

## Scientific substantiation: A key ingredient for functional foods and health claims

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“Functional food” has become a buzzword in the food world and its market share is predicted to grow substantially in the coming years. A lot of people believe that functional foods are those for which health claims can be made. Although this is not always the case it is enough to stimulate a lively debate about the scientific evidence needed to justify health claims.

There have been many definitions of a functional food, but one that recently achieved a scientific consensus is as follows: “A food can be regarded as 'functional' if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects in a way which is relevant to either an improved state of health and well-being and/or reduction of risk of disease. Functional foods must remain foods and they must demonstrate their effects in amounts, which can normally be expected to be consumed in the diet. They are not pills or capsules, but part of a normal food pattern.”

A large EU project on Functional Food Science in Europe (FUFOSE) led by the International Life Science Institute (ILSI- Europe) identified two types of claims that are vital to functional foods:

- 'Enhanced function claims', which require that evidence for the effects of the functional food is based on validated markers of improved target function.
- 'Reduced risk of disease claims', which require that evidence is based on validated markers of intermediate endpoints of disease if not disease itself.

Scientists and consumers are interested in the relation between the consumption of a food or ingredient and the ultimate result of that food on health. In case the time scale in between consumption and outcome is too long, intermediate endpoints need to be used: they are called markers or “biomarkers”. Biomarkers can be defined as “indicators of actual or possible changes of systemic, organ, tissue, cellular and sub-cellular structured and functional integrity, which can be used singly or in batteries to monitor health and exposure to compounds in populations and individuals.” There are biomarkers of exposure, biomarkers of target function/biological response (related to enhanced function claims), and biomarkers of intermediate endpoints (related to reduced risk of disease claims). Taking heart disease as an example, we might investigate the effect of functional food components on markers of improved target function, i.e. lower levels of blood-cholesterol. An example of a marker of reduced risk of disease would be the demonstration of a beneficial effect on the furring up of arteries.

Consumer perception of the benefit of functional foods depends on the actual benefit plus the communication accompanying it. The role of the regulators is to provide a legal framework to control claims. Scientists must provide a scientific basis for the substantiation of the claim/communication. Such a responsible framework will thus ensure the veracity of health claims and avoid consumer confusion.



The EU Commission's Directorate responsible for Consumer Affairs (DG SANCO) has issued in June 2002 a first draft proposal for a regulation on nutrition, functional and health claims made on foods. The two types of claims mentioned above are included within it. The final draft could be adopted as an official EU proposal before summer 2003 and it is expected that formal negotiations involving Member States will begin in the second semester of 2003.

Another EU project PASSCLAIM (Process for the Assessment of Scientific Support for Claims on Foods; also co-ordinated by ILSI-Europe) will develop the necessary tools for the scientific substantiation of health claims on foods. This will be an essential element for a future European legislation on health claims.

## References

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