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Risking public health by approving some health claims? – The case of phosphorus

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Abstract

There is a well-established consensus on the many biological functions of essential nutrients, and related general function health claims will be soon authorised in the European Union. Such claims about the role of nutrients in the body's growth, development and functioning could provide a powerful marketing tool and significant increase in the consumption of specific food products. Even though these claims are scientifically substantiated, there are both health and ethical concerns about whether such claims should be allowed where the intake of these nutrients easily exceeds the recommendations and a bigger intake might have adverse affects. The case of phosphorus and its role in the maintenance of normal bone is discussed.

Key words
health claims, consumer protection, essential nutrients, adverse effects

Introduction

While the history of food legislation reveals a primary orientation to food safety, today there is also a strong focus on providing consumers with non-misleading information and an informed choice while ensuring the free circulation of goods. Recent years have seen progress with novel regulations on the use of health claims. In the European Union *Regulation (EC) No 1924/2006 on nutrition and health claims made on foods* entered into force in 2007 and its implementation has involved a steep learning curve for everyone. The principle underlying the regulation is that all health claims must be scientifically substantiated by generally accepted scientific evidence and pre-approved (Pravst, 2010). In the EU claims are scientifically evaluated by the European Food and Safety Authority (EFSA), an advisory body responsible for delivering scientific advice to Community institutions. Applying risk analysis methodology, the EFSA provides a reasoned scrutiny of a particular case in the light of all relevant knowledge about the subject, enabling authorities to make an informed decision (Szajkowska, 2009). It is in this final stage that health claims are authorised by the European Commission (EC). The regulation distinguishes between different types of claims, although in this communication I specifically focus on issues related to consumer health protection regarding some general function claims about the role of nutrients in the body's growth, development and functioning. The EFSA is finishing the evaluation of these general function claims in 2011 and the EC's authorisation of those with a favourable outcome is planned by the end of 2011.

Protecting the consumer

Health claims are a very convenient tool when it comes to marketing "healthy foods" and influence perceptions of different product attributes (Lahteenmaki et al., 2010). Consumers are very sensitive to health-related communications and the use of health claims is unfortunately often connected with intentions to mislead them. The latest analyses show that in some European countries health claims are now used with over 15% of commonly eaten packed foods (Lalor et al., 2010). It is clear that health claims legislation not only has a powerful impact on marketing, but also greatly affects companies' research, development and competiveness. Decisions on specific health claims in Europe are also carefully monitored by many non-European countries where influencing on local decisions.

Health claims on foods, particularly when connected with strategic commercial communications, can have a major impact on the sales and increased consumption of specific food products. This is a very important fact for both risk assessors and the regulator. Nutrient profiles should be prepared to exclude the use of health claims on foods with an overall poor nutritional status, but unfortunately this critical part of the legislation has yet to be implemented (Cappuccio et al., 2011).

In the last years the EFSA has published several scientific opinions on the substantiation of general function health claims; many of those were unfavourable. A cause-and-effect relationship has been established mainly for essential nutrients where there is a strong consensus among scientific experts. It was recently noted that the EFSA may rely on such a consensus and that, in these cases, it may not be necessary to review the primary scientific studies on the claimed effects (EFSA, 2010). This was also the case of phosphorus regarding bone maintenance (EFSA, 2009a) which I will use as an example of both health and ethical concerns relative to consumer protection.

The case of phosphorus

After calcium, phosphorus is the second most abundant element in the human body; approximately 85% of the 600 g of phosphorus in the body is found in the skeleton, while the remaining 15% is found in soft tissues and blood, largely as phospoproteins, phospolipids and nucleic acids (Geissler and Powers, 2005). In the bones it is mainly found as phosphate in the calcium salt hydroxyapatite. Obviously, there is well established consensus among scientists that an adequate phosphorus intake is needed for normal bone growth and development in children and for maintaining normal bone in adults. Indeed, an insufficient phosphorus intake would have serious consequences for the bone structure. In the health claim evaluation process a cause-and-effect relationship was confirmed by the risk assessor, but there was no evidence of an inadequate phosphorus intake in the general EU population (EFSA, 2009a). It is now up to the European Commission to decide on authorisation of the general function claim “Phosphorus contributes to the maintenance of normal bone and teeth.” It is noted that a claim about the importance of phosphorus for children's development was already authorised in 2009 by *Commission Regulation (EC) No 1024/2009* without any evidence of an inadequate phosphorus intake of children or adolescents.

Phosphorus is naturally contained in many foods and also added when food is processed. Unlike calcium, phosphorus is readily and efficiently absorbed at all levels of dietary intake (Calvo and Park, 1996). In the last few decades, phosphorus intakes have risen significantly due to the greater use of phosphate salts in food additives and cola beverages (Calvo and Park, 1996). The mean daily phosphorus intake of adults in European countries ranges between 1,017 and 1,422 mg, a level well above the current recommendations of about 700 mg/day (Elmadfa, 2009). Here I would like to discuss the concern that, although phosphorus is an essential nutrient, increasing its dietary intake above the current values might have negative effects for bone structure.

The homeostasis of calcium and phosphate is crucial for maintaining healthy bones during one’s lifetime and closely controlled by endocrine regulation, particularly by parathyroid hormone (PTH) and 1,25-dihydroxyvitamin D (the active form of vitamin D) (Geissler and Powers, 2005). Higher levels of PTH stimulate the release of Ca^{2+} from bone (stimulating bone resorption), decrease urinary loss of Ca^{2+} by stimulating reabsorption, and indirectly stimulate Ca^{2+} absorption in the small intestine (by stimulating the synthesis of 1,25-dihydroxyvitamin D in the kidney) (Geissler and Powers, 2005). In cases of the excessive secretion of PTH in response to low calcium levels in plasma, we may talk about *secondary hyperparathyroidism*, which is connected with bone loss.

There is good evidence that phosphorus loading depresses plasma calcium and stimulates PTH secretion; a high phosphorus intake has been shown to cause secondary hyperparathyroidism and bone loss in several animal models (Calvo and Park, 1996). Diets with a low calcium intake and high phosphorus intake also result in elevated PTH in humans (Calvo et al., 1988;Calvo et al., 1990). In relation to this, it is critical to note that calcium intake in the general EU population is only 508 - 1,047 mg per day, well below the D-A-CH (2000) recommendation (Elmadfa, 2009). There is currently no scientific consensus on whether a high phosphorus intake actually hinders the achieving of the optimal peak bone mass or contributes to bone loss. The potential negative effect of phosphorus intake on the calcium balance and skeletal mass was already assessed by the risk assessor in 2005 (EFSA, 2005). It was then concluded that no clinical studies had linked a high phosphorus intake to a lower bone mass in humans. Nevertheless, since then many scientific contributions discussing these issues have been published. Very recent cross-sectional studies on healthy premenopausal women confirm the negative effects of a habitual high phosphorus intake on the serum PTH level (Kemi et al., 2009;Kemi et al., 2010). In another study, acute and negative effects of a high phosphorus intake on Ca and bone metabolism were reported in a dose-dependent manner (Kemi et al., 2006). Further, the fact that an increased calcium intake does not completely counteract the effect of an increased phosphorus intake on bone was reported in an acute dose-response study in healthy females (Kemi et al., 2008). An excessive

dietary phosphorus intake was also recently suggested as a risk factor in cardiovascular morbidity and mortality (Shuto et al., 2009).

Health and ethical concerns

The use of health claims concerning phosphorus and its contribution to the maintenance of normal bone might not only encourage consumers to consume more phosphorus-rich foods, but also stimulate the producers of foods and food supplements to increase phosphorus contents to a level that would enable such claims to be made. Both health and ethical concerns arise as to whether such claims should be allowed and whether there is evidence of potential negative effects of a higher phosphorus intake, even though science is not yet clear on this issue. Paradoxically, if these concerns are actually confirmed the consumers of phosphorus-rich foods formulated to maintain bones might be surprised to learn that their bones are not in very good condition after all. To protect the consumer, such questions should be carefully addressed by both the risk assessor and regulator. In such cases touching on public health, it would also be necessary to stimulate the research community to undertake further detailed studies.

Conclusion

In conclusion, the precautionary principle must be mentioned as it is fundamental to ensuring consumer protection. This principle applies to situations where the scientific evidence is judged to be insufficient, inconclusive or uncertain and where indications emerge in a ‘‘preliminary objective scientific evaluation” that there are reasonable grounds to be concerned about a potentially dangerous effect on human health (Houghton et al., 2008).

In practice, there are three basic decision options in such cases. The two most obvious are either to authorise such claims on the basis of up-to-date risk analyses in which such concerns are found to be wholly unsubstantiated, or to reject them on the basis of possible risks arising by increasing the intake of specific nutrients. The EFSA’s scientific opinion on the substantiation of a health claim related to vitamin B6 and mental performance (EFSA, 2009b) may be regarded as a relevant precedent. In this case, the risk assessor concluded that such a claim would encourage the excess consumption of vitamin B6 and that it therefore did not comply with legal provisions whereby the use of health claims shall not encourage or condone the excess consumption of a food. However, the proposed conditions of use referred to intakes of B6 above the Tolerable Upper Intake Level (UL) (EFSA, 2009b), which is not the case with phosphorus where the UL was not established due to insufficient data (EFSA, 2005). A third and perhaps the best option would be to authorise the claim with specific conditions of use, i.e. preventing its use in fortified foods and food supplements. This solution would not provide food producers with motives to boost phosphorus content in foods, while they would simultaneously be able to use the claim on foods naturally rich in this nutrient. According to Article 10 of the Regulation, other specific conditions of use could also be set during the authorisation process, including a statement about the importance of a sufficient dietary calcium intake to obtain the claimed beneficial effect.

Author Disclosure Statement

The author is a member of the national Experts Group on Nutrition and Health Claims at the Ministry of Agriculture, Forestry and Food of the Republic of Slovenia and of the Nutrition and Health Claims Support Unit at the Nutrition Institute, Ljubljana, Slovenia. No competing interests exist.

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