Letter to the Editor

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Health Claims for Food Supplements and Degree of Evidence

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While assessing the applications for possible health claims for food constituents, we advocate the integration of additional elements, namely grading of evidence, consideration of the risk-benefit ratio and epidemiological and health economic factors. This may be demonstrated very well in the issue of joint health, which is characterised by the WHO as one of two conditions with 'high burden diseases with no curative treatments' [1], presenting a major challenge for the public health system, both in terms of epidemiology and health economics. Due to the current legal situation with the requirement for 'convincing evidence', the EFSA has rejected all applications to obtain health claims for substances in the field of joint health, with the exception of vitamin C used to aid in the normal functioning of cartilage. The main reason for the refusal was the argument that there are no convincing intervention studies on healthy subjects. Furthermore, findings from studies with a diseased population – people with osteoarthritis – were not acknowledged. EFSA published a guidance paper on the scientific requirements for health claims related to bone, joints, skin and oral health [2], in which it suggested possible endpoints for conducting suitable studies. With the exception of biomarkers, these are endpoints that do not permit a measurable positive change after intervention in healthy subjects (functional changes, pain, stiffness, width of the joint space). Starting from this point of view, it must be stressed that the 'convincing evidence' from the general healthy population in the classical sense required is simply not possible in the field of joint health with the means available to the possibilities of research today. In contrast, a large number of high-quality research results show that there are many factors that are strongly indicative of a causal relationship between glucosamine and the benefits on joint function and joint health (bioavailability and uptake [3–5], physiological function and effects, based on chemical, mechanistic, and human data [6–10]). This means that the question regarding whether there is a benefit of glucosamine for the general healthy population can be answered positively with high, although not convincing, probability.

In light of the epidemiological and health economic problems in the field of joint health, this raises the question of whether it is reasonable to ignore the existing evidence and to withhold this information from consumers who would use such food constituent because of diverse risk factors such as obesity, excessive joint loading, advanced age and possibly mild pain, but without any diagnosable osteoarthritis.

Grading of evidence is standard practice in other areas of preventive medicine as, for instance, in cancer risk in connection with nutrition and physical activity [11]. Food constituents have to be by definition safe substances with an outstanding risk-benefit ratio. In contrast, the situation for pharmaceutical products is completely different; that is why convincing evidence must be presented to show a risk-benefit ratio that justifies their use. However, it is a fundamentally flawed approach to apply all the principles of research into disease treatment as such to research into health maintenance and prevention, which is usually the rationale for carrying out research in nutritional science. This is discussed in detail elsewhere [12]. In view of these considerations, grading of evidence should be taken into account and classified accordingly in the global assessment of health claims.

References

1 Kaplan W, Laing R: Priority Medicines for Europe and the World. WHO, Geneva, 2004.
2 Guidance on the scientific requirements for health claims related to bone, joints, skin, and oral health. EFSA Journal 2012;10:2702.
3 Setnikar I, Rovati LC: Absorption, distribution, metabolism and excretion of glucosamine sulfate. A review. Arzneimittelforschung 2001;51:699–725.
4 Block JA, Oegema TR, Sandy JD, Plaas A: The effects of oral glucosamine on joint health: is a change in research approach needed? Osteoarthritis Cartilage 2010;18:5–11.

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5 Persiani S, Rotini R, Trisolino G, Rovati LC, Locatelli M, Paganini D, Antonioli D, Roda A: Synovial and plasma glucosamine concentrations in osteoarthritic patients following oral crystalline glucosamine sulphate at therapeutic dose. Osteoarthritis Cartilage 2007;15:764–772.
6 Derfoul A, Miyoshi AD, Freeman DE, Tuan RS: Glucosamine promotes chondrogenic phenotype in both chondrocytes and mesenchymal stem cells and inhibits MMP-13 expression and matrix degradation. Osteoarthritis Cartilage 2007;15:646–655.
7 Oegema TR Jr, Deloria LB, Sandy JD, Hart DA: Effect of oral glucosamine on cartilage and meniscus in normal and chymopapain-injected knees of young rabbits. Arthritis Rheum 2002;46:2495–2503.
8 Christgau S, Henrotin Y, Tanko LB, Rovati LC, Collette J, Bruyere O, Deroisy R, Reginster JY: Osteoarthritic patients with high cartilage turnover show increased responsiveness to the cartilage protecting effects of glucosamine sulphate. Clin Exp Rheumatol 2004;22:36–42.
9 Yoshimura M, Sakamoto K, Tsuruta A, Yamamoto T, Ishida K, Yamaguchi H, Nagaoka I: Evaluation of the effect of glucosamine administration on biomarkers for cartilage and bone metabolism in soccer players. Int J Mol Med 2009;24:487–494.
10 Pavelká K, et al: Glucosamine sulfate use and delay of progression of knee osteoarthritis: a 3-year, randomized, placebo-controlled, double-blind study. Arch Intern Med 2002;162:2113–2123.
11 Food, Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective. Washington, DC, AICR, 2007.
12 Somogyi A, et al: Scientific issues related to Codex Alimentarius goals: a review of principles, with examples. Regul Toxicol Pharmacol 2011;60:161–164.