

Prof. Francesco Visioli
Department of Molecular Medicine
University of Padova
Viale G. Colombo 3
35121 Padova
Italy

Opportunities and challenges in pharma-nutritional research

Any scientific advice should be “...the conclusion of a skilled evaluation taking account of scientific evidence, including uncertainties”, at least according to the FAO/WHO “Framework for the Provision of Scientific Evidence on Food Safety and Nutrition” of 2007. As of today, nutritional profiles and claims attached to functional foods and nutraceuticals should be based on this proposition.

It must be immediately underlined that the vast majority of the claims that are currently being proposed to provide added value to foodstuffs are not built based on strictly pharmacological approaches. Rather, most claims are based on epidemiological observations or in vitro experiments and lack the full support of randomized clinical trials (RCTs). While RCTs are, indeed, the gold standard of pharmacology and are the only way to provide solid and evidence-based data, they are difficult to apply to nutrition-based settings. Clearly, while the effect of drugs can be “pharmacologically” addressed as it manifests itself through the relief of clinical symptoms, the effect of food components is difficult to detect with classical pharmacology tools. In brief, the effects of medicines are usually strong, short-lived, and centered on clinical outcomes; conversely, the effects of foods, functional foods, and nutraceuticals are subtler and more long-lived, seldom influencing human physiology in detectable ways. This is why it is more difficult to study food items and their components than to study synthetic drugs. The net result is that it is very difficult to make sound claims.

In conclusion, the development of new experimental paradigms to appropriately study the effects of food items on human health should be actively sought after and public health authorities should reconsider their approach to regulations and guidelines.