

Ensuring the safety of vitamins and minerals: European risk assessors and risk managers address outstanding issues

Scientific bodies around the world have invested considerable time and resources in recent years in assessing the safety of vitamins and minerals. The US Food and Nutrition Board (FNB), the EU Scientific Committee on Food (SCF) and the UK Expert Group on Vitamins and Minerals (EVM) are some of the scientific bodies that have undertaken extensive reviews of vitamins and minerals in order to establish the boundaries of safe daily consumption.

However, risk assessment is only half the story. Authorities who are responsible for ensuring public health must translate this scientific information into policy and sometimes legislation. This process is commonly known as risk management. But does risk assessment provide risk management with the necessary answers? Is there sufficient understanding among risk managers of the meaning and implications of risk assessment? And does the risk assessors' task end with the completion of their opinions or should they also play a role in risk management? These were some of the difficult questions addressed to European risk assessors and risk managers at a European Academy of Nutritional Scientists (EANS) workshop held in Brussels in April 2003. During a frank exchange of views, actors involved in both elements of the risk analysis shared perceptions of the potential weaknesses of risk assessment and provided some pointers for future improvement of analysing vitamins and minerals. Some of the issues highlighted during the discussions are set out on the following pages.

How reliable is the risk assessment?

Risk assessment is only ever as good as the available data. Scientific bodies assessing the safety of vitamins and minerals are frequently faced with either inadequate or insufficient data. There may, for example, be insufficient data on the variability of individuals' sensibility due to factors such as age, gender and body weight. The absence of data in relation to children sets a particular problem for risk assessors. A lack of well-designed human studies of significant duration, and insufficient dose-response or exposure data may reduce the precision with which risk assessors can measure risk. Such uncertainty is not, however, accounted for by the risk assessor. In these cases, experts have to use their judgement on the scientific data available, for example, as to whether an effect on a given marker reflects long-term clinical effects or whether it is simply a homeostatic response. Where the quality and sufficiency of the data is questionable or where there is a possibility that certain population groups may be more sensitive to risk, this will be reflected in the establishment of a higher "uncertainty factor" and a lower "upper level of tolerable intake" (UL).

Why don't all risk assessment bodies reach the same conclusions?

In general, risk assessments of vitamins and minerals conducted internationally have provided relatively similar results. Where differences arise, this may be due to different selection of data or different interpretation of those data. Case studies presented at the workshop demonstrated this point. Interpretation of the weight of evidence associating vitamin A and the risk of hip fracture has led to different risk assessment conclusions by the US FNB, the EU SCF and the UK EVM. Taking into account recent epidemiological data on daily intakes between 1500µg and 3000µg vitamin A from food, the EVM acknowledged a potential risk that the SCF judged as not sufficiently established. Conflicting assessments of vitamin B₆ over the past five years are based on a disagreement as to the quality of studies conducted by Dalton and Dalton, which established an association between high blood levels of B₆ and sensory neuropathy. While the US FNB rejected the methodological weaknesses (no placebo control) and inconsistency of the results, the EU SCF chose to include these studies in their evaluation. Such differences reflect genuine differences in the judgements of those experts involved. However, large disparities in risk assessment results (US FNB: 100 mg/day; EU SCF: 25 mg/day) do not facilitate the work of the risk manager. Risk assessors and risk managers attending the workshop felt that such differences are not conducive to effective policy making, and that a consensus needs to be reached with some urgency. They proposed that international bodies come together to align risk assessment opinions for the purpose of clarifying their implications for risk managers and reducing the subsequent impact on international trade.

Is risk assessment accessible to risk managers?

Inconclusive risk assessment is not the only difficulty facing the risk manager. The terminology used by risk assessment bodies (“safe upper levels” by the EVM, and “tolerable upper levels of intake” by FNB and SCF) represent different values and may not coincide with risk managers’ general or legal understanding of “safe levels”. A clear understanding of what is being prescribed in risk assessment, namely the UL or the highest level of tolerable daily nutrient intake from all sources is required. The rationale for the UL must also be clear. A common misconception of risk managers is that they should apply an uncertainty factor to the assessed risk, when, in fact, all the elements of uncertainty have been taken into account during risk assessment. The uncertainties that have been taken into account, such as the limitations of the database, should be clear in risk assessment opinions.

What else influences the policy-making process?

Perception and understanding of the risk assessment process may influence the risk management measures chosen. In Germany, for example, concerns about the UL concept as used by the EU SCF have encouraged risk managers to consider additional safety factors during risk management. This may lead to more restrictive permitted levels of nutrients in foods and food supplements or, potentially, to prohibition of some nutrients. Risk assessors attending the workshop felt that, while risk assessment offers risk managers a range of options, use of additional uncertainty factors reflects a mistaken interpretation of the risk assessment process.

Like risk assessment, effective risk management may also be obstructed by insufficient data about populations’ current dietary patterns. Without such data, risk managers may be uncertain regarding the implications of risk assessment for specific population groups. Nevertheless, it is clear that certain nutrients, such as vitamin A, may be singled out for particular attention by risk managers due to the relatively small safety margin between the recommended intakes and the UL. Other nutrients, such as vitamin C, vitamin E, and most B-vitamins, could be grouped together for the purposes of risk management. An additional complication for risk managers in this respect is the need for an understanding of the limitations of food technology and that not all foods and nutrients lend themselves to fortification. The participants proposed that, in addition to risk of excessive intake, risk of insufficient nutrition is another element that needs to be considered by risk managers. In order to take into account all these elements, a risk management policy may ultimately reflect a balance of scientific risk assessment opinions, broader public health policy and simple pragmatism.

How can the interface between risk assessment and risk management be improved?

There has been a tradition in the EU to separate risk assessment as far as possible from the process of risk management with a view to ensuring scientific independence from political or legislative issues. However, it is increasingly being realised that separation of the two stages of risk analysis may be detrimental to effective outcomes. A constant dialogue would ensure that risk assessors and risk managers understand the needs and fully appreciate the implications of each others' work. "Effective and coherent co-operation between risk assessment, risk management and risk communication functions" are now written into the statutes of the new European Food Safety Authority (EFSA).

Risk managers attending the workshop challenged risk assessors to develop a framework for risk assessment that includes objective criteria and minimises the need for risk managers to use their individual judgement. This would, at least theoretically, reduce the risk of conflicting risk assessment opinions by scientific bodies and simplify the work of the risk manager. The risk managers felt that greater transparency in the areas of contention would be an additional way of facilitating their work. The workshop participants considered that, with scientific knowledge constantly evolving and the demands of risk managers changing, risk assessment should be subject to constant review.

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A full report of the EANS workshop will be published soon in the International Journal of Vitamin and Nutrition Research.