

# From Idea to Health Claim: Finding a Way

*The nutrition and health sector, including functional ingredients, functional foods and dietary supplements, has been one of the fastest growing markets in the food industry for the last 10 years. Every year, new ingredients and products are launched that claim to enhance your well-being or deliver health benefits. Following a period of time, during which marketing was the main consideration when developing nutrition and health products, the food industry now has to deal with new requirements — whereby providing strong scientific evidence to substantiate health claims is becoming mandatory. Consumer expectations and new regulations have raised the level of required proof and, to a certain extent, it is becoming ever-more comparable with the levels required for pharmaceutical products.*

When analysing the nutrition and health market, it is noteworthy that in terms of active ingredients or foodstuffs, delivery systems, health targets, major players and regulatory issues, there is a great deal of heterogeneity. Therefore, the development of a new product in this field requires a specific and step-by-step approach.

## **Step 1: Analyse the Global Product Environment**

At the beginning of the development process, several key questions need to be addressed to characterize the product, its target and specific market.

- What is the regulatory status of my product?  
For example, do I have to consider a Novel Food or GRAS application: that is, does my product have a safe consumption history

or do I have enough toxicological data to demonstrate that it is safe for human consumption?

- What kind of health benefits do I target?
- How will consumer surveys, scientific data and market reports impact the positioning of my product?
- Do I target a B2B or a B2C business?
- Are the existing intellectual property data a threat or an opportunity for my product?



It is important to be able to address these questions very early in the product development process. The choice of B2B or B2C communications, for example, could significantly impact the level of scientific substantiation required.

Another key point in the process is the analysis of the background science/historical data and the association between the product and its health effect. During the data analysis, it is also important to be able to evaluate the quality of any experimental protocol and design. Indeed, regulatory agencies have developed tools designed to quickly evaluate the “weight” of scientific proof — including, for example, scoring grids to assess the credibility of clinical trials results, as well as for the methodologies used — and will use these criteria during the health claim file evaluation.

**Take advantage of past research:** The analysis of existing scientific data allows for the identification of relevant biological targets and the selection of the best candidates for product development. It also enables each product to be evaluated, on the strength of comparative information regarding a specific health effect, to determine what “missing data” are required to reach the health claim objective.

**Identify new opportunities:** If an exhaustive literature survey involves the analysis of scientific data on the product itself, it is important to consider data obtained from similar or related foods, or ingredients or data regarding a different biological target. Indeed, a wide-ranging review may result in the elaboration of a new and innovative strategy.

**Stay aware of new data:** The emergence of new scientific, regulatory or market data must be taken into account, even after the product development process has begun. A system of integrated scientific, marketing, technological and legislative oversight is one of the keys for success in product development, as it allows you to benchmark approaches and anticipate regulatory changes.

Based on the results of scientific data analysis, two main product development strategies are often adopted by industrial players:

- Conduct the same studies with their own product that have been done with other, similar offerings (me-too strategy)
- Evaluate the effect of the ingredient on a new biological target to obtain innovative data.

Many ingredient producers adopt the me-too strategy to penetrate profitable, already established markets, such as the plant sterols sector, for example. The R&D process can then be shortened, could rely on demonstrating equivalency and would significantly reduce

the research budget. However, this approach doesn't provide for any differentiation from the competitors. Once the scientific background and the environmental analyses are done, it then becomes possible to characterize the nature and number of research experiments that have to be undertaken and the budget required to substantiate the health effect of the product. This process is always very dependent on the individual ingredient or food product and the specific biological target, and it may require working with an expert to optimize the process.

## Step 2: Prove the Health Effects

Getting proof of efficacy for the product can be achieved in several ways. Some research plans will only focus on clinical research, whereas others will consist of in vitro and in vivo techniques, combined with clinical trials. The choice will strongly depend on the product's scientific background, and both the biological and marketing targets. Nevertheless, if the objective is to obtain a health claim for a label, it will be mandatory to show that the product is efficacious in humans.

specific target (protein, receptor, transcription factors). The latter allow you to evaluate the effect of the sample directly on a cell. They facilitate the measurement of direct or indirect effects on a specific marker, are generally better adapted to analyse complex mixtures such as plant extracts and food products, and are less prone to artefacts than in tubo assay. Nevertheless, in vitro assays can't be performed on bioactives that have to undergo digestion to be activated.

- In vivo assays rely on animal models to evaluate biological activity, selectivity, the mechanisms of action involved and the toxicity of the compound, extract or food product. Numerous models are available that can mimic human metabolic disorders, such as diabetes and obesity. This approach helps to evaluate and, eventually, validate the health effect of the food product highlighted by the in vitro approach. In vivo assays provide valuable data that will be of great use when it comes to designing human studies.

Recently, new technologies — “omics” — have emerged as powerful tools to explore the

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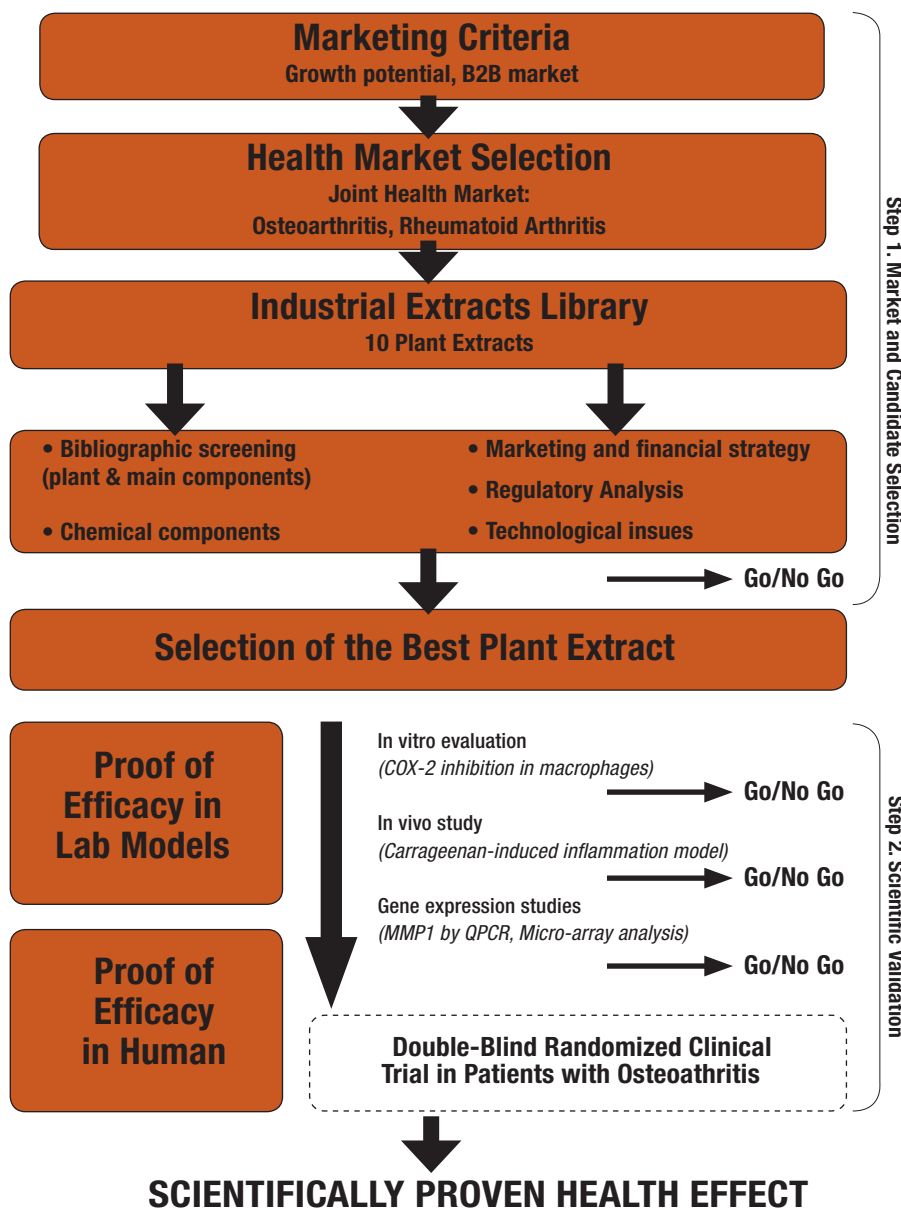
**Proof of efficacy in the lab, the first step to the health claim:** As legislation requires the substantiation of health claims with data obtained in humans, this step is sometimes perceived by the big industrials as optional. In fact, however it is an essential step towards building a complete scientific dossier: it allows you to decipher the mechanism of action and get a better understanding of the active dose requirements; to validate the biomarker(s) of interest; and evaluate the duration of delivery for the product. It is noteworthy that all this information is of great added value when designing a clinical trial and can help to minimize the risks taken during a human study.

To obtain the so-called “preclinical” data, several technologies can be used to investigate numerous and various biological targets; these are usually classified in two main categories:

- In vitro tests include in tubo and cell-based assays. The former are used to evaluate the effect of bioactive compounds or a food on a

effects of nutraceuticals and food ingredients. Omics is a general term for a broad discipline of science and engineering that analyses the interactions of biological information objects in various omes. The main focus is on mapping information objects such as genes, proteins and ligands, finding interaction relationships among the objects, engineering the networks and objects to understand and manipulate the regulatory mechanisms, and integrating various omes and omics subfields (proteomics, transcriptomics, metabolomics). The technologies that have driven these new areas of research include DNA and protein microarrays, mass spectrometry and a number of other techniques that enable high-throughput screening and analyses. All of these approaches represent a key tool for biological and chemical screening, allowing researchers to identify and compare the activity or the health effect of a food product (plant, extract, ingredient). They offer →

Figure 1: A development pathway for a health ingredient product.



### Step 3: From Scientific Papers to Claim File Submission

Regulation (EC) No. 1924/2006 on nutrition and health claims, as well as other legislation worldwide, requires preapproval of the health claim by the authoritative agencies. Therefore, regulatory authorities must validate any health claims before they can be used for marketing purposes. This approval is the final step in obtaining the desired health claim. It requires the collation of pertinent and relevant scientific data, including specific data obtained on the product that demonstrates the claim submitted. Most of the regulatory agencies have now published detailed guidelines that help companies to complete a claim file. Based on those guidelines, you should be aware that it is vitally important to provide strong scientific evidence, with studies published in peer-reviewed scientific journals, or at least obtained using high quality methodologies and designs.

### Conclusion

The nutrition and health sector is becoming a mature market with a wide range of products and associated health claims. To protect the consumer from misleading information, the regulatory agencies have intensified the criteria and the level of scientific proof required to obtain a health claim. Because of that, companies must now face new challenges to meet those requirements. It is, therefore, important to be able to elaborate, at an early stage, the “path” to reach the health claim. Figure 1 illustrates a specific example of the development of a joint health product. However, because all nutrition and health products are essentially unique, your company will need to establish a specific step-by-step approach, one that could be enhanced with internal or external expertise.

many advantages: because they provide an overview of the overall biological effect at once, the results obtained can be classified as a biological signature of the product tested. Moreover, they can be performed using both in vitro and in vivo protocols. And, they elucidate mechanisms of action and provide “fingerprints” of toxicity.

#### Proof of efficacy in human clinical studies:

Clinical studies are the final and mandatory step in the path towards building a scientific dossier and getting a health claim. At this point in the process, organizations must consider, at the same time, the available scientific data, their marketing criteria and the regulatory status of the new product. Indeed, these elements will all be important considerations in the design of the clinical trial. They may all strongly influence

the choice of the target population and the biomarker. When considering a clinical study, it is important to keep in mind that for regulatory agencies, the randomized, double-blind versus a placebo design remains the “gold standard” to effectively demonstrate a biological effect. In addition, it is preferable to select a marker that carries a strong scientific consensus regarding its relationship with the biological target, and one that is easily understood by the “average consumer.” As the design and regulatory issues concerning clinical trials can be wide-ranging and sometimes complex, and may vary from country to country, it is recommended that you work with an expert opinion leader or a specialized organization to maximize the chances of obtaining positive and significant results.

**For more information**  
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