Positive Health magazine column: Robert Verkerk PhD, submitted 29 May 2007

HOW THE EU PLANS TO BAN THERAPEUTIC DOSAGES OF FOOD SUPPLEMENTS

We live in a world where risk is being used as the basis to regulate virtually every facet of our lives. School playground rules, passive smoking in pubs, hand luggage in aircraft – have all found themselves at the hands of the new breed of regulatory police – the risk assessment scientists. It would probably not be so bad if the science was a real science, but over the last three years, the ANH has spent a lot of time examining risk as it is applied to foods and food supplements. Our conclusions? Well, of course there are many – too many to allow for a proper discourse on this page. But one of the main take-home points is that the type of risk assessment being applied to food supplements is very different to that being applied to other classes of foods. And it is deeply inappropriate.

The newly developed art of so-called food supplements science (yes, it is more an art than a science, and what science there is, is certainly not good science) tries to do everything it can to ensure that all food supplements are safe to 97.5% or more of the population. This includes so-called vulnerable groups. The science is based on the most precautionary evidence available, science that may represent data that are outliers from that which is more widely accepted. This is how the much castigated paper by Dalton & Dalton (1987) gets used in an attempt to bring in a new maximum limit for vitamin B6 of a mere 10 mg a day – too little to be of therapeutic benefit to almost anyone. Even when the UK Expert Group on Vitamins and Minerals published its key 2003 report (EVM, 2003), for which they had been given the inside track on how Dalton and Dalton's paper was completely flawed, they still continued to use the paper.

This is not greatly dissimilar to the reliance by those responsible for risk assessments of beta-carotene on the ATBC (ATBC, 1994) and CARET (Omenn *et al* 1996) studies. These were studies done on lung cancer prone asbestos workers or smokers, in which *synthetic* beta-carotene was administered often for relatively short periods, starting generally well after the major exposure risks had occurred. These studies, shoehorned into a risk assessment framework such as the ones presently being considered for EU-wide application, may well limit us to less than 6 mg of beta-carotene daily. Putting this into perspective, that's less than you might find in a single healthy, carotenoid-rich carrot! And this maximum level will be applied to both synthetic *and* natural forms of beta-carotene, despite copious evidence that high doses of natural carotenoids in the diet substantially reduce our risks of chronic diseases like heart disease and cancer.

So, I hear you ask, how come such fundamental problems are allowed to find their way through teams of supposedly well-meaning scientists, working in the interests of the European Commission and EU Member State governments? The most important reasons for this in my opinion are three-fold:

1. **Inappropriate reliance on the 'precautionary principle'**, which is now rife through all aspects of the risk assessment process in the EU. Designed originally for the laudable task of protecting penguins, whales and rainforests, this principle has been misapplied to food and food supplements. It entered the EU almost silently in 2002 in the EU Directive that established the Parma-based European Food Safety Authority and we now increasingly see its catastrophic effects. The principle basically says that where there is scientific uncertainty, the most cautious legal measures should be taken – and of course this opens the door to making sure that laws are in place which ensure that we are exposed to no more beta-carotene than that which might make a diseased smoker or asbestos-worker ever so slightly more prone to lung cancer.

2. **Ignoring the benefit tail**. Foods and food supplements act in a two-tailed manner, the effects of inadequacy give rise to one side or tail of risk (its corollary being benefit), while the effects of excess provide the more commonly viewed tail. But if you want a system that ensures that 97.5% of the population is guaranteed to be safe, allowing for sometimes dodgy and often incomplete science, you end up limiting the dosages to such an extent that some people, who have greater individual or genetic needs, can't get enough! But, when it comes to good old risk assessment science as applied to food supplements, this benefit tail is simply ignored. If we used the same one-tailed approach currently used for food supplements on conventional foods, please understand that all foods containing dairy, wheat, gluten and – of course – peanuts, would be banned. This is simply nonsense. The way around handling such potential risks, is through the risk *management* process of label warnings – not directly in risk *assessment*, where legally enforced bans are the inevitable outcome.

3. **Prejudice or unwitting bias**. This simply can't be ignored. Those at work to develop risk assessment for the EU, and other major health authorities around the world, seem so often to be rather close to pharmaceutical interests, and of course their prime expertise is with pharmaceutical substances, which act in particular pharmacological and pharmacokinetic ways. It is sometimes difficult to know how much of the bias these risk assessment scientists show is down to deliberate use of bad science for the purpose of limiting beneficial doses of food supplements. The obvious end game of such an approach would be that we would then be forced into the orthodox world of pharmaceutical healthcare whenever major health challenges arose. But there is also the possibility that some of the bias is unwitting. If you have had no experience of the beneficial effects of food supplements, and if your remit specifically excludes looking at this side of the science (who was responsible for this madness?), it is just possible that you could end up supporting the bad science that is increasingly becoming accepted as the norm.

So – if you care about the future of therapeutic food supplements, or the sustainability of natural healthcare, please don't just read this and do nothing. All therapeutic dosages are at grave risk from the EU regulators, and European Commissioner Kyprianou has made clear in January 1997 that it is the Commission's intention that food supplements should not be therapeutic (European Commission website, 2007). This is a time for action!! We are in the process of launching a major campaign initiative on this issue – so keep your eyes peeled to our website (www.anhcampaign.org) or, to find out how you can get involved, telephone our office in Dorking, Surrey, on 01306 646 600. Thank you.

References

Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group. The effect of vitamin E and beta-carotene on the incidence of lung cancer and other cancers in male smokers. *New England Journal of Medicine* 1994; 330: 1029-1035.

Dalton K, Dalton MJT. Characteristics of pyridoxine overdose neuropathy syndrome. *Acta Neurol Scand* 1987; 76: 8–11.

European Commission website, January 2007. Collective response by Commissioner Kyprianou concerning the establishment of maximum amounts in food supplements. *http://ec.europa.eu/food/food/labellingnutrition/supplements/coll_answer_en.htm*

EVM. *Safe Upper Levels for Vitamins and Minerals*. Food Standards Agency, London. *http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf*.

Omenn GS, Goodman GE, Thornquist MD, Balmes J, Cullen MR, Glass A, Keogh JP, Meyskens FL, Valanis B, Williams JH, Barnhart S, Hammer S. Effects of a combination of beta-carotene and vitamin A on lung cancer and cardiovascular disease. *New England Journal Medicine* 1996; 334: 1150-1155.