluation of the necessary ingredients, to assess the nutritional composition and to calculate the expected cost of the product. The specific questions related to the food products with health claims listed below need to be evaluated for the feasibility assessment based on the samples produced earlier.

2.2.5.1 *Technical feasibility assessment*

- Are the ingredient(s) containing the bioactive compound on which the health claim is based and the other raw materials and the ingredients available (in sufficient quantity and quality)?
- Is the health beneficial effect of the bioactive compound(s) in the product established? If not, can it be demonstrated?
- Is all the necessary information available to characterize the food/ingredient/bioactive compound? What type of information has to be collected?
- Are there any limitations for the product composition which have to be considered to meet the balanced diet recommendations or any other legal requirements?
- Can the ingredient withstand the processing conditions and is there information available on the stability of the bioactive compound during the planned storage, distribution conditions and preparation for use?

Further considerations

- Harmonization of production and delivery dates with the human studies.
- Capacity problems regarding limited food storage /handling/preparation facilities at clinics, health centres providing the human studies.
- Cost effective logistics of a few pallets of sample or less to distant places (centre(s) providing the human studies) particularly if they are chilled or frozen.
- Lack of exchange of practical knowledge between food manufacturers, nutritionists and medical experts.
- Considering the different microbiological acceptance criteria of food products in countries participating in human studies.

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2.2.5.2 *Marketplace feasibility assessment*

Marketplace feasibility focuses on whether the product is viable on the market or not. A new health claim may represent high value for the consumers and a good business opportunity for the company with high profit potential. However because of its novelty there may be higher costs and the risk of not being able to provide satisfactory evidence for the scientific substantiation of the claim and not achieving the EC authorisation is high, which results in a higher risk of failure of the project and loss of invested money and efforts.

- Are there any consumer and market research results about the targeted market and consumer acceptance of the product with health claim and products supporting the healthy diet?
- As a part of the feasibility assessment the length of the time necessary to achieve the claimed effect should also be considered. The length of this time may influence the decision of the consumers, whether they are ready to start to consume a product with a health claim and influences the length and costs of the human studies.

2.2.5.3 Financial feasibility assessment

- What are the costs of product development, substantiation of the health claim, and preparation of a dossier for authorisation of the health claim and its evaluation (as necessary)?

Additional aspects of information, which are necessary for the feasibility assessment of all new products are listed in Annex 3.

2.2.6 Planning and project management

The aspects, which have to be considered here are the same as those used for all new products independently from health claims. These are presented in Annex 4.

2.2.7 Steps from prototype development to scaling-up to factory level

Usually the prototype product development consists of 3 stages:

- small scale bench work-prototype development;
- pilot scale work;
- production scale factory trials.

Here only the recommended practices specific for products with health claims are presented. Further information on recommended good practices can be found in Annex 5, which are to the development of all new products independently from health claims.

Small scale bench work- prototype development

The minimum effective dose of the bioactive compound should be described clearly for the product development team in the product development brief, and achieved at preparation, production of all samples and maintained during their shelf-life. If it is not known yet, it is the

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first task of the product development team to define it based on the literature available and any internal data at the company's disposal. The nature of the product and the bioactive compound should also be reviewed and checked if the planned manufacturing process has an influence on their stability/degradation.

The first draft product specification should be set up during the small scale bench work, although some of the parameters can only be defined during pilot scale trials.

The sensory and nutritional properties of the test and control product should be tested to make sure they match each other. The nutritional composition of the test and control product should be monitored to verify they comply with all legal requirements. Although at present there is no regulation on the nutrient profile, to check it is recommended.

Pilot scale work

A good product specification includes the information listed below (modified from Campden & Chorleywood, 2007) to ensure standardised properties. For products with health claims specific attention has to be paid on the clear description of the following information:

- product name, document identification: date;
- product composition:
  - product formulation;
  - % of the ingredient, bioactives in the recipe for standard production volume;
  - list of ingredients, specifications of all ingredients, raw materials;
  - bioactive compounds having the beneficial health effect, bioavailability with the limits of variability within the finished product;
  - information for characterisation of the bioactive compounds and the food matrix;
  - allergen and sensitivity information;
  - religious and ethical information;
  - GMO information.

Additional aspects of information necessary for the product specification for all new products independently from products with health claims:

- relevant legal information;
- additives used;
- short description of the manufacturing process: HACCP summary, CCPs;
- quality and quantity parameters:
  - nutritional parameters/ nutritional labelling information / nutritional profile (as appropriate) and their maximal acceptable variability;
  - product structure and the bioavailability of food / bioactive constituent;
  - sensory parameters and their maximal acceptable variability;
  - chemical, microbiological, physical properties;

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  - quality assurance and food safety limits - physical, chemical, microbiological.
- filling weight;
- packaging, type of the primary and secondary packaging, specifications of the packaging materials;
- shelf life at set storage condition;
- storage requirements;
- transport requirements;
- labelling
  - product label;
  - health claims;
  - nutritional values;
  - allergen, sensitivity information;
  - religious, ethical information (as appropriate);
  - GMO information;
  - users instructions;
- warranty statements;
- approval by authorised person.

All of the necessary information on food safety, ethical, religious, sustainability and nutrition information together with a clear preparation/users' instruction and storage and handling requirements should be listed in the product specifications.

The specification of the finished test and control products should be provided to the centres carrying out the human intervention studies (HIS). Researchers performing the HIS should in turn provide feedback to the product development team regarding any necessary modifications of the product, the packaging, the portion size and the preparation method as early as possible to enable smooth implementation of the study.

Production schedules of the test and control products for HIS have to be developed by the food producing company and clinical centre.

A simple description of the test and control product should also be provided, which enables the organiser of the HIS to inform the volunteers on the nature of the products.

Process specifications ensure that the production processes are carried out in a standardized way to reduce the variability of the composition, including that of the bioactive constituent and of the product properties and that the food safety of the product (with the health claim and the control product) is achieved and maintained. In addition to the parameters described in the finished product specification, the main aspects to be covered are described in Annex 5. For products with health claims specific attention has to be paid to clear description of the maximal acceptable variability of the bioactive constituent within a batch and between batches. It should be considered which process control measures are necessary to achieve the required reproducibility.

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Specific aspects related to the products with health claims include the uniform concentration and stability of the bioactive compound and the reproducible structure of the food, including the maximal acceptable variability of the bioactive compound within a batch and between batches. It should be considered which process control measures are necessary to achieve the required reproducibility. These are mostly the same measures, which have to be used for the process content for all products. The typical elements for achieving low variability with batches and between batches are listed in Annex 5.

Identifying the key control points, where parameters influencing the concentration of the bioactive constituent, the structure of the food and composition, verification/testing of the concentrations of the bioactive compounds.

Factory scale production trials

It is a general industry practice to assess the reproducibility of the key parameters including the concentration of a specific component such as the bioactive compound based on at least 3-3 samples taken at different times from different parts of a batch from 3 independent production trials.

Here only those questions are listed, which are specific to products with health claims. Additional information can be found on questions to be considered at the development of all new products in Annex 5.

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Table 1: Checklists for the stages of product development specific aspects for products with health claims (modified from Campden & Chorleywood, 2007)

	Small scale production	Pilot scale production	Factory scale trials
Ingredients	Are the ingredients suitable/permitted/available in the target market? Is the constituent permitted/available? Do they satisfy claims made on the product? Consider the bioactive compound and the food market. Health and Data Sheets for every ingredient and the bioactive compound should be requested.	It is worth to reconfirm that the used ingredients are permitted in foodstuffs of the proposed type in the market.	
Recipe	Is the health claim compliant with target market?		
Product cost	Calculating the **material cost** for the product: cost for ingredients/ raw materials and quantity Include the cost of the bioactive compound. Estimation of the approximate quantities purchased at planned production should be provided to the suppliers.	Listing the **accurate cost of all ingredients and the bioactive compound** and raw material to be able to calculate the material cost for the products Estimate the cost of the human studies.	

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2.2.8 Product, process, packaging and labelling approval

During the product development the actual versions of product specifications have to be revised following the changes and approved.

For products with health claims the information about the minimum daily intake necessary to reach the claimed effect has to be stated. The results of the shelf-life tests have to be evaluated and it should be checked whether the minimum amount of the intake of the bioactive compound can be ensured at a realistic pattern of consumption. In addition, the required minimum level of the bioactive compound related to the health claim has to be available in the product during its whole shelf-life.

The company has to be able to provide evidence for the food control authorities by request.

Labelling

Regulation (EC) No 1169/2011 summarizes the main requirement in terms of labelling. Mandatory particulars of labelling are reported in Annex 1.

For products with health claims it has to be checked whether the same wording of the claim is used, which was authorised or a version which is equivalent. It has to be checked whether the requirements of the general conditions of use of health claims are complied with according to the Guidelines for implementation of specific conditions for health claims (and claims in Article 10 of Regulation (EC) 1924/2006) (Commission Implementing Decision 2013/63/EU).

In particular, the availability of the following information has to be checked:

a) A statement indicating the importance of a varied and balanced diet and a healthy lifestyle.
b) The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect.
c) Where appropriate, a statement addressed to persons who should avoid using the food.
d) An appropriate wording for products that are likely to represent a health risk if consumed in excess.

In addition to these requirements for reduction of disease risk claims, the labelling, or the presentation, or advertising should contain a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

Requirements for food contact materials are described in Annex 6.

2.2.9 Market introduction

For products with health claim, the wording of the claimed effects is important as it should be understood by the lay population. Health claims tend to be regarded positively by consumers, if they are phrased clearly and are easy to understand. Wording that is scientific or refer to

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unfamiliar components of the products tend to be misunderstood or not accepted by the consumer (Wills et al., 2012) and therefore will not be approved by the European Commission. The wording is originally proposed by the applicant and can be amended according to propositions by EFSA. The final wording is adopted by the European Commission during the authorisation process.

Simple wording and familiarity with the compound supports consumers' trust. Health claim-products are the focus of consumers aware of nutritional quality and address the health-conscious segment of customers. Consumers eager to maintain a healthy lifestyle or suffering from food allergies/intolerances are most likely to be susceptible to health claim-labelling (Hawkes, 2004). Trends in consumption show preference for products of value, concerning health or social issues, and for food from sustainable sources with "natural" being the keyword (Euromonitor, 2012). Addition of bioactives tends to make a product seem less natural in the eyes of the consumers (Lähteenmäki - Lampila, 2008). Thus, it is crucial that consumers get familiar names of bioactive compounds in order to gain trust in the claimed benefits. Accompanying information can be provided in leaflets or on-line and is desirable for successful communication about bioactives and their health effects. Consumers assess the reliability of health claims based on their own knowledge.

In addition to the health claim itself, the carrier-product is also of importance for the perception of the claimed health effects. According to results of the ACCLAIM-project the addition of Omega-3-fatty acids was perceived positively in bread, but negatively in pork (Lähteenmäki- Lampila, 2008). Health claims on processed food are more trusted than e.g. on raw meat. Bioactives that are assumed familiar to a certain food product (e.g. probiotics in yogurt) are found more reliable as a basis for health claims.

2.3 Ensuring food safety

2.3.1 General food safety requirements and aspects of products for human consumption (food safety management system based on HACCP)

For all food products, including those with health claims, a product-specific HACCP study is mandatory, before the release on the market. The HACCP study should be carried out following the Codex Alimentarius principles (CAC/RCP 1-196) and the relevant EU guideline (http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf). Other relevant food safety and hygienic regulations are listed in Annex 7.

2.3.2 Safety of the test products (for sensory and consumer testing)

As reported in the REDICLAIMS guidelines (Pravst, I. et al. 2017), in the process of scientifically evaluating a health claim, the safety of a food (constituent) is not systematically assessed. Safety is an important concern that must be addressed since the beginning, i.e. while producing the test products for sensory and consumer testing

Any samples received/provided for a sensory assessment/consumer test or for a human intervention study should be safe and fit for human consumption. The general principles and measures for ensuring food safety are the same as for all product samples.

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Here only the specific aspects are described. More detailed information is provided on the necessary actions to ensure food safety of the samples for sensory and consumer testing in Annex 9.

For products with health claims specific attention has to be paid to the hazards represented by the potential adverse effect of a bioactive compound at high concentration. For such bioactive compound for which an adverse health effect was reported, the lowest limit published in scientific studies and in legislation should be considered as the highest allowable level of intake. For such nutrient substances for which no evidence is available on adverse health effects the highest observed intake (HOI) can be used. "The highest observed intake (HOI) is derived only when no adverse health effects have been identified. It is the highest level of intake observed or administered as reported within (a) study(ies) of acceptable quality" (WHO, 2015). HOI approved to nutrient risk assessment is used to establish guidance levels for those nutrients for which no toxicity has been observed.

The company supplying the test and control products for the organisations carrying out the consumer/sensory tests and/or consumption tests for human intervention studies should provide the users with the necessary information described in this procedure.

2.4 Determination of shelf life

Shelf life of a product is the time after production during which it remains acceptable for consumption at specified storage temperature and other conditions, as applicable:

- remain safe;
- retain desired sensory, chemical, physical and microbiological characteristics;

In addition, for products with health claims shelf-life must be also considered:

- stability and consistency of the food/bioactive compound, which is expected to exert the claimed effect is ensured (e.g. contained at the appropriate level) in the final product as consumed (EFSA 2017a);
- retain nutritional parameters to comply with any label declaration of nutritional data.

Here only the specific aspects relevant for the shelf-life determination of products with health claims are described. Additional information is provided on the requirements of shelf-life determination for all new products in Annex 10.

During the shelf life assessment the parameters of a product with health claim, the consistency and stability of the food/ingredient/bioactive compound for which the claim is proposed in the final product as consumed (EFSA 2017a), sensory, microbiological, chemical and biochemical properties and composition of the product are assessed. The expiry of shelf life is the point at which it becomes unacceptable from one or more of these aspects.

For products with health claims safety and level of the bioactive compound are of major concern – safety is a legal requirement, the level of the bioactive compound is a pre-requisite of communicating a health claim.

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In addition, stability of bioactive compound(s) represent an additional, important factor influencing the shelf-life of food products with health claim. In some cases, it could represent the limiting factor of shelf-life.

Recommended practices for sensory and consumer testing are described in Annex 9.

3. Specific considerations related to the selection and verification of health claims to prepare scientific substantiation

Any health claim must be accepted by the competent authorities of the country where the product is sold (Codex Alimentarius, 2004). Among the different relevant jurisdictional groups are the European Union through the European Commission (after consultation to the European Food Safety Authority - EFSA), USA Food and Drug Administration (FDA), Australia and New Zealand by the bi-national regulator Food Standards Australia New Zealand (FSANZ), Japan with its policy "Foods for Specific Health Uses" (FOSHU). Although the legislation, regulatory authorities and politics concerning health claims vary from country to country, there is a general and essential principle in all of them, namely that health claims should be based on scientific evidence. In Europe, the Panel on Dietetic Products, Nutrition, and Allergies (NDA) of the EFSA is responsible for evaluating the evidence from all the studies presented.

The scientific substantiation of a health claim requires showing convincing evidence to support the claimed effect. Based on the Codex Alimentarius the health claim must consist of two parts (Codex Alimentarius, 2004):

1. Information on the physiological function of the nutrient or on an accepted diet-health relationship.
2. Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole range of foods whereby the research does not link to specific bioactive compounds of the food.

In the PASSCLAIM project the criteria for the scientific substantiation of health claims on foods, which are included in the European Regulation were defined, as follows:

- The food or food component to which the claimed effect is attributed should be characterised.
- Substantiation of a claim should be based on human data, primarily from intervention studies.
- When the true endpoint of a claimed benefit cannot be measured directly studies should use markers.
- Markers should be biologically valid (i.e. they should have a known relationship to the final outcome), and be methodologically valid with respect to their analytical characteristics.
- Within a study, the target variable should change in a statistically significant way.
- A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing up of the evidence (Aggett et al. 2005).

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This chapter presents the **main aspects to be considered for the validation of a health claim** based on the current European Regulation (EC) No 1924/2006 and EFSA guidance mainly. EFSA (2011b, EFSA 2017b) proposes a scientific and technical guidance for the preparation of an application for authorisation of a health claim. Besides this document, EFSA provides additional specific information as further guidance on the substantiation of health claims in specific areas, such as guidance on the scientific requirements for health claims related to: gut and immune function, and those related to antioxidants, oxidative damage and cardiovascular health, appetite ratings, weight management and blood glucose concentrations; bone, joints, skin and oral health; physical performance; and functions of the nervous system, including psychological functions. The EFSA's documents are updated based on recent scientific data.

In accordance with the requirements of the Regulation, the health claim application must contain the following considerations initially:

- information on the characteristics of the food/ingredient/bioactive compound for which a health claim is made. Where applicable, this information should contain aspects considered pertinent to the claim, such as the composition, physical and chemical characteristics, manufacturing process, stability, and bioavailability. This information should be described in detail in the finished product specification (see Chapter 2) or in additional documents related to it.
- all pertinent scientific evidence which form the basis for substantiation of the health claim. This includes data from the human intervention study where the link between the bioactive enriched product and the health effects and supporting information is demonstrated to strengthen the evidence (from bioavailability studies, mechanistic study to a compilation of data from bibliography). A comprehensive review of the data from human studies addressing the specific relationship between the food/bioactive compound and the claimed effect is required. This review and the identification of data considered pertinent to the health claim should be performed in a systematic and transparent manner in order to demonstrate that the application adequately reflects the balance of all the evidence available. If the claim is for a specific formulation or fixed combination of bioactive compounds (as distinct from the individual bioactive compounds), the pertinent studies are performed with this specific formulation or combination, and not with the individual bioactive compounds. A fixed combination of bioactive compounds is referred as two or more nutrients, and/or other substances in which all of them are necessary to get the claimed effect, ideally in specific amounts (EFSA, 2011c, EFSA, 2017b).

Based on the EFSA guidance the scheme of the specific considerations to verify health claims is presented in Figure 6.

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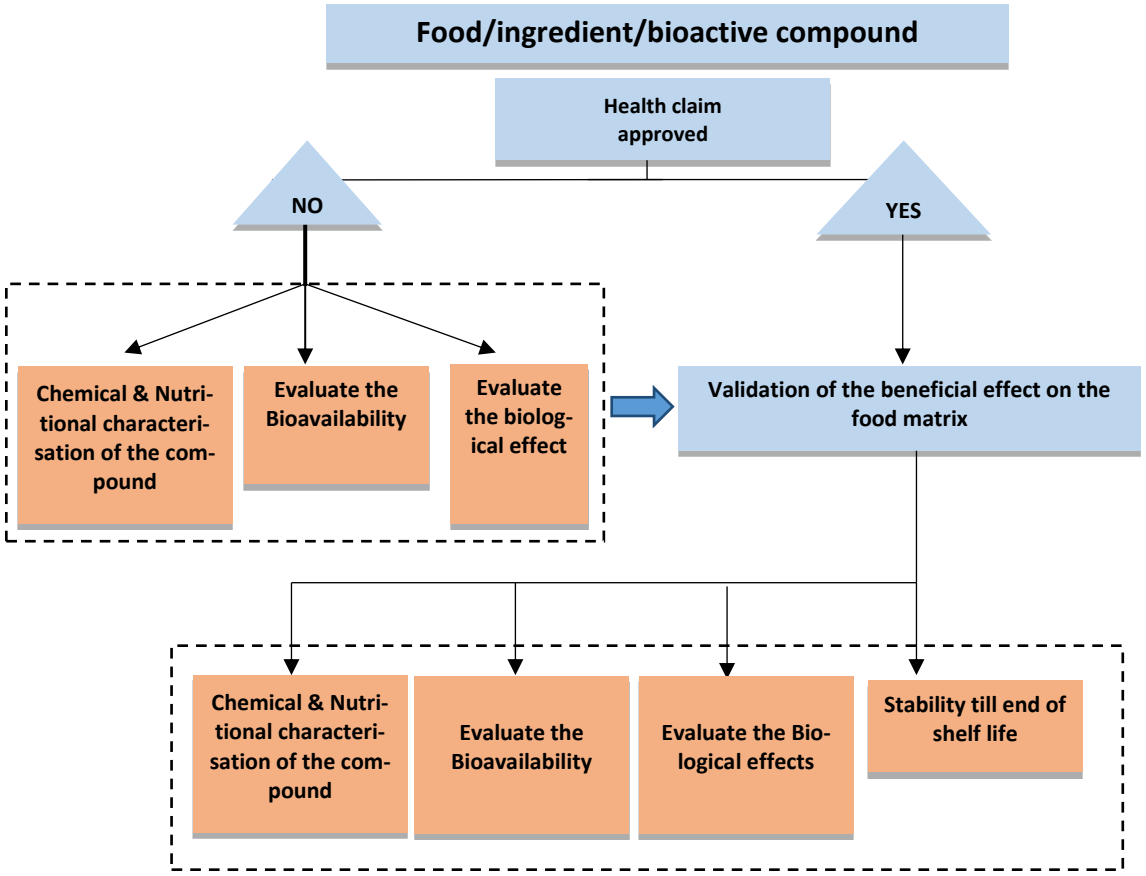

Figure 6. Scheme of the specific considerations to verify the health claims to prepare the scientific substantiation

However, EFSA does not specify the obligation of this protocol, but according to the observations based on the experience of technological partners of PATHWAY-27 project, it is observed that the actions of a bioactive compound can vary after the formulation in a food matrix and/or food processing. This is the reason why it is proposed to carry out a study of the compound alone and incorporated in the alimentary matrix.

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3.1 The health claim on the bioactive compound/food is not authorised

In case of a new health claim yet to be authorized EFSA's previous opinions on the ingredient/bioactive compound should be checked, since they provide important positive and negative comments. Opinions are published in the open-access EFSA Journal.

In case of a new health claim yet to be authorised, the food/bioactive compound must be characterised and its beneficial effect in the target audience demonstrated.

CHARACTERISATION OF THE INGREDIENT/BIOACTIVE COMPOUND

Any food/ingredient/bioactive compound, for which the health claim is made must be characterised and this information shall be described in the specification of the bioactive compound (see 2.2.7). This information has to be provided in an early stage of the product development.

The source of the bioactive compound and the ingredient which contains it and its specification and the specifications of the food or food category for which the health claim is made should be provided (see the product specification in 2.2.7). For the identification and characterisation of the bioactive compound/ingredient/food usually advanced analytical techniques are required. This includes identifying new substances, characterizing their structure and activity, as well as the critical factors of the quantification in the natural matrix and controlling the specifications of the product (Bernal, 2011).

Analytical methods have to be fit for the purpose and need to be validated thoroughly for that purpose.

The analytical methods used in the characterization of the bioactive compounds, food ingredients, and nutrient analysis of foods and macronutrients should be standardized and/or validated according to appropriate guidelines (UNE-EN ISO/IEC 17025:2005; Eurachem Guide and ENAC Guides for method validation). According to the EFSA guidance (EFSA 2011b) the measurements should be performed in a competent laboratory where the data can be certified and the quality system established in the laboratory is indicated. Information on the accreditation of the involved facility should be provided (EFSA, 2017)

Regarding analytical methods, it is necessary to use detectors able to identify compounds structurally, and not only to quantify them by retention time, wavelength, etc.

Nowadays, gas or liquid chromatography tandem mass spectrometry (LC_MS) is one of the analytical methods showing greatest potential for undertaking these aspects. The analytical methods developed should be validated in terms of precision, accuracy and reliability (Betz, 2011).

Some examples pf analytical methods for determination of bioactive compounds is presented in Annex 11.

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VALIDATION OF THE EFFECT OF THE BIOACTIVE

The substantiation of a health claim is based on verifying the relationship between the consumption of the food containing the bioactive(s) and the claimed effect, so at least a human intervention study must be done. Before carrying out the clinical trial it is recommended to elaborate a comprehensive review about the current state of the art, to complete information of previous use of the bioactive. This information can be useful for the design of the product and RCTs (to avoid unnecessary approaches) and as supporting information regarding the health benefit of the bioactive.

Human intervention trials are essential for the validation of the health claim. The data and evidence derived from studies in animal and/or *in vitro* models provide supporting information, which can provide evidence on the mechanisms of action and support the biological plausibility of the specific claim (EFSA 2011b; EFSA, 2016). Moreover, the *in vitro* studies and/or studies with animals can be considered as an earlier step (exploratory studies) to have experimental data of the relationship between the food/bioactive compound and health, and then to elaborate the hypothesis and then to design the human intervention studies. It is recommended to make use of models and biomarkers commonly used by experts of the area.

In the process of validation of the cause-effect relationship of the bioactive substance there are two concepts to be considered: bioavailability and functionality of the bioactive by itself before being incorporated in a food matrix. More information is provided on bioavailability, bioaccessibility and bioactivity in Annex 12.

According to Regulation (EC) No 1924/2006, the use of health claims shall only be permitted if the food/bioactive compound for which the claim is made has been shown to have a beneficial physiological effect. In the validation the specific physiological effect on which the health claim is based, as well as the target population for whom the claim is intended must be taken into consideration.

Regarding the “beneficial effect” a distinction should be made between (EFSA 2011b):

- The function claims, where a beneficial effect may relate to maintenance or improvement of a function.
- The reduction of disease risk claims, where “beneficial “refers to whether the claimed effect relates to the reduction (or beneficial alteration) of a risk factor for the development of a human disease (not reduction of the risk of disease).

The validation of the effect must be supported by human studies. There are guidelines which provide information about conducting human studies, for example in Europe, the Commission of the European Communities Regulation (EC, 2008), in USA the FDA (US FDA Guidance for Industry, 2009), in Canada (Health Canada, Bureau of Nutritional Sciences, 2009) or even in the FAO/WHO Codex Alimentarius Commission (CAC/CG 23-1997).

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The PATHWAY-27 consortium developed also a “Set of integrated guidelines for the scientific community” focusing on the design of human intervention studies in parallel with these guidelines.

Further, in 2011 a comprehensive document commissioned by the ILSI Europe Functional Foods Task Force was published with guidelines for the design, conduct and reporting human interventions studies to evaluate the health benefits of foods commissioned by the ILSI Europe Functional Foods Task Force (Welch et al., 2011).

To evaluate the health benefits of foods the design, conduct and reporting of the human studies shall be considered. As a starting point the hypothesis of the beneficial effect should be established and then the study shall be designed and conducted to test the hypothesis. The definition of the hypothesis of the beneficial effect can be based on earlier knowledge or on theoretical effects. An extensive literature search is required to know the current state-of-the-art on the beneficial effect on health. This is an important input to evaluation of the feasibility (2.2.5) as well. If there is any previous knowledge (e.g. other intervention studies or in vitro studies) it is recommended to evaluate first the effect based on in vitro and/or in vivo studies before carrying out a new intervention study.

Other important aspects to be taken into account for human intervention studies are the selection of outcome measures (clearly relevant to the intended effect), the eligibility criteria of the participants in the human studies, the statistical analysis and assessment of the compliance.

More information can be found on these in the Scientific Guidelines prepared by the PATHWAY-27 project team.

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3.2 Interaction between the active compound and the food matrix

Once the ingredient/bioactive compound is incorporated in a food matrix for the development of a product with a health claim, the following studies shall be carried out to identify whether the matrix interferes in the effect of the bioactive(s).

The bioactive(s) in the food matrix should be quantified by the validated analytical methods. Besides, the matrix effect should be assessed to prove that the analytical methods used are able to quantify the bioactive components in the specific food matrix. The study should be performed on the test and control product.

The stability information for both food and bioactive compound(s) should be provided. Where applicable, a summary of the studies undertaken (i.e. conditions, batches and analytical procedures), and of the results and conclusions of the stability studies, should be disclosed. The conclusions concerning storage conditions and shelf-life should also be provided.

As specified in the Regulation (EC) No 1924/2006 the quantity of the food/bioactive and the pattern of consumption required to obtain the claimed effect should reasonably be achieved as part of a balanced diet.

In addition, to ensure that the claims made are truthful it is necessary to test that the bioactive substance is available in the food/bioactive compound.

3.2.1 Physical, chemical and microbiological characterization

PHYSICAL ANALYSIS

The main physical characterisation is the measurement of changes in the texture (Lan, 2013). The rheological changes can be induced by chemical reactions produced by interaction of bioactive compounds or by external factors. The method of texture measurement has to be chosen carefully depending on the product in order to obtain a correlation between instrumental analysis and sensory tests.

CHEMICAL ANALYSIS

Many chemical reactions can occur in a product during storage, which can influence the stability of the food/bioactive compound and consequently the bioactivity of its components. It is important to ensure that the dose and the nature of food/bioactive have not suffered any changes during storage. For example, if the health claim is related to the amount of a number of polyphenols from a vegetable or a fruit, the required concentration and the stability of these compounds must be demonstrated by validated chemical analysis throughout the shelf-life of the food/bioactive compound (EFSA, 2013).

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MICROBIOLOGICAL ANALYSIS

For the characterisation of the food/bioactive compound microbiological analyses should be focused on:

- Microbial growth, which causes the spoilage of the food/ bioactive compound.
- If the health claim is related to the presence of a specific/or blend of microorganisms, the characterization by molecular strain typing should be provided. Furthermore, the information related to the stability of such microorganisms in the food/bioactive compound and its microbiological safety should be specified (EFSA Journal, 2013).

3.2.2 Validation of the health effect

BIOAVAILABILITY

The incorporation of bioactive compounds into a food matrix requires integration of diverse aspects, such as identifying the bioactive compound(s), performing a toxicology assessment, and making stability and bioaccessibility measurements, which must be considered, evaluated and brought together to create the product (Korhonen et al., 2002). Measuring bioaccessibility is a key factor in the design of foods that claim a health benefit due to containing one or several bioactive compounds.

Before carrying out a clinical trial, once the final product is developed the evaluation of the impact of the food matrix and the food process on the bioaccessibility and bioavailability of the bioactive compound(s) is strongly suggested). The bioavailability is directly influenced by the composition of the food matrix and by the synergies and antagonisms that may be established between the different components.

To evaluate bioavailability, as mentioned in section 3.1, human studies would be recommended but they are difficult to perform. *In vitro* bioaccessibility studies can provide information about the influence of the food matrix and the food process on the bioaccessibility of the bioactive compound(s).

Since bioavailability and functionality are fundamental pillars in the validation of the health effect, the use of *in vitro* models can be useful to adjust the design of the product before the human intervention studies.

3.3 Conclusions

A health claim must be supported by human data from well-designed human intervention studies (see PATHWAY-27 Guidelines for the scientific community). All prior knowledge about the food/bioactive compound and selected food matrix will help to design a study (including published and internal data from *in vitro*/*in vivo*/ or pilot human studies).

The following main aspects are discussed in detail in the Scientific Guidelines:

✓ Scientific substantiation of a health claim: reviewing the evidence and defining the conditions of use
  - Systematic review (SR) (Chapter 2.1)
  - Evaluation of the quality of human dietary interventions (Chapter 2.2)

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  - Rationale on biological plausibility (Chapter 2.3)
  - Number of studies needed for scientific substantiation of a health claim and scientific judgment: weight of evidence (Chapter 2.4)
  - Conditions of use (Chapter 2.5)

✓ Scientific substantiation of a health claim: designing, conducting and reporting human dietary interventions (focus on RCTs)

  - Research question and study hypothesis (Chapter 3.1)
  - Study design (Chapter 3.2)
  - Test and control products (Chapter 3.3)
  - Outcome measures (Chapter 3.4)
  - Selection of participants: study population and eligibility criteria (Chapter 3.5)
  - Ethical approval and study registration (Chapter 3.6)
  - Recruitment and participant flow (Chapter 3.7)
  - Compliance (Chapter 3.8)
  - Statistical analysis (Chapter 3.9)
  - Reporting of randomised controlled trials (Chapter 3.10)
  - Discussion and interpretation (Chapter 3.11)
  - Roles and responsibilities of the research team (Chapter 3.12)

To provide evidence of the health effects of food enriched with bioactive compounds on Metabolic Syndrome, in the PATHWAY-27 project the following steps were applied:

1. Selection of three authorised bioactive compounds: docosahexaenoic acid (DHA), beta-glucan (BG) and anthocyanins (AC) and 3 foods.
2. Selection of 3 different food matrixes: bakery, dairy, and egg-based products
3. Selection of 3 foods in each matrix, each food enriched with five different bioactive combinations, based on technological and sensory characteristics.
4. Development of 45 prototypes of bioactive enriched food (BEF).
5. Screening of the products for the pilot study considering sensory attributes, results of consumer acceptance tests, microbiological quality, *in vitro* bioaccessibility and chemical stability
6. Evaluation of the effectiveness of 15 food prototypes in pilot studies.
7. Selection of one bioactive enriched food in each food matrix, according to the results of pilot studies.
8. Validation of the health effect in a human intervention study (randomized clinical trial).

The development of BEFs and the selection of the products for pilot testing are described in Figure 7.

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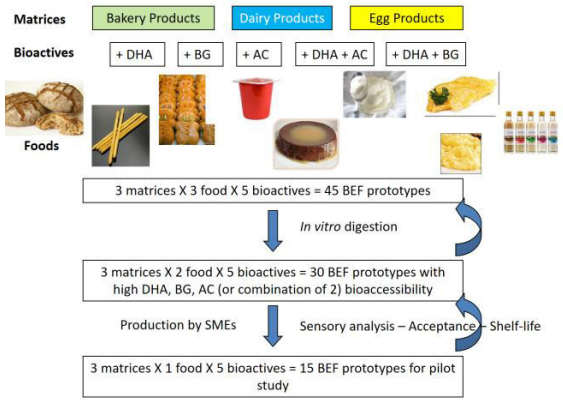

Figure 7: Development and selection of BEFs in PATHWAY-27

Validation process of the health effect in the project (Figure 8):

- Running of pilot studies in humans using the best product within each food matrix. The selected products were enriched with five different combinations of bioactives
- The most active enriched food within each pilot study was then used in a larger randomized, placebo-controlled, multi-centric human intervention study (LIS).

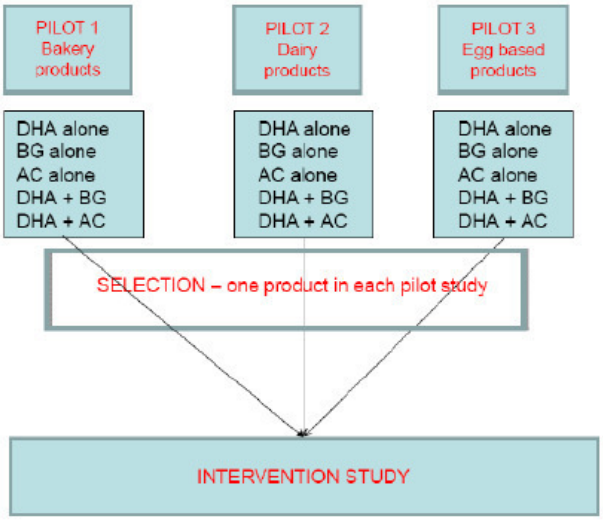

Figure 8: Validation of health claim in PATHWAY-27

Supporting information: mechanism of action and rationale

- Development of *in vitro* studies with cell culture to understand the protective role and mechanism of action of each bioactive compound (DHA, BG, and AC), alone and in combination, their cross-talk at the cellular level and their role in the aetiology and development of the Metabolic Syndrome (MS).
- Development of an in vivo study in minipigs to analyze the impact of food digestibility on bioactive availability.

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4. Identifying the role of the new product with health claim in a business

4.1 Developing a business plan, paying special attention to SME context.

Development of products with health claims provides potentially enhanced sales due to a unique position in the market. Developing a business plan is critical when considering the launch of products with a health claim. There are a number of key elements that need to be taken into account for health claim products when considering the impact on the business and its planning:

- greater level of interaction with third parties. These will include businesses, such as clinical research organisations, that may not be part of the current interfaces;
- higher cost, primarily related to increased level of testing;
- increased time needs, similarly to take account of the level of testing required;
- dedicated marketing and communication, likely to require input from "new" stakeholders e.g. health expert bodies;
- well-founded revenue estimates, the primary incentive to achieve health claim status being to provide opportunity for enhanced revenue streams.

Strategic factors, consideration for launching products with a health claim typically is driven by two opportunities:

1. Discovery or invention of a material or combination of materials that may provide a benefit.
2. The consideration that a brand or business has a good fit with a specific health position.

In both cases a review of existing health claims is merited.

In the development phase there will be development costs over and above conventional product development primarily due to the increased level of product testing needed to cover the health claim substantiation. This will be a significant investment. The time to launch will likely be longer than a conventional development due to the increased testing, time required to prepare dossiers and time to get feed-back from EFSA. It is recommended to allow 18-30 months additional time for development of products with approved claims.

This should include a risk analysis covering:

- sourcing the critical/new raw material (health benefit);
- consistency of supply;
- ability to provide stable product of consistent quality with added components;
- likelihood of achieving a health impact in the final product;
- approval of the claim.

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TECHNOLOGY

The early development of a product with a health claim may have been derived from a product produced at a relatively small or pilot scale, to reduce risk/cost at the pre-commercial stage. If so, then a phase of scaling-up will be required to cover:

- ability to reproduce the test product (sensory aspects, stability etc.) at commercial scale;
- ability to produce the product at a scale that will satisfy market demand in the medium term (e.g. 1-5 years);
- the most profitable route to scale-up/manufacture.

Scale-up carries a number of risks, which should be assessed as part of the project plan. This may include usage/assessment of specific items of equipment specific to the scaled-up process. These include:

- the ability to reproduce the concentration of the active compound and the sensory quality. This should consider for example, impact of heat transfer rates, flow rates, shear, mixing efficiencies etc.;
- the variability in concentration of the bioactive compound and sensory quality at commercial production volumes (product consistency);
- the stability (shelf-life) of the product under full manufacturing conditions in the final pack format;
- the need for any pre-blends, intermediate blends, or stock solutions;
- verification of the HACCP system;
- actual production rates vs projected rates. Run lengths and impact of stoppages on product quality.

MANUFACTURING OPTIONS, INCLUDING MAKE OR BUY CONSIDERATIONS

This section will provide guidance on the considerations necessary if the new product, supporting the health claim requires adaptation of an existing line or set-up of a new manufacturing line.

If the Make option flags concerns on the in-house option, then a review of Buy options should be carried out. The Buy option generally reduces risk at the initial manufacturing stages. The Buy option will consider manufacturing options “in the public domain” that use existing technology. If the manufacturing requires “new to your company” processes but not novel processes then this route becomes an option.

Co-manufacturers will rarely want to invest in new technology for new ventures, hence Health Claim products requiring new technology are likely to require in-house investment. More complex partnership options could be explored in these situations where partners would include the brand/health claim owner, a site set-up for comparable food manufacture and a supplier of the novel technology. IP ownership and usage will need to be carefully controlled by contracts.

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SEVENTH FRAMEWORK PROGRAMME

Capital investment and installation whether on an owned or third-party site can be a lengthy process and should consider significant installation and commissioning trial phases.

Although reducing risk and upfront capital commitment, the Buy option requires careful management of Confidentiality and Intellectual Property (IP). Co-manufacturers will be operating with a wide range of clients, some of-whom maybe operating in competitive areas.

It is advisable to put in place appropriate agreements before any significant information exchange takes place. Absolute clarity on the ownership of existing IP is critical.

Key considerations around the Buy options are as follows:

- Availability of manufacturers.
- Location of manufacturers in relation to the sourcing of incoming materials and the distribution of the finished product. Include consideration of import/export tariffs.
- Operational standards of the manufacturer. Accreditations, certifications, audits.
- Conflicts of interest. Typically in relation to their current client list.
- Operational capability. Based on the known required process flow for the new product, does the manufacturer have all the necessary items? If not, can an agreement be reached for investment by one or both parties?
- Staffing and support levels. Does the manufacturer have sufficient number and quality of staff to service the manufacturing and supply needs? Consider; Operations, Quality, Technical, Development, Logistics, and Customer Support.
- Capacity. Based on the volume projections is sufficient product capacity available.
- Distribution and Logistics. How will the product be handled, stored and distributed post-production? Does the site have sufficient storage capacity in appropriate conditions? Who will be responsible for distribution/transport from the site to the customer(s).
- Costings. Be clear on the basis for the costings. Agree whether it is appropriate for the manufacturer to buy all the materials. Consider keeping control of the key ingredient or ingredient blends that contribute to the health claim. Enhanced protection can be gained by preparing pre-blends via in-house, ingredient suppliers or specialist third-parties that contain key “active” ingredients. Co-manufacturers will have minimum cost-effective run sizes (minimum order quantities – MOQ); careful thought on volumes in the early stages is needed to ensure a viable business with the manufacturer.
- Contracts and Continuity of Supply. Co-manufacturers will be constantly reviewing their business base to maximise profitability. A contract needs to ensure continuity of supply, such that if circumstances dictate, sufficient time is available to seek alternative manufacturing options.
- Co-manufacturing is sometimes an interim option while in-house facilities are developed; ensure realistic time scales are considered with regards moving production in-house, particularly if capital/new purchases are required.

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5. Dossier development

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods lays down the following provisions:

1. For health claims which **fall under Article 14 of the Regulation** an application is needed. Applications for authorisation are subject to scientific evaluation (i.e. scientific Opinion) by EFSA according to the procedure laid down in Articles 15, 16, 17 and 19 of the Regulation, prior to their inclusion in a Community list of permitted claims.
2. Health claims (other than those referring to the reduction of disease risk and to children's development and health) which **fall under Article 13(1)** have to be included in the Community list of permitted claims provided for under Article 13(3) of the Regulation.

For inclusion in the afore-mentioned Community list of permitted claims, the applicant should contact

- the National Competent Authority of a Member State in the EU where the health claim applies.

Health claims which **fall under Article 13(5)** of the Regulation are subject to scientific evaluation (i.e. scientific Opinion) by EFSA according to the procedure laid down in Article 18 of the Regulation, prior to their addition to the list of permitted health claims referred to in Article 13(3) of the Regulation.

EFSA has developed several guidelines which are available on the following website. http://www.efsa.europa.eu/en/nda/ndaguidelines.htm.

The scientific and technical guidance provides help in developing a well-structured application for authorisation of health claims which fall under Article 14, or 13(5), or for the modification of an existing authorisation in accordance with Article 19 of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (EFSA, 2016; EFSA, 2017b).

The General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims document aims to explain the general scientific principles applied by the NDA Panel for the evaluation of all health claims and outlines a series of steps for the compilation of applications (EFSA, 2011d).

EFSA offers public consultation on the updated drafts. Updated drafts are available online concerning specific guidance on gut and immune function (http://www.efsa.europa.eu/en/press/news/150209).

The EFSA health claim application form is divided into five parts and should be completed with the necessary information as described.

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Part 1 contains the specific requirements for the administrative and technical data, such as the application form, information related to the applicant and the nature of the application (including the national and international regulatory status of the health claim), health claim particulars, and the summary of the application.

Part 2 contains information specific to the food/bioactive compound and its characteristics (such as the composition, physical and chemical characteristics, manufacturing process, stability, and bioavailability data).

Part 3 contains summaries (tabulated summaries of all pertinent studies identified, and written summaries of data from pertinent human and non-human studies) and overall conclusions, which follow the scope and the outline of the body of scientific data identified under Part 4.

Part 4 contains all identified pertinent scientific data (published and unpublished, data in favour and not in favour) which form the basis for substantiation of the health claim.

Part 5 comprises the glossary or abbreviation of terms quoted throughout the different Parts, copies/reprints of pertinent publications identified, full study reports of unpublished pertinent data, and scientific opinions of national/international regulatory bodies.

Where some of the data that are required as described below in this guidance document do not apply to a particular application, reasons/justification must be given for the absence of such data in the application.

If a study appears under different parts of the application, cross-references should be given.

The PATHWAY-27 Scientific Guidelines address best practices for designing and running human clinical trials that serve to demonstrate the claimed effect and are a requirement of the health claim dossier.

The REDICLAIM project developed recommendations for the successful substantiation of new health claims in the European Union (Pravst, I. et al. 2017).

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SEVENTH FRAMEWORK PROGRAMME

6. Development of "market launch" concept

6.1 IP rights

The developers of products with health claims invested significant effort and money to create the product and make them marketable.

It is important that the company developing the product with health claim should pay attention to the protection of confidential information in a very early stage of the project that will strengthen their position and discussion of the terms of sales contract to get fair return in their investment. Applicants frequently request confidentiality of the information submitted for scientific substantiation for EFSA. EFSA States that in order to comply with its requirements for transparency as outlined in Article 38 of Regulation (EC) No 178/2002 and Article 16 of Regulation (EC) No 1924/2006, data essential for the scientific assessment of a health claim may need to be disclosed in the final scientific opinion published by EFSA. Confidentiality can only be given to specific parts of a study if duly justified, and not an entire study. Once a scientific option for a health claim is adopted by the NDA Panel, and before its publication on the EFSA website, the scientific opinion is sent to the applicant in order to check whether the scientific opinion discloses any data that EFSA had accepted to keep confidential. In principle and without prejudice to Regulation (EC) No 1049/2001 on public access to documents, if a study has not yet been published and its disclosure would undermine the commercial interest and rights of the applicant, EFSA will not make such a study available to third parties. It should also be noted that where evidence for substantiation includes a request for the protection of proprietary data, the NDA Panel considers only whether the claim could have been substantiated with or without the data claimed as proprietary by the applicant (EFSA, 2015).

In relation to food products, health claims are to be authorised by European Commission before they can be applied in marketing or labelling of the particular food product.

An IPR-like regulation applies to health claims that are accepted and authorised by the EC. Article 15(3) of Regulation (EC) No1924/2006 protects the rights either of the manufacturer or distributor who invested substantial capital to collect all the necessary scientific data required in the application.

Regulation (EC) No 1924/2006 states: "The scientific data and other information in the application required under Article 15(3) may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:

> (a) the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and
>
> (b) the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and

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(c) the health claim could not have been authorised without the submission of the proprietary data by the prior applicant.

Until the end of the five-year period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether a claim could be or could have been included in the list provided for in Article 14 or, where appropriate, Article 13 without the submission of data designated as proprietary by the prior applicant".

Additional protection can be achieved by patenting.

6.2 Legislation and labelling

6.2.1 Existing legislation

Regulation (EU) No 1169/2011 “food information consumers”

The provision of food information to consumers is regulated in 55 articles and 15 annexes, and is focussed on consumer protection. Labelling and information is regulated concerning inter alia identity and composition of food, quantity, potentially harmful components, durability, storage conditions, business operator, instructions for use, health impact, nutritional characteristics, responsibilities of producers and caterers, and protection of fraud.

Regulation (EC) No 1924/2006

The Regulation on nutrition and health claims made on food is central for the labelling of bioactive food products. It applies for all claims that are made in commercial communication and includes a wide variety of nutritional compounds present in food. Nutrition claims can be made according to a list included in the annex of the regulation. Health claims must be approved by the authorities, before they can be used.

Nutrition claims can be made according to a list included in the annex of the regulation.

Commission Regulation (EU) No 536/2013

A list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health is set up in this regulation.

Commission Regulation (EC) No 983/2009 and Commission Regulation (EU) No 384/2010

The regulations contain a list of permitted and rejected health claims with regard to claims on reducing a disease risk and including children’s development claims.

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6.2.2 Labelling requirements

Information provided to the consumer must be fair and not misleading. Formal appearance has to comply with provisions of Regulation (EU) No 1169/2011.

According to Article 10(2) of the Regulation 1924/2006 additional labelling required for health claims. "Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
c) where appropriate, a statement addressed to persons who should avoid using the food;
d) and an appropriate warning for products that are likely to present a health risk if consumed to excess."

According to Article 14(2): "...for reduction of disease risk claims the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that:

- the disease to which the claim is referring has multiple risk factors and altering one of these risk factors may or may not have a beneficial effect."

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6.3 Sales Campaign Development

For sales campaign development the following aspects and steps have to be covered:

- distribution channels;
- target customers and their requirements;
- core product and company data;
- listing presentations;
- phrasing;
- and roll out.

For the majority of these steps, the activities and recommendations are generally applicable for all products. This information is provided in Annex 13. Here only those aspects are described which contain a specific consideration for products with health claims such as the "Core Product and Campaign Data "and the content of the "Listing presentation".

CORE PRODUCT AND CAMPAIGN DATA AUTHORISATION

The unique selling point (USP) needs to be clear and communicable in the retail environment. The authorisation of a health claim will, by its nature, provide a number of benefits:

- appeal to a defined consumer group/need;
- a competitive advantage, at least in the short term, and in many cases in the midterm;
- and a message that can be legally and clearly communicated; supported by sound science.

Core product data to consider include:

- the health claim
  - context of lifestyle, health and well-being;
  - relevant/target consumer groups;
  - the ingredient/raw material driving the claim.
  - associated nutritional position e.g. vegetarian, low fat, high fibre, dairy-free;
  - features appealing to target consumer group – age profile, sex, vulnerable groups, demographics;
  - consumer usage;
  - storage and shelf life;
  - frequency of usage, regime, ensuring the delivery of the benefits;
  - fit with daily diet and diet regimes;
  - consideration for avoidance groups/warnings e.g. pregnant women, children etc.;
  - and price: on-shelf cost, cost per dosage, comparative cost versus other routes to control the target condition e.g.: dietary supplements, Over The Counter (OTC) medicines.

Many elements of this information are defined in the product development brief and in the finished product specification. The product features and the route to promoting these features will need to deliver the trust in the health benefits and credibility amongst consumers

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that lead to sale. Critically the consumer needs to be able to understand the specific benefit to their health in a simple, rapid fashion.

SMEs operating in this field may be launching both a new product and a new brand. The campaign will need to build the story behind the brand and lead to product (benefit). Examples of successful campaigns would be those linked to plant sterols and stanols for cholesterol control by McNeil Consumer Nutritionals (Johnson and Johnson/Raisio) and Unilever.

Although both had multinational food company backing, one was building on existing trusted brand (Flora/Becel) and the other was linked to a new brand (Benecol).

Scientific data can be a powerful part of the communication mix to build trust. The average consumer has relatively limited scientific and nutritional knowledge, much of which may be influenced by the popular press and media. Simplicity around the message is critical.

Consumers are primarily interested in "solving a (health) problem" rather than a specific ingredient e.g. heart health/cholesterol control needs vs stanol/sterol in the case of McNeil/Unilever ranges. Multiple routes are available to build the campaign and these are likely to be driven by the available budget.

Since the national interpretation of the EU Health Claims legislation varies from one country to another a careful consideration of the legality of the messages is necessary, in line with the national acceptation practice of the consumer information. Information can be collected from the national food safety offices.

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7. Implementation of the product launch

The main aspects of implementation of the product launch are the following:

- Overview and co-ordination.
- Sales requirements and wording.
- The manufacturing schedule.
- Launch campaign.
- Press release, Events, PR, Advertising and Promotion kick-off.

For products with health claims, the launch phase is an opportunity to build awareness based on the "condition" being targeted e.g. bone health, eye health, by linking with organisations and associations with expertise or interest in these health topics. This might include respected academic institutions that may have a focus of research in the topic. The compliance with the acceptable practice in the country should always be checked and ensured. These need to be co-ordinated with the launch activities and could include:

- interviews with respected experts in the relevant health field;
- articles and editorials with expert contribution;
- product or promotional item give-aways linked to specific relevant organisations or sponsored events (health-related, sports, social, music, entertainment);
- conference activities either as part of national/EU trade conferences or possibly; dedicated launch events with appropriate educators;
- web and social media highlights and links to the brand/product;
- possible joint press releases/ statements.

Historically, personal or organisational endorsements have proved powerful sales/marketing supports for products with a health benefit. Careful selection and briefing of the endorser (individual or company) is needed. The focus can be lifestyle-related, where a celebrity or sports personality may be relevant or focused on the scientific/nutritional elements or where a reputable consumer group or health association may be relevant. These endorsements and usage/case studies need to be circulated and released as part of the launch phase.

The most powerful endorsements will come from groups who have consumed the product and observed the claimed effect. This can require a possibly lengthy pre-launch trial phase, over and above the clinical trials needed to support the claim.

Launch Campaign

A product supporting a health claim is likely to present additional challenges in the launch phase compared to conventional products. There will be an educational requirement necessary to communicate the (additional) product benefits (specific health impact).

This will need to be impactful, trustworthy and comprehensible to the target audience. Messages need to be simple and easy to assimilate in what might be, a complex nutritional/health area.

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The launch campaign must be able to rapidly target the key consumers in its style and delivery. For a variety of reasons products with health claims need to command premium pricing and need to be able to convince the target consumer that consumption of the food product is a complementary or better route to the "health solution" than other alternatives e.g. supplements, OTC medicines, herbal therapies etc.

The launch activities, in addition to conventional new product launches, can benefit from the following:

- endorsements from users/case studies;
- recommendations/ endorsements from targeted health bodies/associations and/or academic institutions;
- profile media events or interviews;
- reduced cost trial periods or introductory offers;
- promotion and/or give-aways at events linked to the targeted health condition/claim e.g. running events for rehydration claims;
- publications in respected popular press outlets linked to the health condition;
- point-of-sale literature highlighting the effects and mechanisms;
- reduced price or free testing facility/option related to the health condition (e.g. cholesterol or blood sugar measurements);
- and joint promotions or cross promotions with complementary products (food or non-food).

Communication that the health claim is independently endorsed/approved in law by European authorities (rather than derived by company marketing), can help enhance credibility. The depth of testing and scientific research supporting the claim/effect can be raised (in overview).

Consensus on the health condition being targeted (e.g. bone health, heart health) and the rationale or approach taken to provide a benefit (via the new product) will be important. Advanced briefings with Key Opinion Formers (KOF) and influential public/private bodies in the area are recommended. Pre-launch engagement including product trials with key health bodies or associations with interest in the target health condition would be beneficial. Identifying KOF who are willing to either actively promote or at least provide positive feed-back will be a significant advantage.

At this pre-launch stage consider all parties who may have an interest/angle on the health area being targeted, such that their position can be understood and managed (in relation to their likely reaction to the launch). By example, if a product has a relatively high dose of fat soluble vitamins to achieve an effect, will there be counter-arguments with regards "over-dosing" risk for these vitamins.

Promotion for products with health claims can be as powerful as conventional advertising (where consumers may be sceptical around company-funded adverts). PR can be a cost effective route to raise awareness vs conventional advertising.

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Statements, comments, endorsements, approval from the following can be considered, if they comply with the acceptable practice in the country of application on fair advertisement:

- respected academic or research organisations;
- medical bodies;
- health associations (e.g. national Heart Foundations, Diabetic Associations,);
- sports bodies or coordination associations;
- personalities linked to the health area being targeted by the consumers who by participating in trials, can describe benefits.

The compliance to the acceptable practices should be checked.

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8. Practical recommendations

The development of food products with health claims is a more complex process than the development of conventional products. It requires an even higher level of collaboration and harmonised interactions between several disciplines and independent partners, including external knowledge and service (human intervention studies, statistics, etc.) providers. Therefore, a careful and systematic design of the product development process and planning of the activities is crucial. Specific attention has to be paid to ensuring high reproducibility and uniformity – low variability within a batch and batch to batch – of the test and control product samples provided for human intervention studies. This includes the reproducibility of the concentration of the bioactive compound through the whole shelf-life till consumption, the composition, and energy content, structure of the food matrix, the appealing sensory properties and acceptability for regular consumption. The food safety of all samples must be guaranteed. All the above listed aspects should be ensured for the commercial product.

For an efficient and timely product development process, experimental (test) and control product samples must be provided in the right quantity, in the right place for all analysis and testing and human intervention studies. To meet these requirements and for avoiding unnecessary costs and delays the number of changes should be kept to a minimum, the need for changes should be identified as early as possible during the product development process, particularly those which influence the stability and uniformity of the concentration and distribution of the bioactive compound throughout the whole shelf-life. This may include changes of the composition, processing, presentation technology, packaging and storage conditions, shelf-life and time of the human interventions studies (Sebők et al. 2016).

A planning tool is provided in Figure 5 on page 20. The main health-claim specific items for product development are the following:

- Market and qualitative consumer research on the consumer appeal of the concept (health claim related to a specific food type). This is a primary gate to pass to the next development stages.
- Identification of appropriate bioactive
    - Clarification of commercial sources
    - Collation of existing research data on bioactive and health impact.
    - Confirmation of food safety and usage approval (e.g. consider requirements of the Novel Foods regulation)
- Characterization of bioactive, collation of specification data. Definition of dosage, in product, per serving and/or per day to comply with required claim
- Definition of draft (manufacturing) process flow and prediction of impact on bio-active. Considerations for formulation.
- Test and control product formulation, with a focus on bioactive levels.
- Food safety assessment/HACCP study of the test and control samples.
- Trials to balance sensory impact and ensure that test and control products are “matched”.

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- Identification, screening and selection of human intervention study (HIS) centre. More details can be found in the PATHWAY-27 Scientific Guidelines.
- Production planning for HIS, focus on volumes (contingency), labelling, timing, shipment and handling. Can the production (volumes) be managed at bench, pilot or factory trial scale. Associated review of production plan.
- Requirement for early-stage scale-up (pilot/factory) to manage HIS volumes. Associated scale-up trials as appropriate.
- Analysis of the bioactive compound content of the test product prior to HIS.
- Final definition of HIS production schedule, process flow and HACCP.
- Production for HIS.
- Stability testing – from samples produced at pilot or ideally factory scale. Focus on safety, sensory quality and bioactive ingredient levels.
- Review of HIS output with reference to required BEF modifications. Re-formulation and possible further HIS as required (looped process).
- Extended factory trials to assess bioactive variability and tolerances.
- Refinement of draft health claim wording.
- Final finished product specification with all raw material/ingredient specifications. Specific reference to bioactive handling and usage.
- Preparation of health claims dossier (More details can be found in the PATHWAY-27 Scientific Guidelines) – collation of all data.

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9. Appendix I. List of organizations and individuals from whom help, information or comments has been received

D. Artloft (Chr. Hansen)

A. Benke (HUNBISCO - Association of Hungarian Confectionery Manufacturers)

A. Christ (Royal Canin)

E. Costa Larrión; (BioiberiCA SAU)

T. Cutcliffe (Nutraingredients)

E. Danckaerts (Flanders' FOOD)

M. Del Duca (DICOFARM SPA)

C. Díaz Morillo (Biosearch Life)

P. Fança-Berthon (Naturex)

L. (Fernandez Celemin) EUFIC

U. Freitas (Lonza Ltd)

C. Gubbiotti (FoodDrinkEurope)

L. Lahteenmaki (Aarhus University)

L. Le Bellego (Danone)

R.; Mensink (Maastricht University)

D. Obis (Danone)

M. Pérez-Haro (Biostatech)

B. Pot (Yakult Europe)

M. Raats; (University of Surrey)

M. Ramirez (Abbott Nutrition)

P. Ronfard (Solactis)

Y. Sanz Herranz (Institute of Agrochemistry and Food Technology (IATA-CSIC))

K. Schebesta (UNIDO)

M.-B. Schmidt Andersen (Pfizer Consumer Healthcare)

C. Shortt (Johnson & Johnson)

E. Simonetti Kamut (Enterprises of Europe)

E. Ana (Sirvent Segura; Biopartner)

S. Stadler (Goldsonne GmbH)

S.Theis (Suedzucker / Beneo Group)

J Türk (Yakult Deutschland GmbH)

S. Valtuena Martinez (EFSA)

S. Van der Made (Newtricious R&D)

K. Venesz (The Healthy Food Development Ltd)

J. Walter (ADM Wild Europe GmbH & Co.KG)

S Dell'Elce (CNA Emilia Romagna)

S. Gamberini (CNA Emilia Romagna)

S. Wiseman (Unilever)

M. Sass (ADM)

A. Goux (Mondelēz International R&D)

A. M. Minihane (University of East Anglia (UEA))

D. Polacek (Redbull)

B. Dezamics (National Food Chain Safety Office of Hungary, NÉBIH)

P. Korányi (SCITEC Kft)

Sz. Horváth (Bonduelle Central Europe Kft.)

Zs. Keserűné Tóth (Alföldi Tej Kft.)

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11. Glossary

BIOACCESSIBILITY. Amount of an ingested nutrient/food component that is potentially available for absorption. It is dependent only on digestion and release from the food matrix**.**
BIOACTIVE COMPOUNDS. A type of chemical found in small amounts in plants and certain foods (such as fruits, vegetables, nuts, oils, and whole grains). Bioactive compounds have actions in the body that may promote good health.
BIOACTIVE. A substance that has an effect on or elicits a response from living tissue.
BIOAVAILABILITY. Amount of an ingested nutrient/food component that is absorbed and available for physiological functions. It is dependent on digestion, release from the food matrix, absorption by intestinal cells, and transport to body cells.
CLAIM. Any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics (Regulation (EC) No. 1924/2006).
FOOD CONSTITUENT/COMPOUND. A nutrient or any substance or combination of nutrients/ other substances
CONTROL PRODUCT. Product that does not provide the bioactive constituent that is being tested, but matches to the dietary properties and sensory properties of the test product as much as possible. Also called placebo.
FOOD SUPPLEMENTS. Foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities (Directive 2002/46/EC).
FUNCTIONALITY. Functionality of a of food/constituent is defined as the physiological effect with beneficial consequences which affect one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease.
HEALTH CLAIM. Any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health" (Regulation (EC) No. 1924/2006).
INGREDIENT: Any of the foods or substances that are combined to make a particular dish.
INTERVENTION. Process or action that is the focus of a clinical study. This can include giving participants drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available .
MOQ (MINIMUM ORDER QUANTITY). The lowest level of product that can be ordered that fits with the manufacturers' capacity, logistics and profitability.

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NOVEL FOOD. Foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories: (a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC; (b) foods and food ingredients produced from, but not containing, genetically modified organisms; (c) foods and food ingredients with a new or intentionally modified primary molecular structure; (d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances. EFSA Guidelines on Novel food and on the required information for the risk assessment: http://www.efsa.europa.eu/en/efsajournal/pub/4594
NUTRIENT. Protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Directive 90/ 496/EEC, and substances which belong to or are components of one of those categories (Regulation (EC) No. 1924/2006).
NUTRITION CLAIM. Any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: (a) the energy (calorific value) it (i) provides, (ii) provides at a reduced or increased rate, (iii) or does not provide; and/or (b) the nutrients or other substances it (i) contains, (ii) contains in reduced or increased proportions, (iii) or does not contain(Regulation (EC) No. 1924/2006).
REDUCTION OF DISEASE RISK CLAIM. Any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease (Regulation (EC) No. 1924/2006).
OTC (MEDICINE. OVER THE COUNTER MEDICINE). Medicines that can be sold without prescription or doctors' recommendation/certification e.g. mainstream analgesics/pain-killers.
TEST PRODUCT: is a food under investigation, which contains the bioactive constituent causing the beneficiary health effect.

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USP (UNIQUE SELLING POINT). The properties of a product that cause it to be different to other comparable products. This can be related to sensory/taste, a nutritional property, the price, aspects of packaging etc.
VALIDATION: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.
VERIFICATION: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

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12. List of abbreviations

AC	Anthocyanins
ACCLAIM	ACcelerated CLAdding and Integrated Machining
ACNFP	Advisory Committee on Novel Foods and Processes
ANCC	Associazione Nazionale Cooperative di Consumatori
ANCD	Associazione Nazionale Cooperative fra Dettaglianti
BG	β-glucan
BOGOFF	Buy One Get One For Free
BRC	British Retail Consortium
CCP	Critical control point
DHA	Docosahexaenoic acid
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FCD	Fédération des Entreprises du Commerce et de la Distribution
FDA	USA Food and Drug Administration
FOSHU	Foods for Specified Health Use
FSANZ	Australia and New Zealand by the bi-national regulator Food Standards Australia New Zealand
GCP	Good Clinical Practice
GHP	Good Hygienic Practice
GLP	Good Laboratory Practice
GMO	Genetically Modified Organisms
HACCP	Hazard Analysis and Critical Control Points
HDE	Handelsverband Deutschland
HIS	Human Intervention Study
HOI	Highest Observed Intake
IPR	Intellectual Property Rights

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ISO	International Organization for Standardization
KOF	Key Opinion Formers
LDL	Low-density lipoprotein
LIS	Large Intervention Study
MOQ	Minimum Order Quantity
MS	Metabolic Syndrome
OSP	Official Selling Price
OTC	Over The Counter
PASSCLAIM	Process for the Assessment of Scientific Support for Claims on Foods
QUID	Quantitative Ingredients Declaration
R+D	Research and Development
SME	Small and medium-sized enterprises
USP	Unique Selling Point
WHO	World Health Organization

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13. Annexes

Annex 1. Labelling requirements: List of mandatory particulars according to Regulation (EC) No 1169/2011, article 9 (Subchapter 6.2.2)

"In accordance with Articles 10 to 35 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory:

(a) the name of the food;

(b) the list of ingredients;

(c) any ingredient or processing aid listed in Annex II of the Regulation - or derived from a substance or product listed in Annex II of the Regulation - causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;

(d) the quantity of certain ingredients or categories of ingredients;

(e) the net quantity of the food;

(f) the date of minimum durability or the 'use by' date;

(g) any special storage conditions and/or conditions of use;

(h) the name or business name and address of the food business operator referred to in Article 8(1);

(i) the country of origin or place of provenance where provided for in Article 26;

(j) instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions;

(k) with respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume;

(l) a nutrition declaration."

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Annex 2. Product development brief (Subchapter 2.2.2)

2. Procedures and general methods for developing products with health claims

2.2.2 Setting the target- product development brief

The product development brief is an internal document for all contributors, where the targets and required outcomes of the development activities are specified before any detailed, experimental, technical, research work is implemented. It specifies the key acceptance criteria of the outcomes of the product developed including technical criteria, proven health effect, legality, handling and storage requirements, labelling, targeted consumers, marketability, competitive products and benchmarks, cost and price constraints and targets, time scale, etc. It helps mutual understanding between the representatives of different disciplines, including the external knowledge providers, service and material suppliers. It provides an agreed base for the whole R&D process and a common reference document for all modifications, which may be necessary during the progress of the work. All participants must understand and accept the brief. The brief should be flexible as the company will review it regularly due to the changes of the market (Campden & Chorleywood, 2007).

Annex 3. General aspects for screening feasibility of all new food products (Subchapter 2.2.5)

2.2.5 General aspects for screening feasibility of all new food products

During the feasibility study the company needs to gather information and perform analysis to assess whether it is worthwhile and realistically manageable to carry out the product development process.

1. Technical feasibility assessment
    - Is there a need for a specific packaging solution? Is it available?
    - Is it realistically anticipated that samples having the required properties can be produced with the available or accessible technologies and equipment?
    - Are the produced samples microbiologically and chemically safe and stable over the required shelf life?
    - Can the product be processed with the existing machinery and technology?
    - Can the food safety of the planned product be ensured with the planned composition, ingredients and processing steps?
    - Are the properties of the new ingredients and the commercialised products compatible with food safety requirements (including food allergens, contaminations) of the production environment of the existing products?
    - Are the experimental samples compatible with the food safety requirements of the production environment of the existing products?
    - Is there a food manufacturer for whom the production of the product and/or the sample can be outsourced?

    Further considerations:
    - All experimental samples should have a HACCP plan.

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- Proper segregation of experimental production from standard products to avoid cross contamination.
- Availability of pilot size equipment to produce small scale samples.
- Maintaining high risk areas during experimental production in case of high-risk products.
- Consequences of introducing a new allergen into the production facility- gluten, egg, milk, etc.
- Necessary controls for ensuring safety of ingredients (specifications, food safety declaration etc.).
- Safety of samples potentially produced at non-food grade / not approved research / university laboratories-potential of chemical and microbiological cross-contamination.

2. Marketplace feasibility assessment

The following checklist supports the evaluation of the marketability of the products developed.

- What are the critical attributes of the new products and are they likely to be met to achieve competitive advantage in the market?
- Does this offer sufficient strength and confidence in success?

Sales/ Trade assessment

- Is there a market for the product?
- What is the budget for a marketing support programme? Will this provide enough support to the product to overcome the initial launch/ lag phase?
- What options are there for targeted launch period? What are the restrictions: are there any alternatives or the date an imperative?
- Has the company suitable sales and distribution networks for the product type?

3. Financial feasibility assessment

- How much more are people likely to pay for the product?
- Expected sales volumes.
- Can the product be produced profitably? Will the targeted retail selling price bring the expected profit margin?
- How flexible is the target retail selling price? Can it be increased if the costs are higher than expected or if they are increasing to avoid eroding margins considering the competitor products?
- Is capital expenditure required? If so, what is the expected payback time?
- Is there any feasible source for the investment?

The financial assessment is based on the prime cost which is the combination of the cost of the recipe, the packaging material and labour cost compared to the target retail selling price. Furthermore, the prime cost increases because adding the margin required by the company and the retailer.

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SEVENTH FRAMEWORK PROGRAMME

The development of the brief often goes in parallel with sample preparation as it is difficult to assess the feasibility of an abstract idea (Campden & Chorleywood, 2007).

Annex 4. Planning and project management (Subchapter 2.2.6)

2.2.6 Planning and project management

After having an established brief and the viability and feasibility of the new product has been examined, it is necessary to identify the resources which are required, and ensure that they are available within the company. The gaps in resources should be identified and the potential of involving external resources to fill in the gaps – e.g. third party experts – have to be considered.The following checklist includes the typical, necessary resources (technical and financial), but additional resources may be necessary depending on the nature of the product:

- Staff: Is the staff member qualified and experienced to cover all aspects of product development? Do they have available time for this or are they bound to other tasks? Is all the necessary competence available in-house or within the organisations cooperating on the project, or is it necessary to involve external support? Typical areas, which have to be considered whether external support is necessary: checking compliance to health claims legislation and labelling, including the context of the marketing messages to consumers, laboratory testing for the characterisation of the food/constituent and providing information on the availability of the active constituent in all batches, carrying out human studies for the substantiation, statistical aspects of the human studies and data evaluation, preparation of the dossier.
- Capital expenditure: Is new machinery or factory expenditure required? Is the capital likely to be available?
- External support for the production.
- Factory labour capacity: will extra labour or shift be required?
- Factory storage capacity: Is there enough storage space for new/old raw material and the finished products?
- Consumables: the cost of materials and the packaging should be calculated.
- Consumer and market research: In general, a third party is involved and this task has a significant cost.
- Other project resources needed: e.g. training, education, computer capacity (Campden & Chorleywood, 2007).

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Annex 5. Steps from prototype development to scaling-up to factory level (Subchapter 2.2.7)

2.2.7 Steps from prototype development to scaling-up to factory level

Since tasting of the samples is necessary for the evaluation of the product, therefore a HACCP based food safety study is necessary to ensure the safety of the sensory evaluators and consumers.

Small scale bench work- prototype development

The aim of the small scale bench work is to determine the proper formulation to screen alternative product versions for physico-chemical and sensory properties establish all parameters of the new product and confirm that it can be produced in a reproducible and a cost effective way. Samples from this stage can be used as benchmarks in the next steps. The feasibility and viability of the product should also be reviewed.

During the activities from small scale bench work up until factory trials the information has to be collected, evaluated, revised and adjusted systematically for the finished product specification and also with regard to ingredient specifications, recipe, and product properties, variability of the concentration of the constituent within a batch and between batches and the stability of the constituent during shelf life, cause- effect relationship, food safety and HACCP, processability, costs and consumer acceptance.

Pilot scale work

During the pilot scale work, batch sized products are produced with similar type of equipment or sometimes with the same equipment and process as that which will be used in full-scale commercial production. At this stage the processability of the product can be evaluated. The sensory characteristics, microbiological and chemical composition, physical parameters, shelf-life and the HACCP study of the test and the control products defined at small scale bench work should be confirmed. It should be verified that the test product match the control product for the samples to be provided for the human intervention studies.

The product properties have to be compared with the draft specification for compliance, particularly the chemical, microbiological parameters, weight, physical parameters of the products and sensory properties.

A formal written specification (including that of the packaging and process) is needed when the factory scale trial stage has been reached. It will outline the requirements and the limitations of the ingredients/finished products and allow identification of any gaps in the available information. It is also a good way to avoid misunderstandings and provide helpful information to the suppliers/food manufacturers and the food manufacturers/consumers of the food product.

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Process specification

- process description
  - description of process steps;
  - performance criteria (F_o for sterilized products, P for pasteurized products, uniformity of composition, weight, - target and tolerance etc.);
  - batch size, if relevant;
  - process parameters (time, temperature, pressure etc.): target and acceptance limits;
  - method of monitoring of the key parameters, frequency, responsibilities;
  - actions at deviations, responsibilities;
  - validation, verification.
- HACCP summary
  - CCPs /and CPS, identification, descriptions;
  - critical limits;
  - method of monitoring, frequency, responsibilities;
  - corrective actions, responsibilities.

The process control measures, which have to be applied for ensuring low variability within batches and between batches typically include the following elements:

1. Designing the performance criteria
   a. Defining what has to be achieved at this step considering food safety, quality, legality and uniform composition and properties
   b. Defining the control process for each step.
2. Identifying the key control points, where parameters influencing the concentration of the bioactive constituent, the structure of the food and composition, legality, food safety hazards and quality attributes can be and need to be controlled (key control points and CCPs). These controls must be in place permanently.
3. Identification of the key process parameters (target values and acceptance/critical limits).
4. At the selected key control points establishing a monitoring system, based on frequent checks or continuous measurements, observations. The results of the monitoring have to be recorded. The monitoring activities, their frequency and responsibilities have to be defined.
5. Establishing corrective actions, which have to be implemented at deviations. The actions and responsibilities have to be defined and the actions taken have to be recorded.
6. Verification and validation of the process performance. This can be made by reviewing of the process control data and by testing the key product parameters and attributes such as concentration of the bioactive compound, by measuring the value of the parameters of the key process steps ensuring food safety, microbiological testing, sensory evaluation etc.

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SEVENTH FRAMEWORK PROGRAMME

During the pilot scale trial the yield, the losses and the packaging material have to be measured and assessed and an estimated cost of the production and overall costs has to be calculated. Packaging trials should be conducted. It should be verified that the test product matches the control product for the samples to be provided for the human intervention studies.

Factory scale production trials

The aim of this stage is to be able to produce food products on a larger scale reproducibly to verify that the required concentration of the bioactive compound causing the beneficial health effect can be consistently ensured within a batch and between different batches.
The complete final version of the product should be delivered consistently at the appropriate cost and right quality. Usually a series of factory scale production trials is carried out and each one is built upon the previous one. All staff responsible for the production should be involved in these trials.

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Table 2 summarizes the 3 product development stages.

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Table 2: Checklists for the stages of product development general aspects (modified from Campden & Chorleywood, 2007)

	Small scale production	Pilot scale production	Factory scale trials
Ingredients		The company has to gather the specifications of ingredients with a clear indication to the price.	Specifications and health and safety data sheets should be gathered and submitted to the quality control management.
Recipe	Is the recipe compliant with target markets?	The recipe has to be presented in a clear format to every relevant person.	If the recipe was modified during the pilot-scale trials, the modifications should be included into the final recipe and it should have another reference code.
	Does it satisfy the compositional standards?	Each individual recipe has to be coded or numbered to avoid any confusion between preliminary and later trials. It is worthwhile to reconfirm the whole recipe.	
Manufacturing	Document all process parameters (e.g. time, temperature).	It is needed to provide specification for the product and the process.	Product specifications with appropriate targets and limits.
	Outline new equipment/capital investments.	The plant requirements also have to be provided.	Process specification.
	Manufacturing requirements of the new product		Plant/new plant.
Product assessment	Performing an objective sensory analysis to get a description of the product to be able to compare with the original idea or the specification.	Perform a sensory analysis to compare the small scale samples with pilot scale samples.	After the final version of recipe has reached the sensory attribute acceptance ranges have to be set down in terms of which batches of product can be rejected or accepted.

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	Considerations for the HACCP plan assessment.	Comparing the proposed microbiological specification with the results of the microbiological tests performed during the pilot scale work.	Microbiological specification also required with criteria for acceptance and rejection.
	Shelf-life determination (real-time or prediction) - Stability tests; microbiological tests and check the relevant food law in the different countries if it is necessary.	Confirm the initially predicted shelf life of the product by comparing the data with the results of the pilot- scale data.	Provisional shelf-life should be available from earlier work, though production samples may also be subjected to testing for final confirmation.
Product costs	Manufacturing cost: costs for packaging material and possible new machinery. Process of the constituent	Assessing the costs for packaging material and any new capital expenditure. Preparing an accurate assessment of manufacturing overheads with establishing process and packaging requirements. Estimate the **losses** of products and packaging. **Total cost** should be compared with potential sales volume and proposed selling price to confirm the financial viability of the project	**Total final cost** should be confirmed including the cost for materials, packaging, and overheads.

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Packaging	The suitability of the proposed product packaging should be confirmed and during the consumer studies the packaging also should be evaluated.	Provide a packaging specification. Perform trials to check the usability of the packaging with and without the actual product.	The final packaging assessments should be taken place.

Product, process, packaging and labelling approval

During the product development process the actual versions of product specifications have to be revised following the changes and approved.

Market introduction

The development of the marketing strategy starts with identifying the consumers' needs and providing products or services that satisfy this demand.

Annex 6. Requirements on food contact materials (Subchapter 2.2.4 and 2.2.8)

Regulation (EC) No. 1935/2004 – materials and articles intended to come into contact with food

Related to effects of the packaging on the food product certain requirements are stated in Regulation 1935/2004. Article 3 sets general requirements for "materials and articles, including active and intelligent materials and articles which come, or may come, into contact with food, either directly or indirectly to be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

a) endanger human health;

b) bring about an unacceptable change in the composition of the food;

c) bring about a deterioration in the organoleptic characteristics thereof."

Article 16 sets the principles and requirements for a Declaration of Conformity each food operator and packaging producer has to obey:

"Materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to

the competent authorities on demand. In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for declarations of compliance for materials and articles."

A food business operator has the responsibility to use only packaging material, which is suitable for the intended use.

Annex 7. Food safety and hygiene related regulations

White Paper on Food Safety issued by the European Commission
URL: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l32041

Recommended International Code of Practice – General Principles of Food Hygiene issued by Codex Alimentarius Committee of Food Hygiene by FAO/WHO.

URL: http://www.fao.org/docrep/w8088e/w8088e04.htm

(EC) No 178/2002- Food and feed safety
URL: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:f80501&from=EN

(EC) No 852/2004- Regulation on the hygiene of foodstuffs.
URL: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2004:226:FULL&from=EN

(EC) No 853/2004- Regulation laying down specific hygiene rules for on the hygiene of foodstuffs.
URL:http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0055:0205:en:PDF

(EC) No 854/2004- Regulation laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0083:0127:EN:PDF

(EC) No 882/2004- Official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
URL: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:f84005&from=EN

(EC) No 2073/2005- Regulation on microbiological criteria for foodstuffs
URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:338:0001:0026:EN:PDF

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SEVENTH FRAMEWORK PROGRAMME

Annex 8. Ensuring food safety (Subchapter 2.3.2)

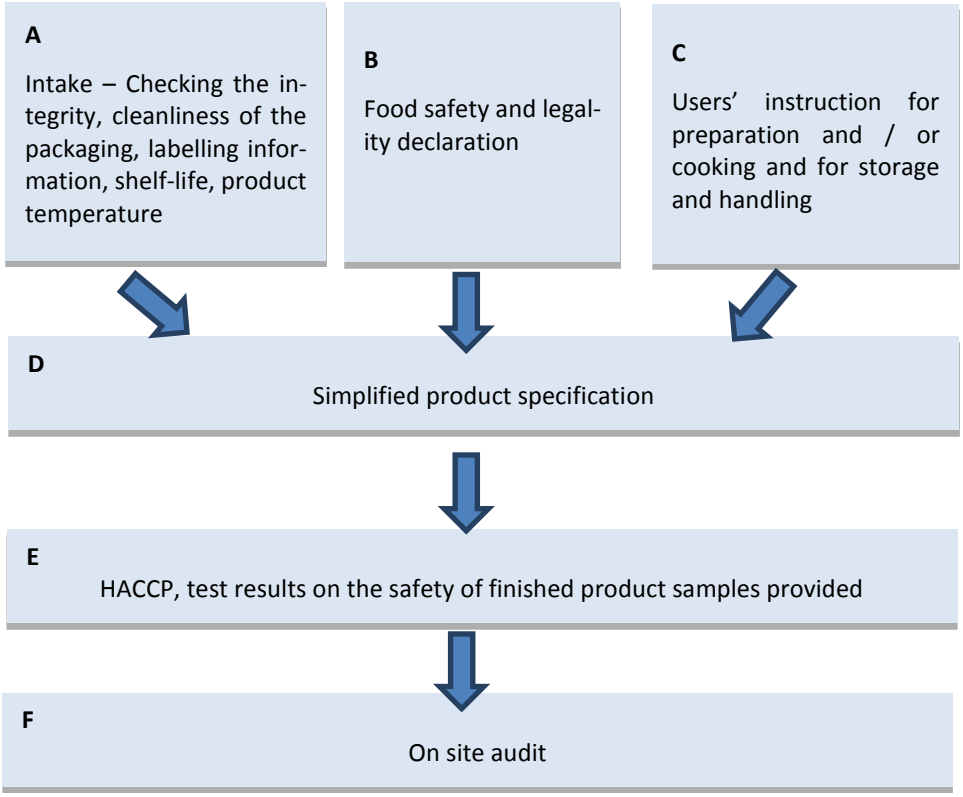
2.3 Ensuring food safety

2.3.2 Safety of experimental products (for sensory and consumer testing) for all new product development

For experimental products a HACCP study shall be carried out by the manufacturer. This is the responsibility of the manufacturer, who is the provider of the test product.

The same approach should be used by the manufacturer of the test product for any ingredient, packaging materials used for the production of the test or control product and for provision of the reference samples/benchmarks. The compliance of the test and control product to food safety requirements should be checked at receipt by the users. The product provided for sensory assessment within a project can be a commercial food product (e.g. as benchmark product) or an experimental product.

The different types of products should be assigned a risk level, based upon a consideration of its source. Subsequent actions must be undertaken according to the following protocol as illustrated below in Figure 9.



Note: the higher the risk, the compliance to more requirements should be complied with

Figure 9. The hierarchy of the precautions to ensure the food safety of samples received

For products received the following information should be checked to assess compliance to food safety requirements (Figure 10):

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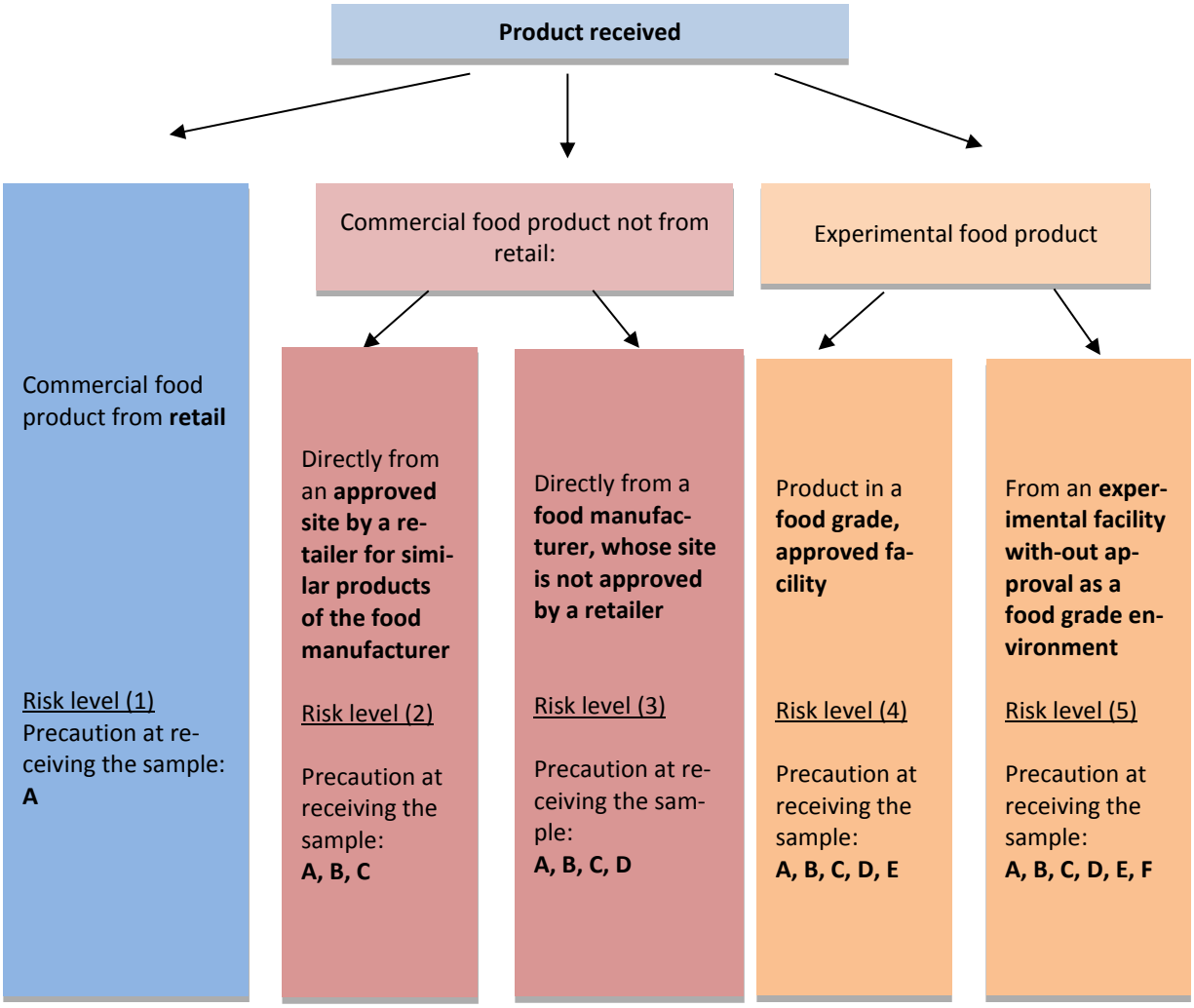

Figure 10. The origin of received samples and related risks together with precautions, which are necessary to control hazards

For samples received the information described below should be checked to assess food safety compliance:

Requirements for food product purchased/collected from retail

Intake checks (Requirement A)

Food products purchased/collected from retail are assumed as safe. At the purchasing/receipt of the product the integrity and cleanliness of the packaging, the legibility/visibility of labelling information, the shelf-life, and for chilled or frozen products the temperature of the product should be checked and recorded.

If the product contains allergens or genetically modified organisms (GMOs) the consumers/testers/volunteers should be informed.

During the preparation of the sample for consumption the user instructions provided on the packaging should be followed.

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Requirements for a commercial food product not collected from a retailer

Food products - which are not on the market yet, but are produced at a site approved by a retailer, a retailer branded product which is the same as/or similar to the current food products - represent a relatively low risk.

In addition to the intake checks (requirement A) a food safety and legality declaration shall be requested/provided with the product.

Food safety and legality declaration (requirement B)
The food safety and legality declaration should contain the following:

- a statement, that the products are fit for human food consumption;
- a statement, that the manufacturer implements and maintains a food safety management system based on the HACCP principles and this is applied for the production of the product;
- a statement of compliance to all relevant European and national food regulations related to the food product;
- GMO warranty statement (concerning the absence of GMO, or GMOs in a proportion no higher than 0.9%, or GMO content);
- declaration of allergens (concerning the absence of allergens, or list of the allergens in accordance with the current legislation).

Preparation, storage and handling instruction (requirement C)
Clear, simple, tested user instructions should be provided for the preparation of the food product for consumption and followed by the organisation carrying out the consumers and sensory tests as well as by volunteers participating in the intervention studies. Furthermore, storage and handling instructions should be provided and followed for the food product sample.

Requirements for products from a food manufacturer, whose site is food grade, but not approved by a retailer or its supplier

The requirements for intake checks (requirement A), food safety and legality declaration (requirement B), and user instructions (requirement C) should be applied.

In addition a simplified product specification should be requested from/provided by the supplier of the product.

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Simplified product specification (requirement D)

The simplified product specification should contain at least the following information:

- values of the level of/absence of microbiological contaminants to a specified limit;
- values on the level of/absence of chemical contaminants to a specified limit;
- list of the allergens in accordance with the current legislation;
- GMOs (absence or labelling);
- list of ingredients;
- packaging materials and short description of the packaging;
- reworked materials (if any);
- required conditions (temperature and / or relative humidity, if applicable) of the transportation and the storage;
- shelf life of the product;
- user instructions for preparation.

The simplified product specification should be up-to-date, unambiguous, and should comply with the legislation and should comply with the requirements of the client (who arranged the experimental work).

If the supplier does not list the quantity of ingredients referring to confidentiality, then the listing of the ingredients in descending order as a minimum is required for every product.

Requirements for experimental products

Experimental products can be produced in an approved food grade facility or in experimental facilities (research laboratories, testing facilities, and pilots) not approved for food production.

Requirements for experimental products from a food grade production facility approved for food production

Requirements for intake checks (requirement A), food safety and legality declarations (requirement B), users' instructions (requirement C) and simplified specification (requirement D) should be applied.

Specific attention should be paid on the adaptation/application of the HACCP system of the product provider on the specific product and on all information necessary to inform the consumers (allergen, GMO, ethical issues).

This should be provided by the manufacturer/provider of the product. In addition to that test results should be provided on the food safety compliance of the product.

Test results on the food safety compliance of the product (requirement E)

Test results should be provided on the compliance to food safety requirements of the products (microbiological and chemical, as necessary) in line with the key parameters described in the simplified product specifications.

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Requirements for experimental products produced in an experimental facility without approval as a food grade environment

Requirements for intake checks (A), food safety and legality declaration (B), users instruction (requirement C), simplified product specification (requirement D), test results on the safety of finished product samples provided (requirement E) should be applied.

In addition to this an onsite audit of the experimental site/facility may be necessary.

On site audit of a non-food grade experimental facility (Requirement F)

When an experimental product is developed / produced by a research partner at its experimental facility (research laboratory, university laboratory, multi-purpose pilot plant, etc.) not approved as food grade, this type of experimental site should be audited before the provision of experimental samples for sensory, consumer testing, consumption during clinical studies. The audit should be carried out by a registered IFS (International Food Standard) or BRC (British Retail Consortium) standard auditor (or a registered auditor of another appropriate commercial food safety management standard approved by the Global Food Safety Initiative (GFSI).

During these type of audits it should be confirmed that the products are produced under such specific circumstances, which guarantees the food safety. For auditing the experimental facility the checklist developed by CBHU and tested with University of Bologna in the NAMASTE project (2013) or any other equivalent checklist developed on the basis of an acknowledged food safety standard by the GFSI should be used.

The findings of the on-site audit should be documented by the auditor in a report. The report should be signed by both parties (by the auditor and by the auditee). The report should be sent to the responsible manager of the organisation carrying out the consumer/sensory /clinical tests, where the sensory assessment will be carried out. The sensory assessment should be carried out only after the facility, including the experimental facility of the product supplier, had been approved in advance by the auditor.

Traceability, transparency

Traceability of food products is a mandatory requirement within the EU. As a minimum the appropriate identification of the finished product must be ensured, which enables traceability and effective recall. Appropriate records have to be kept about the receipt and supplier of all ingredients and packaging materials, which is the basis of their traceability. The private food safety and quality management standards of the retailers (BRC, IFS) are more comprehensive than the legal minimum; they require full traceability from the finished product back to the raw material, ingredients, packaging materials and production and distribution records and vica-versa from raw materials to finished product.

By linking appropriate content to the traceability, there can be transparency about the validity of the claims that can be applied for prevention of food fraud.

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Annex 9. Recommended methods for Sensory and consumer testing (Subchapter 2.4)

The aim of this chapter is to present some of the methods related to sensory and consumer testing, but not in detail, only highlighting those points which are useful for the industry to choose. A successful product with claims should support health and be appealing and have a good taste as well.

Sensory evaluation

Sensory testing can be used for assessing product quality and for discrimination or detailed description of food products. All methods require a controlled environment and a specific number of trained assessors. Consumer testing collects subjective responses of consumers to products / prototypes, and consumer behaviour, etc., and can also provide assistance in brand positioning, communication and advertising. The general requirements of sensory and consumer tests are established in ISO standards.

Difference tests

Difference tests are the simplest and very effective method of product testing.

These tests are carried out with trained assessors to determine:

- if one sample is different from another- *Overall difference tests*
- whether or not a difference in some specific attribute exists between two samples- *Attribute difference test*

Difference tests can be applied for: routine quality control; monitoring the effects of changes in the product or the process (e.g. effect of ingredient substitution, process modifications, and changes in raw material suppliers). These tests are often used as the first step in a more complex sensory evaluation, where a difference between samples indicates the need for further testing. However, the methods cannot be used to determine the extent of the difference between the samples.

A triangle test is suitable for identifying differences and determining the degree of similarities. Three number-coded samples are presented simultaneously. The assessors are asked to identify which sample is the odd one out of the three. There are six possible combinations in which the samples ‘A’ and ‘B’ can be presented in triad:

AAB	ABA	ABB
BBA	BAB	BAA

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Use each possible presentation order in an equal number of times to have a balanced presentation order. Questions about the degree of difference, acceptance after the initial selection of the odd sample may cause bias, so it is not advisable to ask these types of questions, only in separate tests. A comments section asking why the choice was made may be included for the assessors' remarks.

Table 3 General considerations for triangle test - testing for differences (Kilcast, 2010b)

Time to set up	Time to conduct	No. of assessors (No. of highly trained assessors)	Assessors experience
Low	Low	24 (18)	Low

It also can be used to determine the degree of similarity between the products. The number of assessors, when testing for no meaningful difference (similarity), requires twice as many assessors (i.e. approximately 60) as the difference test (to achieve the same sensitivity). (Table 3)

Triangle test is applicable:

- if the nature of the difference between the samples is unknown. It does not determine the size or the direction of the difference. The attribute(s) responsible for the difference is not identified.
- if the products are homogeneous
- in case of an ingredient / process step or packaging is changed in the product

Example for Attribute Difference test- Ranking test (ISO 8587:2006)

The ranking helps to compare several samples / prototypes according to a specific attribute. This method can provide assistance in cases when we want to compare the effect of the different ingredients or their different levels on a specific attribute (e.g. effect of sweeteners on sweet taste). According to the test procedures the assessors are provided with 3 or more coded samples and directed to rank them in order according to a specific attribute. The reasonable maximum number of the simultaneously presented samples is 5 to avoid fatigue. The order of the sample presentation should be balanced, this way each sample is assessed in every position an equal number of times. It is recommended to use not less than 10 assessors for a ranking test and the discrimination is much improved if 20 or more assessors can be used (Table 4).

Table 4 General considerations for ranking test (Kilcast, 2010b)

Time to set up	Time to conduct	No. of assessors (No. of highly trained assessors)	Assessors experience
Low	Low	30 (5)	Low

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Descriptive Analysis (ISO 6658:2005, ISO 13299:2003)

In sensory descriptive testing, trained assessors collect the main attributes of the presented product(s), and then use these descriptors to quantify the differences between the samples. Descriptive tests can be applied for defining the sensory properties of a sample from new product development and their competitor products, also determining products' attributes, to understand or compare the effect of a change in the product or in the manufacturing process (e.g. ingredients, temperature) on the sensory characteristics of the product, tracking the changes of properties over time (e.g.: shelf life test) and mapping products' sensory attributes in relation to instrumental, chemical or physical properties.

A 'descriptive panel' is made up of 8-12 highly trained assessors recruited and trained in compliance to ISO standards (ISO 8986:12, Kilcast, D., 2010a). The sensory assessors first generate attributes through training with the relevant samples. Key attributes with their definitions are selected and organised into attribute groups required (appearance, odour, flavour, texture and mouthfeel) and agreed by the whole panel. The assessors evaluate each attribute on an intensity scale. Figure 11 shows the graphical presentation of a sensory profile.

In case of descriptive methods, continuous monitoring of panel performance is needed in order to ensure a high level of competence of the assessors. The free PanelCheck software provides a user friendly and quick way for the evaluation of panel performance: (http://www.panelcheck.com/).

Methods for consumer testing

Methods to explore consumer opinion and measure liking of the product from product development:

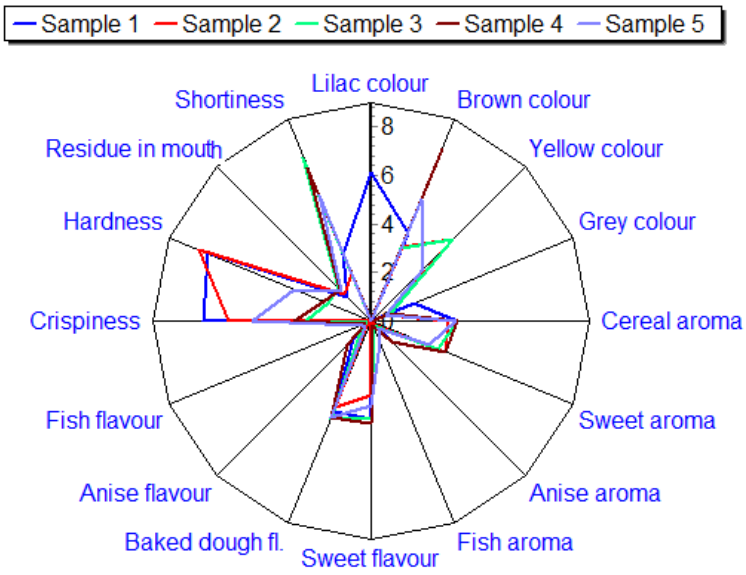

Figure 11. Sensory profile of different biscuit prototypes

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Hedonic tests are applied to compare liking levels of the new product with the benchmark products, most frequently to determine the eating enjoyment, to evaluate the effect of the change of formulation on the eating enjoyment and assist in the optimisation of sensory attributes, and to determine the best before date of the product from the consumers' perspective.

There are two main groups of hedonic test involving consumers according to ISO 11136:2014 standard.

- Acceptability tests are used to measure the intensity of the enjoyment at consumption. The most frequently used test type is the rating test.
- Different tests can be applied to determine consumers' preference:
  - if one sample is preferred to another- *Paired comparison test,*
  - if there is a rank in preference between the samples when dealing with more than two samples- *Ranking for preference.*

It needs to be emphasized that the information gained through preference test is relative. It does not give information about the acceptability of the product. It is possible that a consumer does not accept the product, but can make a distinction of preference behaviour.

The calculation of the sample size is dependent on the required precision of the test as described in ISO 11136:2014. Consumer sample conforming to this standard shall never be less than 60. Where no information is required for the calculation of the sample size, the ISO 11136:2014 fixes the minimum sample size at 100.

Safety, health and ethical aspects of the sensory and consumer tests

During the sensory and consumer tests all procedures should be carried out in a way that minimizes the risk on the health of participants.

The ACNFP (Advisory Committee on Novel Foods and Processes, 2002) is of the opinion that, in general, there is no need for protocols for taste trials to be referred to for consideration provided that certain conditions are met:

(1) "Those carrying out the trial are satisfied, after taking suitable professional advice, that it poses no hazard to human health"; (2.) "The protocol for the taste trial had been referred to, and cleared by, an independent Ethics Committee"; (3) "Appropriate records are kept".

To meet these conditions the following steps need to be taken:

- To carry out a risk assessment of the products / food ingredients produced with active constituents at experimental facilities.
- An Ethics Committee needs to evaluate the consequences of participation in the trial, in the context of the welfare of the subject and the objectives of the investigation. The committee consists of people who have technical competence, knowledge of the national legislation of the countries involved (at least one national representative), and

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can make an informed judgment. However, the Committees also need to accommodate respected lay opinion so as to provide effective representation of community, as well as scientific interests. Similar considerations are applicable as for the human studies.

- The participants need to be informed about the tests on non-standard food products (e.g.: ingredients are not consumed normally the samples are not from standard products, food stored under not standard conditions etc.) and should be allowed to withdraw from the panel at any time without giving reasons.
- The people conducting the test / working with the food received adequate training in food hygiene.

Records are kept on the conduct of, and results from taste trials and include the names and particulars of the individuals involved, including their health status, and also details of the food involved in the trial. All personal data are treated confidentially according to the relevant data protection legislation of the country concerned.

Annex 10. Determination of shelf life (Subchapter 2.4)

2.4 Determination of shelf life

The shelf life depends on the nature of the food itself, and the preservation treatments to which it has been subjected. The type of packaging used to contain the food will also have an inherent effect. It is up to the manufacturer of the food to determine and assign the shelf life of the food, keeping in mind the requirements of relevant legislation (Betts, G. et al., 2014).

For quality issues the opinion of the consumer can be very important. If the quality is poor in their eyes before the end of the stated shelf-life, then complaints are likely to be made, and/or the product will not be purchased subsequently (Betts, et al., 2014).

Several factors influence the shelf life of a product:

- raw materials;
- hygiene;
- product formulation;
- intrinsic properties of the product, such as salt content, water activity, pH, preservatives;
- processing steps and parameters;
- storage, temperature, humidity;
- packaging, including gas atmosphere, oxygen content;
- distribution time and temperature;
- consumer handling.

Intrinsic factors and extrinsic factors influencing shelf-life

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Intrinsic factors - the characteristics of the food itself

THE NATURE AND QUALITY OF THE RAW MATERIALS, INGREDIENTS, CONSTITUENTS, BIOACTIVES

The stability of the constituent has to be monitored during the shelf life and the degradation curve of the compound determined. It is essential to be able to define the targeted shelf life.

Good quality raw materials with low numbers of microorganisms present should result in products with a consistently acceptable shelf-life. If there is the potential for raw materials to sometimes be heavily contaminated, this needs to be accounted for during processing, e.g. extra washing of plant material when harvested in wet conditions, to achieve the same and consistent shelf-life. If the numbers of spoilage microorganisms or pathogens are highly variable this may impact on the process and consequently shelf-life. In this case consider setting microbiological limits (specifications) on raw materials.

The stability of the constituent/bioactive should be measured during the processing and storage as to whether the beneficial health effects have changed or not.

PRODUCT FORMULATION INCLUDING THE USE OF PRESERVATIVES

Note that mould and bacterial spoilage can be inhibited or slowed down by removing moisture, but they may survive. It is also important to realise that substitution or removal of ingredients legal requirements or guidelines may allow the growth of microorganisms where previously these were inhibited e.g. sugar replaced by artificial sweeteners, changing the type of acid used, removal of nitrates and salt from processed meats, etc.

PRODUCT STRUCTURE

While liquids and semi-solid foods will usually have a homogeneous composition, many ready-to-eat foods do not. Moisture and flavours will migrate between layers, and coatings and surface treatments will restrict or enhance the spoilage potential. The product structure may have impact on the bioavailability.

OXYGEN AVAILABILITY AND REDOX POTENTIAL WITHIN THE FOOD

This can have a major effect on which spoilage and pathogenic microorganisms will grow on the food. This also impacts on oxidation-reduction reactions which cause rancidity, loss of vitamins, browning, and flavour changes. Moulds need oxygen to grow and so are usually found on food surfaces.

External factors (i.e. extrinsic) to the food

PROCESSES APPLIED TO THE FOOD

The impact of technology should be investigated on the stability of the constituent/bioactive. While canning processes can be used to inactivate the most heat-resistant organisms, milder heat processes will inactivate only some bacteria and a proportion will survive. The more there are in the raw materials, the greater the number of bacteria that will survive and shorten shelf-life. The more intense the process, the longer the shelf-life generally.

TYPE OF PACKAGING INCLUDING THE GASEOUS ENVIRONMENT

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Packaging will have a primary role of protecting a food after processing but may also be used to extend the shelf-life. However if the gaseous environment is changed e.g. vacuum packing or gas flushing, this will favour the growth of certain pathogens and spoilage bacteria, while inhibiting the growth of microorganisms that require oxygen (including moulds). Also specific attention should be made to psychrotrophic pathogens, pathogens which may grow at low temperature of the cold chain.

STORAGE TEMPERATURE I.E. AMBIENT, CHILLED OR FROZEN

While frozen storage will stop the growth of microorganisms, there are a few pathogens and spoilage microorganisms, that chilling would still permit to grow slowly. A number of spoilage microorganisms and some important pathogens will actively grow as they are psychrotrophic (cold-tolerant), although their growth will usually be slower than would occur during ambient storage (IFTS, 1993)

Table 5. Psychrotrophic microorganisms (Campden & Chorleywood, 2004)

Micro-organism	Minimum growth temp. (°C)	Heat resistance temp. (°C)
Salmonella	5,2	62,8
Staphylococcus aureus	4 7	62
Bacillus cereus (spores/heat resistant)	4	85
Clostridium botulinum:		
proteolytic A, B, F	10	121
non-proteolytic B, E, F	3,3	
	3	80
Listeria monocytogenes	-0,4	62
Escherichia coli	ca. 7-8	56
Clostridium perfringens	12	121
Vibrio parahaemolyticus	5	70
Yersinia enterocolitica	-1,3	60
Aeromonas hydrophila	-0,1	51
Psychrotrophic spoilage organisms		
Pseudomonas	0	60
Lactic acid bacteria	4	70
Micrococci		
Yeasts	-3,4	60
Moulds	-12	93

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CONDITIONS DURING DISTRIBUTION, STORAGE, RETAIL DISPLAY AND STORAGE BY THE CONSUMER

At any point in the product's shelf-life, it may be exposed to conditions that will lead to the food showing signs of deterioration and a shortened shelf-life. These conditions influencing the stability of the bioactive constituent include elevated or fluctuating temperatures, U.V. light, high humidity, freezer burn, etc. For the consumers unequivocal instructions should be provided.

The vulnerable point is the delivery of the product from retail to household by consumers (Campden &Chorleywood 2007; Food Safety Authority of Ireland 2011).

The proper establishment of the shelf-life is very important. If it is too short then the manufacturing costs may be high and the profit margins may be low. Also, there might be significant wastage of a good product, disposed of in the belief that it is no longer fit for consumption. If it is too long then there is the potential for food quality to become poor or unacceptable or for the growth of food pathogens to occur - and the product will not meet the requirements of food safety legislation. It is therefore important to assign the shelf-life in a systematic and scientific manner, taking all relevant factors into consideration (Betts, G. et al., 2014).

Recommended practices for shelf life testing

Evaluation of shelf-life is also important when products are reformulated; for example, minor changes in product reformulation can have a major impact on growth of microorganisms, or on product texture and stability. (Betts et al., 2014) Any product formulation change should trigger a re-evaluation of the product's shelf life. If any parameter of the product, the processes change during the product development, the validity of the former shelf-life results must be verified, the test has to be repeated! The consequences of these changes on the content of the bioactive constituent, sensory and other properties, food safety can be assessed reliably only if the shelf-life tests were made on the same product, in the same packaging, processed with the same technology.

Before the start of the shelf-life evaluation, HACCP analysis has to be carried out to identify and highlight the critical factors affecting the safe shelf-life. The safety of the sensory assessors involved in the testing of the shelf-life is a pre-requisite. Therefore the safety of samples must be verified before they are tested. This needs specific attention for the shelf-life studies of perishable foods, where pathogens may grow in the product during storage.

The number of test occasions depends on the target shelf-life of the product. Sampling should be carried out at the beginning of shelf life, at the end of the target shelf life and at least 3 occasions in between. For instance with 2-5 days target-life, the product should be tested every day, while less perishable products may require twice weekly, or weekly or monthly testing intervals. It is good practice to have one additional test date which is 30% beyond the target shelf life. For temperature sensitive constituents, like bioactives it is a good practice to carry out tests at optimal and higher temperatures. Testing at optimal and higher temperatures will indicate the impact of the deviation from the optimal storage temperature.

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In any case, parallel samples (at least two, with three recommended) have to be stored and processed at each point of analysis. With increasing number of parallel sample, there is increased statistical reliability is.

The product should be stored at the specified storage temperature. For those products, which need to maintain cold chain during their storage and handling it is good practice to carry out additional tests to check the impact of the temperature abuse. For these tests the usual practice is to store the product for 2/3 and 1/3 of the time at the required temperature and store it after these periods for 1/3 and 2/3 of the time at eliminated temperature of the potential abuse.

Some of the tests for monitoring the shelf life (mostly sensory and microbiological ones) can be made more frequently to detect and better understand the possible changes in time.

The usual storage temperature for chilled, processed products is +3°C to + 8°C, depending on the national legislation and practice applied in the country, for frozen products it is -18°C.

Additional information can be gained for determination of the shelf-life:

- a thorough evaluation of the shelf-life of similar products already being produced.
- the use of predictive microbiological models for predicting when microbial growth (pathogens and spoilage organisms) might reach a critical level and render the product unacceptable (Betts et al. 2014).
- forced storage e.g. at increased temperature is used to accelerate deterioration processes and thus reduce the duration of the shelf life assessment, which is especially of advantageous, if market introduction shall be achieved quickly after product development. Since not all reactions during food spoilage follow the Van't Hoff-rule (temperature-increase of 10°C generally accelerates chemical reactions by a factor 2-3), this method has its restrictions, but can nonetheless be used to get fast results regarding shelf life behaviour of a food product. (Another method is to use storage at fluctuated temperatures).

In practice, all of these methods have limitations and combinations of all might need to be looked at for some products, in order to reach a safe and sensible decision.

One limitation with all trials, particularly of microbiologically unstable foods, is the assumption that the consumer will follow the storage instructions given on the package. Allowance must always be made for a reasonable degree of product abuse.

In determining the shelf-life of a particular food, it has to be considered what particular characteristic of the food is going to be the limiting factor of its shelf-life. Determining that biscuits have a microbiological shelf life of several years, can be irrelevant, if they are going to become soft and of an inedible quality sooner. Sometimes, there may be more than one factor that needs to be assessed. For example, the shelf-life of chilled, raw meat pies might be limited by micro-organism levels, but there may also be a quality issue with development of rancidity, or with water or fat migration from the meat into pastry, affecting quality.

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Microbiology

If it is possible that there could be pathogens present in the product and they could grow during storage, it is important that growth studies are undertaken. The microbiological status needs to be validated. The following methods are suitable:

- Predictive microbiological models to estimate the rate of microbial growth or to obtain an indication of whether growth of a particular microorganism, pathogens and spoilage organisms will occur under a specified set of conditions.
- Literature references.
- Challenge tests where the food is inoculated with a cocktail of several strains of the pathogen and then tested at intervals to establish a growth curve. (Betts et al., 2014)

Chemistry

Possible changes in critical key parameters of the product should be monitored by using standard methods (rancidity, bioavailability of bioactive, moisture content, pH etc.).

Sensory

The aim of the sensory analysis during the shelf-life test is to monitor and record the most obvious changes that occur in appearance, aroma, taste, flavour, colour and texture.

The maximum shelf life must be set as the shorter of either the safety, the concentration of the bioactive constituent, or quality limit, whichever is the shorter time period.

All documentation related to the establishment and validation of the shelf life of the food product should be available as evidence to support accuracy of the shelf-life: product specification outlining the sensory, physical, chemical and microbiological characteristics of the product; details of recommended storage conditions for the product during its shelf-life; HACCP plan; details of any laboratory based analysis including durability and/or challenge tests, if necessary; scope of accreditation in relation to laboratory, if it is necessary; details of any mathematical modelling carried out, if applied.

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Annex 11. Analytical methods for the determination of bioactive compounds (Sub-chapter 3.1)

Table 6. Examples of analytical methods for the determination of bioactive compounds (AOAC., 2006)

Bioactive compounds		Analytical Technique
Polyphenols		High performance liquid chromatography (HPLC)
		HSCCC (High Speed Counter Current Chromatography)
		Supercritical fluid chromatography (SFC)
		Paper chromatography (PC) technique
		Thin-layer chromatography (TLC) technique
		Gas chromatography (GC)
		NMR spectroscopy
		Chromatography–Mass Spectrometry (LC–MS) technique
		Near infrared (NIR) spectroscopy
Omega-3		Capillary gas chromatography
Vitamins	Vitamins A and E	Simultaneous Determination of Vitamins A and E by HPLC and Column Switching
		Simultaneous Determination of Vitamins A and E in Infant Formula by Normal-Phase HPLC
		Fluorescence, Ultraviolet Light Source
	Vitamin D	Simultaneous Determination of Vitamins D3 and D2 by ESI LC-MS/MS
	Vitamin C	Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula by HPLC with UV Detection
		Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula by UPLC-UV
	Vitamin B12	Liquid Chromatography/UV Detection
Minerals	Minerals in Infant Formula, Enteral Products, and Pet Foods	Atomic Absorption Spectrophotometric Method
	Minerals in Animal Feed and Pet Food	Atomic Absorption Spectrophotometric Method
	Minerals and Trace Elements in Infant Formula and Adult/Pediatric Nutritional Formula	Inductively Coupled Plasma-Mass Spectrometry

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Bioactive compounds		Analytical Technique
Glucose	Corn (Glucose) Syrup in Sugars and Syrups	Polarimeter
	Glucose in Sugars and Syrups	Shaffer-Somogyi Micro Method
	Determination of Trace Glucose and Fructose in Raw Cane Sugar	Anion Exchange Chromatograph
	Sugars in Cane and Beet Final Molasses	Chromatography/Liquid Chromatography
	Glucose (Commercial) in Honey	Chromatography/Paper Chromatography
	Glucose (Commercial) in Maple Products	Polarimeter
	Glucose in Corn Syrups and Dextrose Products	Zerban-Sattler Modification - Sichert-Bleyer Modification – Polarimeter
		Glucose Oxidase Method - Spectroscopy/Spectrophotometer
	Carbohydrates in Fruit Juices	Chromatography
Amino acids	Amino Acids in Vitamin Preparations	Microbiological Methods, Turbidimetric Method, Titrimetric Method
	Sulfur Amino Acids in Food and Feed Ingredients	Ion Exchange Chromatographic Method
	Lemon Juice	Quantitative Chemistry: Polarimeter, Sampling, Potentiometer, Spectroscopy/Spectrophotometer
	Amino Acids in Feeds	Amino Acid Analyzer
	Lysine, Methionine, and Threonine in Feed Grade Amino Acids and Premixes	Amino Analyzer - Ninhydrin or OPA PCD: Chromatography/High Performance Liquid Chromatography, Amino Acid Analyzer
	Whey Protein Content in Milk-Based Infant Formula Finished Products	Amino Acids Calculation Method
Probiotics		Molecular methods by sequencing

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Annex 12. Definition of bioavailability, bioaccessibility and bioactivity (Subchapter 3.1)

BIOAVAILABILITY

The term bioavailability can be defined as the fraction of ingested component available at the site of action for utilization in normal physiological functions and is determined through in vivo assays. Bioavailability is the result of three main steps: digestibility and solubility of the element in the gastrointestinal tract, absorption of the element by the intestinal cells and transport into the circulation; and incorporation from the circulation to the functional entity or target (Verhoeckx, et al. 2015).

To provide a beneficial effect any bioactive compound must enter into the human body and reach its functional target. Then it is important to know the mechanism of entry to the human body: if it can be absorbed through the small intestine or if it is not absorbed at that level and then it reaches the colon where it is metabolized or transformed. The guidance indicates that where applicable, relevant data and rationale should be provided that the bioactive compound for which the health claim is made is in a form that is available for use by the human body (e.g. absorption studies). If absorption is not necessary to produce the claimed effect (e.g. plant sterols, fibres, and lactic bacteria), relevant data and rationale should be provided that the bioactive compound reaches the target side. If available, data on any factors (e.g. formulation and processing) that could affect the absorption or utilisation in the body of the bioactive compound for which the health claim is made should be provided (EFSA 2011b).

BIOACCESSIBILITY

Although bioavailability and bioaccessibility are often used indistinctly, it must be clarified that bioavailability is an overarching term that includes bioaccessibility and bioactivity.

Bioaccessibility has been defined as the fraction of a compound that is released from its food matrix within the gastrointestinal tract and thus becomes available for intestinal absorption (typically established from *in vitro* procedures).

Although bioavailability should be determined by human studies, *in vitro* studies are useful to provide knowledge on bioaccessibility, evaluating possible interactions between nutrients and /or food components, the effect of luminal factors, food preparation, processing practises, nature of the matrix, etc., on either micronutrients absorbability or on the potential for a nutrient to be absorbed (Etcheverry et al. 2012).

BIOACTIVITY

The bioactivity or functionality is related to the data of the effect of bioactive on human health. Bioactivity in turn includes events linked to the way the nutrient or bioactive compound is transported and reaches the target tissue, how it interacts with biomolecules, the metabolism or biotransformation it may experience, and the generation of biomarkers and the physiological responses induced (Verhoeckx, K, et al. 2015).

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Annex 13. Recommendations for Sales Campaign Development and Product Launch for all new product (Subchapter 6.3)

The following aspects should be considered:

DISTRIBUTION CHANNELS

Typical distribution channels will be:

- Local store networks, via centralised distributor companies.
- Multiple retailers with dedicated centralised distribution.
- Internet-based sales with distribution via national courier services, typically only suitable for ambient long-life products.
- Food service/catering. Least relevant to products with health claims.

Ultimately, generation of viable volumes (to support the typical investment needed to achieve a health claim) is likely to need buy-in from multiple national retailers. Web-based or local distributor networks can be entry level channels, particularly for new brands and to establish consumer interest in the products. These routes, and evidence of their success, can contribute to supporting listing presentations with multiple retailers.

The multiple retail chains generally operate at a national level within Europe, with a few retailers operating some multinational operations e.g. Aldi, Lidl, Tesco, Spar etc.. Strategically it is likely that national retailers will form the focus for products with claims at least initially, as pan-European distribution will require significantly higher complexity with regards distribution channels, local legislation, pack communication and consumer appeal.

In most European countries, retailers will be represented by co-ordinated trade bodies/associations e.g. British Retail Consortium (BRC) in the UK, Handelsverband Deutschland (HDE) in Germany, Federation des Entreprises du Commerce et de la Distribution (FCD) in France, Associazione Nazionale Cooperative di Consumatori (ANCC), Associazione Nazionale Cooperative fra Dettaglianti (ANCD) and Federdistribuzione in Italy etc. These associations can provide guidance on the distribution channels available and the typical industry standards/expectations.

TARGET CUSTOMERS AND THEIR REQUIREMENTS

The sales volume requirements for new products with health claims, to achieve acceptable return on investment, will typically dictate listings with multiple retailers both at national and international level.

Within this customer base, the premium pricing likely to be dictated by added value health products will require appropriate selection of the retailer profile.

Retail customers will focus on a number of key areas when considering listing of new (health) products:

- Fit with their customer demographic and profile.
- Fit with their understanding of consumer trends and behaviour.

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- Financial return per shelf-space area.
- Opportunity to provide innovation and variety.
- Existing branded and own-label offerings in comparable categories.
  Further typical requirements of the retailers include:
    - Agreed specification for the finished product including packaging.
    - Compliance to the food safety and quality management standards.
    - Compliance to the labelling and legal requirements.
    - Uniform quality.
    - Assuring uniform quality of nutritional, chemical, microbiological and sensory parameters.
    - Meeting ethical standards.
- Compliance for the specific requirements of the voluntary food safety and quality management standards (IFS, BRC Food) for products with health claims.
- Status of the supplying company (existing, new, established, new-venture etc.).
- Opportunity to gain an advantage over their competitors. Linked to this can be exclusivity arrangements.
- Opportunity for "ranging" and extensions e.g. flavour variants vs single offerings, joint promotional opportunities.
- Fit within their product categories. Location within the store.
- Status of the category, for each retailer (growth, strategic, tactical, static, declining).
- Opportunity for (regional or store category) trialling, with strict success criteria prior to full listing status.

In the consideration of the target customer there will be some common elements but also some "retailer-specific" considerations. A fit with all elements for each customer (retailer), and appropriate research will be required.

Profitability for the retailer will be key and hence an understanding of retailer margin expectations, on-shelf pricing expectations, and minimum selling price will be required ahead-of listing presentations. This may require some consumer research data to be collected/presented. At the same time the product owners/ manufacturer want to have a clear view on his /her own profitability in terms of expectations in return for their investment into the research and development.

CORE PRODUCT AND CAMPAIGN DATA AUTHORISATION

The unique selling point (USP) needs to be clear and communicable in the retail environment. The authorisation of a health claim will, by its nature, provide a number of benefits:

- appeal to a defined consumer group/need,
- a competitive advantage, at least in the short-term, and in many cases in mid-term.
- a message that can be legally and clearly communicated; supported by sound science.

Core product data to consider to include is listed in sub-chapter 6.3.

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Much of this information is defined in the product development brief and in the finished product specification The product data required by the retailer to set-up and manage the logistics of a product launch for a health claims product will be comparable to that of a conventional product and will include all elements related to bar coding, pack size/dimensions, tray configurations and labelling, pallet configurations and labelling, etc.

The product features and the route to promoting these features will need to deliver the trust in the health benefits and credibility amongst consumers that lead to sales.

Critically the consumer needs to be able to understand the specific benefit to their health in a simple, rapid fashion.

SME operating in this field may be launching both a new product and a new brand. Awareness is critical and advice should be taken on the most cost-effective routes for the specific product, but campaigns can include:

- TV, likely to be restricted to existing established brands or sub-brands from established companies;
- direct mail;
- printed press;
- social media/web-based;
- endorsements, possibly via medical charities or medical research bodies;
- sponsorship, linked to the health condition relevant to the claim;
- radio;
- bill-boards;
- events.

The campaign should consider the launch phase (first trial) and repeat usage. This may take account of the phased launch of flavour variants.

Since the national interpretation of the EU Health Claims legislation varies from one country to another a careful consideration of the legality of the messages is necessary, in line with the national acceptation practice of the consumer information.

LISTING PRESENTATIONS

Presentations need to be made to all targeted retail and food-service customers/companies. These present the “reason to stock” and the core benefits the customer will gain from stocking.

The targeted customers should be identified. These could be national retail chains co-ordinated from Head Office premises, local retailers and distribution companies which cover a range of store outlets.

Critically, most major retailers have a limited number of scheduled range reviews per category per year. This feeds in to opportunities for new products to appear on-shelf. These may vary from one retailer to another and may be linked to seasonal purchase patterns for each category.

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The core detail required by each customer is likely to be similar but the style of presentation will need to be adapted according to the specific customer. This will require an understanding of the customer's business focus, the existing offerings in the area of the target product, their demographic (re their customers) and any regional considerations (logistics). The position with regards to any possible supply exclusivity needs to be considered, particularly in relation to any outlets that have a particularly strong fit with the health claim/product format being offered. E.g. a product targeted for elderly consumers may wish to focus on store chains that have that demographic in their client base.

Additional price benefits should be requested in return for offering exclusive supply.

For national retailers (where the volume opportunities lie), each category will have its own management team. Hence a clear understanding of the category position of the product within each retailer is required.

The personnel that control the buying of new products for the target category need to be identified. For companies already supplying a specific retailer this information can be gained from existing contacts. For new suppliers this may require support from external sales specialists.

The Listing Meeting will require:

- presentation and/or Fact File with all relevant product data.
- examples of the product suitable for tasting at the meeting or scheduled separately within the retailer category team.
- the packaging – primary and secondary – or at least a mock-up of the format. This needs to include all legal product data and bar coding.

The Listing Presentation, as a minimum should contain:

- the concept/product rational;
- the key product features, with a focus on the health claim and benefits provided by it for the consumers and for the retailers. The (flavour) variants available;
- background to the concept in relation to a consumer need. Setting the scene with regards to the consumer landscape;
- the competitor landscape, and/or other ways in which the consumer might currently be achieving the benefits which the new product offers (e.g. versus a dietary supplement);
- the health claims approval sign-off. Endorsements from health bodies or any linked programmes with health associations;
- sustainability and environmental features. E.g. raw material sourcing, recycling of packaging approval of environmental bodies;
- distribution details, tray/outer formats, pallet configurations, shelf-life, storage conditions;
- costings – selling price;
- timings, with regards availability, linked to delivery schedules and volumes;

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- current range and range extension plans;
- consideration of any exclusivities.

PHASING

The output from the Listing Presentations will allow a schedule to be built up of the phased demand for the product and the volumes per delivery points (e.g. customer central warehouses). All Listing Approvals need to be followed through with the appropriate category team within each retailer such that the product is registered with the logistics systems with all relevant coding. Where multiple flavour variants have been developed/presented, this data will allow the breakdown requirement (production) for each variant.

Where third-party Distributors are being used, full briefings for the Distributor are required. Careful account needs to be taken if the product is likely to be transported through more than one country, particularly if these are not EU countries.

This information can be built into a required production schedule and fed-into the raw material and packaging orders. Slots can then be scheduled with the manufacturer or in-house production, taking account of lead times. Product release criteria, e.g. microbiological/food safety clearance, and associated lead times need to be considered.

ROLL-OUT

Key requirement is the co-ordination of:

- production, including availability of all associated material;
- distribution, to ensure delivery slots for each retailer are met;
- promotional activities. Launch events. Product give-aways. For products with health claims this may include articles in popular and/or specialist press, radio/media interviews, press releases etc.;
- retailer-specific promotional/launch activities.

IMPLEMENTATION OF THE PRODUCT LAUNCH

The majority of these activities are generally applicable for all food products. Therefore the full set of considerations is provided in Chapter 7., and here in the main body of the guidelines only the aspects specific for products with health claims are presented such as some information on sales requirements and phasing and campaign launches and a press release, events, PR, Advertising and promotion kick-off. (EFSA General Scientific Guidance for Stakeholders or Health Claims Applications, 2015)

OVERVIEW AND CO-ORDINATION

The Listing Presentations (see above, Chapter 7) and associated negotiations will have built the picture of the timed/phased launch delivery requirements, and hence when product will first be available for sale. This feeds into a detailed launch plan and timetable.

The key elements to be co-ordinated in this phase are:

- sign-off of promotional materials, e.g. give-aways, leaflets, offers. Order and delivery of all promotional materials;

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- draft and scheduling of Press Releases;
- draft and scheduling of promotional articles (journals, popular press, radio, social media);
- co-ordination of broader marketing campaigns e.g. events, links with health associations, endorsement opportunities, in-store activities such as tastings, other sampling opportunities;
- raw material and packaging ordering, including any specific launch/promotional items. Packaging to include all secondary and tertiary packaging. For products with health claims, there may be novel materials or adapted material that may have non-standard production processes or extended lead times;
- check on all coded items and all legal requirements (label data);
- manufacturing slots and production schedule;
- local warehousing;
- collection and delivery schedules, taking account of retailer-specific requirements and delivery slots.

SALES REQUIREMENTS AND PHASING

The launch-phase sales requirements will be focused around the Listing activities (see above, Chapter 8). The output of the Listing Presentation will be a series of negotiations if the retail customer shows interest in stocking the product. This will include:

- pricing elements;
- volume related discounts;
- store siting/promotional locations;
- specific store listings (geographical or linked to limited test marketing);
- linked promotional/launch activities;
- promotional mechanics.

All retailer-specific data on product, packaging and logistics need to be provided, checked and confirmed.

For products with health claims, the launch phase is an opportunity to build awareness based on the "condition" being targeted e.g. bone health, eye health etc., by linking with organisations and associations with expertise or interest in these health topics. This might include respected academic institutions that may have a focus of research in the topic. These need to be co-ordinated with the launch activities and could include:

- interviews with respected experts in the relevant health field;
- articles and editorials with expert contribution;
- product or promotional item give-aways linked to specific relevant organisations or sponsored events (health-related, sports, social, music, entertainment);
- conference activities either as part of national/EU trade conferences or possibly; dedicated launch events with appropriate educators;
- web and social media highlights and links to the brand/product;
- possible joint press releases/ statements.

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Historically, personal or organisational endorsements have proved powerful sales/marketing support for products with a health benefit. Careful selection and briefing of the endorser (individual or company) is needed. The focus can be lifestyle-related, where celebrity or sports personality may be relevant or focused on the scientific/nutritional elements where a reputable consumer group or health association may be relevant.

These endorsements and usage/case studies need to be circulated and released as part of the launch phase.

The most powerful endorsements will come from groups who have consumed the product and observed the claimed effect. This can require a possible lengthy pre-launch trial phase, over and above the clinical trials needed to support the claim.

All promotional, sales and marketing mechanics need to coincide with early in-store availability.
Generally, the listing agreement will be tied to rate-of-sale requirements, to secure on-going or wider distribution. These often have challenging time periods for the new product to deliver the required rate of sale and hence all promotional spend needs to be focused on driving initial trial and repeat sales.

In addition to the above elements, the following items are important requirements in the initial selling phase:

- co-ordination of manufacturing and distribution with retailer requirements;
- stock management;
- store-level checks – are the products merchandised appropriately according to the Listing agreements;
- press releases/interviews;
- launch events (and associated product/merchandise give-away);
- radio/TV/social media/web campaigns.

The aim of the initial campaign will be to build awareness and momentum that will lead to wider interest to generate:

- appropriate rate of sale within initial listings;
- extended trial listings;
- broadening trial listings to full listing, extending into wider store locations;
- extended shelf-space, with consideration of extending the facings with additional or alternative flavour variants;
- use of initial sales data to justify listings with other retailers or outlets;
- building volume to sustain the launch needs to be linked to the manufacturing capacity; and raw material availability. Lead-time considerations are critical.

THE MANUFACTURING SCHEDULE

The Listing presentations and negotiations will be converted into initial volume requirements over the early weeks from launch, including required phasing and variants of flavour volumes. In the early stages, this needs careful planning at a manufacturing level in relation to minimum

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batch sizes, wastage and efficiency, shelf-life and stock management, and scheduling in relation to existing product commitments.

Start-ups, SME and established brands moving into new sectors may well be utilising co-manufacturing facilities. This provides risk-reduction and flexibility but reduces the control particularly in the early phases. Close co-ordination with the co-manufacturer is critical. The new launch customer may be one of many customers that the co-manufacturer is servicing. It is possible/likely that launch volumes may be below the desired minimum batch sizes for the designated production facility. This will require a compromise and financial commitment. Options are limited but typically include:

- use of (third-party) pilot or manual/semi-manual production and packing;
- holding bulk product prior to packing off (long-life product);
- holding stable pre-mix elements;
- manufacture and freeze for certain chilled or ambient products proven to be freeze-thaw stable;
- factoring-in wastage levels to initial batches, taking account of possible re-work opportunities.

Each retail customer will require a minimum amount of residual shelf life as the product is received in their system. The typical requirements are that at least 2/3 of the shelf life should be left by the time of the delivery to the retailer. This needs to be factored into the manufacturing and stock management planning. A detailed understanding of product stability and optimal shelf-life will help this aspect.

In frozen and long-life ambient products food safety and quality risk/losses are minimised by the, typically, stable nature of the product. This is not necessary valid for the bioactive material content, thus its stability, available concentration at the end of shelf life has to be proven.

Chilled short-life products present the highest manufacturing-schedule challenges. After the launch, where some manufacturing losses/inefficiencies are likely, close attention to forecasting will be critical to build a viable/profitable business. Close contact with retail ordering departments is required. Some retailers may expect refunds or payments for products in their system that are not sold after the coded expiry date.
The manufacturing schedule needs to take account of the following items for planning purposes:

- availability and lead-times for packaging (primary, secondary and tertiary). For printed items, the lead times for printing (both for new/launch stock and follow-on stock) need to be considered. The availability of the raw material stock (e.g. cardboard, paper, PET bottles, caps, etc.) needs to be considered. Most packaging will have MOQ, which may require significant controlled on-site storage of packaging materials;
- availability and lead times for raw materials. These can be most challenging for low addition-rate ingredients that fall below supplier MOQ. Decisions will then be required on options to store unused materials on-site. Ingredients that support the health claim may be new or involve new processes or process combinations at suppliers. This

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requires close co-ordination. These ingredients may warrant Certificate of Analysis per batch which can impact order lead time;
- new (to site) processes or items of equipment or combinations of processes that may require training or extended testing;
- scheduling manufacturing time in relation to existing commitments (note the additional challenges when working with co-manufacturers);
- quality Assurance /Release/Quarantine requirements. Note any retailer-specific requirements and need for Certificate of Analysis per batch;
- warehousing requirements, where production is additional to existing stock;
- pick-up arrangements with transport companies, particularly critical for short-life products.

LAUNCH CAMPAIGN

Many of the requirements are highlighted above (Overview and Co-ordination and Sales Requirement sections).

A product supporting a health claim is likely to present additional challenges in the launch phase compared to conventional products. There will be an educational requirement necessary to communicate the (additional) product benefits (specific health impact). This will need to be impactful, trust-worthy and comprehensible to the target audience. Messages need to be simple and easy to assimilate in, what might be, a complex nutritional/health area.

The launch campaign must be able to rapidly target the key consumers in its style and delivery. For a variety of reasons, products with health claims need to command a premium pricing and need to be able to convince the target consumer that consumption of the food product is a complementary or better route to the "health solution" than other alternatives e.g. supplements, OTC medicine, herbal therapies etc.

The launch activities, in additional to conventional new product launches, can benefit from the following:
- endorsements from users/case studies;
- recommendations/endorsements from targeted health bodies/associations and/or academic institutions. Profile media events or interviews;
- reduced cost trial periods or introductory offers;
- promotion and/or give-aways at events linked to the targeted health condition/claim e.g. running events for rehydration claims;
- publications in respected popular press outlets linked to the health condition;
- point-of-sale literature highlighting the effects and mechanisms;
- reduced price or free testing facility/option related to the health condition (e.g. cholesterol or blood sugar measurements);
- joint promotions or cross promotions with complementary products (food or non-food).

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PRESS RELEASE, EVENTS, PR, ADVERTISING AND PROMOTION KICK-OFF

As in the above sections, a product with a health claim will require all the conventional launch sales and marketing tools to inspire initial trial and repeat purchase with the added challenge of the need to communicate the health benefit.

The pack presentation on-shelf will be critical but can be enhanced by a number of support activities in the launch and subsequent phases, many of which have been highlighted in the above chapter.

An engaging press release needs to be backed-up by a route for consumers or customers to enquire about further details and stockists. A critical element in early trial phases (launch) is ensuring consumers have high awareness of where to purchase.
An informative web and /or social media presence is critical to back-up the awareness campaign.
Communication that the health claim is independently endorsed/approved in law by European authorities (rather than derived by company marketing), can help enhance credibility. The depth of testing and scientific research supporting the claim/effect can be raised (in overview)

Consensus on the health condition being targeted (e.g. bone health, heart health etc.) and the rationale or approach taken to provide a benefit (via the new product) will be important. Advanced briefings with Key Opinion Formers (KOF) and influential public/private bodies in the area are recommended. Pre-launch engagement including product trial with key health bodies or associations with interest in the target health condition would be beneficial. Identifying KOF who are willing to either actively promote or at least provide positive feed-back will be a significant advantage.

At this pre-launch stage consider all parties who may have an interest/angle on the health area being targeted, such that their position can be understood and managed (in relation to their likely reaction to the launch). For example, if a product has a relatively high dose of fat soluble vitamins to achieve an effect, will there be counter-arguments with regards “over-dosing” risk for these vitamins.

PR for products with health claims can be as powerful as conventional advertising (where consumers may be sceptical around company-funded adverts). PR can be a cost effective route to raise awareness vs conventional advertising.

Statements, comments, endorsements, approval from the following can be considered, if they comply with the acceptable practice in the country of application:

- respected academic or research organisations;
- medical bodies;
- health associations (e.g. national Heart Foundations, Diabetic Associations,);
- sports bodies or co-ordination associations;
- personalities linked to the health area being targeted consumers who by trial, can describe benefits.

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Presenting at both trade, consumer, or governing body conferences or seminars can be a low cost route to raise awareness and build credibility. These presentations allow the total picture/story of the product's (claim) evolution to be communicated. They can enhance or lead to endorsement opportunities.

Advertising approaches will depend on funding, with national TV/Radio coverage requiring significant investment. Advertising needs to be targeted to the consumers likely to benefit, in terms of their lifestyle, the media they consume, the events they attend, the sports and hobbies they engage in, the societies they belong to etc. Advertising linked to or endorsed by organisations, societies, sporting bodies, targeted magazines, e-news, etc. can be most cost-effective.

Promotions can be a key factor in driving trials; critical at the launch phase. Making products available (either directly or via couponing) for trial (free or reduced cost) at events, via printed media, via social media, targeted mail-outs etc. will be an option. Promotional/trial quantity requirements need to be built into the manufacturing schedule and costed accordingly.

As the health benefit will likely require regular/repeated (regime) consumption, the purpose of the initial trial will be to gain consumer's confidence in the sensory and usage aspects of the product that would lead to repeat purchase. Promotions could thus provide reduced price access to the product over a reasonable trial period.

Likewise, promotions, and associated literature provision, are an opportunity to provide educational/guidance material in relation to diet and health (relevant to the claim). This can be used to help consumers understand where the product fits into their diet and lifestyle. Events, PR, promotions, advertising and associated launch requirements will require significant planning and resource. Typically, to account for materials, products, schedules, lead times etc., planning for these launch activities needs to start 6-9 months in advance of the launch.

FOLLOW-UP AFTER MARKET LAUNCH

The development of a new food product, particularly a food with health claims and launching it to market needs a significant amount of effort and resources. Therefore after the product launch it is worthwhile to review whether the outcome matches what was expected. The product development team and the company management should review the results within a few months up until one year. In order to make these effective it is advised to define performance indicators for the new products.

The following aspects should be considered:

- Was the timing of the product launch right?
- Is the market response appropriate?
    - Sales figures, profitability, consumer/customer awareness, competitors.
- Is the sales support appropriate?
- Are the distribution channels appropriate?
- Is there a need for change?

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