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Foreword

Both of the papers in this supplement draw upon the individual and the overall consensus reports of the ILSI coordinated Concerted Action on the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)[1]. This activity developed from a previous concerted action, also initiated and coordinated by ILSI Europe, on Functional Food Science in Europe (FUFOSE)[2]. In essence, FUFOSE emphasised the importance of sound nutritional science and explored and demonstrated ways to attain this by way of hypothesis-led science and innovation achieved by strategically and intelligently using quality-assured and validated markers of ultimate and intermediate outcomes. The latter was seen as a chain of markers mapping (1) exposure to a food or food component, (2) its absorption, and subsequent distribution, and metabolism, (3) later intermediate and functional effects and, if possible, (4) the ultimate outcome in terms of health and well-being or a surrogate thereof. Thus, FUFOSE provided a mechanistic schema which could inform both the use of existing evidence and the acquisition of new evidence to demonstrate functionality for a food or food component.

PASSCLAIM developed the concepts of FUFOSE in the context of how the portfolio of evidence should be constructed to substantiate a health claim. It produced a generic guidance tool, comprising key criteria, for assessing the quality and logical coherence of a portfolio of evidence submitted to competent authorities for the substantiation of health claims. PASSCLAIM did not formally provide guidelines on how to conduct human intervention studies which would meet its criteria. Additionally, although it referred to the use of the full spectrum of evidence in substantiating claims, PASSCLAIM did not suggest how the evidence should be evaluated and graded. This supplement therefore represents a significant milestone in the substantiation and use of health claims related to foods and food components and their use in public health nutrition practice and policy. The importance of these papers should be appreciated in the context of the environment in which their lessons and questions will be addressed.

Following international agreements on trial registration and ethical approval, there is an increasing expectation that human intervention studies will need an independent data monitoring process to ensure appropriate data collection and quality control; recording and reactions to unintended effects, and adverse events, and also to protect the interests of all participants, not just the study participants but also the funders, researchers and sponsoring agencies and institutes. The thorough guideline produced by Welch *et al.* additionally provides a marvellous platform for instituting such measures to support research governance and integrity in the area.

The second paper, 'A standardised approach towards PROCLAIM', brings to a focus a particularly important dilemma, the heart of which is how the evidence substantiating a claim is to be applied. This can best be simplified as two issues, the resolution of these would facilitate the understanding and approach to the sections on 'weighing the totality of the evidence' and the 'conclusions and key recommendations'. The first issue is to understand better the purpose and intended use of claims, i.e. are they simply to support a commercial or market advantage, or are they to be part of a broader strategy in public health nutrition practice and policy, or both? The second issue is to realise that establishing causality is not necessarily the same as establishing a claim. In the Risk Analysis model for developing practice and policy, the initial stage comprises one or more risk assessments, the conclusions of which are then passed as reasoned and explicit appraisals to risk managers whose responsibility is to consider the assessment(s) and all other relevant interests, perhaps as a risk–benefit analysis, and perhaps with an iterative discussion with the risk assessors, to determine what appropriate risk management action, if any, should be taken. In the context of Health Claims in the European Union, the assessment of scientific evidence is the responsibility of the European Food Safety Authority, and is an assessment of the probability of causality. The ensuing responsibility for allowing, allowing with qualification or conditionality, or disallowing a claim lies at the level of risk managers, i.e. with the European Commission. How the risk managers react to the risk assessment, of course, depends, in part, on what they think the purpose of a claim is. PASSCLAIM dealt mainly causal inference or causality that is the risk assessment, and as such was incorrectly named.

Understanding better what the purpose of a claim might be and how such a claim would be used also influences how other points and perspectives raised by Gallagher *et al.* could be applied, in particular 'benefits to health' and 'biological plausibility'. For example, in public health nutrition, it is appreciated and accepted that interventions which have an apparently small impact on individuals can at a population level have appreciable benefits; arguably, determining this aspect of plausibility and relevance to health should be considered by the risk managers rather than by the assessors. This paper also highlights very well the perpetual problem in nutritional research of acquiring data from randomised controlled trials in human subjects. The authors justifiably argue that there needs to be a universal agreement on how the relevant evidence base can be integrated to support causality. An analytical approach is emerging from experience elsewhere in biomedical science whereby this can be achieved. This is 'Evidence-based Mechanistic Reasoning'[3]. It entails analysing the mechanistic chain between the initial intervention and eventual outcome and ascertaining the probability of causality between the constituent steps to determine the overall probability of causality along the complete chain. Thus, needs and issues raised in this supplement bring us, via an improvement cycle, back to

the FUFOSE mechanistic schema and its possible role as a tool to guide the quality assessment, presentation and analysis of available evidence in the development and substantiation of health claims in individual and public health nutrition.

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