

Who says Codex isn't a risk to nutritional therapy in Australia?

*This article arose from recent conversations between the Alliance for Natural Health and Michael and Alex Hall of BioCeuticals. BioCeuticals recently joined the Alliance for Natural Health's newly established Innovators' Club and are keen to do whatever they can to protect the future of natural healthcare. Michael and Alex remain unconvinced the existing regulations for nutritional substances in Australia will not be changed by future governments to bring them in line with what is alarmingly occurring in Europe. They believe it is imperative the Europeans resist the implementation of what can only be called draconian restrictions. In this article, **Dr Robert Verkerk, ANH's Executive & Scientific Director**, explains why he feels Michael and Alex are right to be concerned.*

The Australian Therapeutic Goods Association (TGA) has long espoused a view that Codex will not impact the Australian natural health industry. The Australian regulator's key argument has been the Codex Alimentarius Commission, created in 1963 by the Food & Agricultural Organization (FAO) and the World Health Organization (WHO) of the United Nations, deals with setting international guidelines and standards for food products, not medicines. Since the TGA - at odds with many governments including those of Europe and the United States - views natural healthcare products as medicines, the TGA argues these products therefore fall outside of the Codex/food remit.

So far, so good. But things aren't this simple. If they were, you might think the Australian Government would not be interested in playing such an active role in the key Codex Committee that deals with matters of nutrition. This couldn't be further from reality: the Australian delegation is not only a very active participant in the relevant Committee, it also heads up one of the most important working groups - one that deals with the pivotal area of risk assessment. The Committee in question is the Codex Committee on Nutrition and Foods for Special Dietary Uses (more commonly referred to by its acronym, the CCNFSDU, that, after some practice, begins to roll off the tongue with moderate ease).

The CCNFSDU's annual meeting, of which there have been 27 to date, has typically been in Bonn, Germany, conveniently close to the CCNFSDU's ideological heart in the Berlin-based Federal Institute of Risk Assessment (BfR: Bundesinstitut für Risikobewertung), an organization that few would argue carries a very substantial, if not disproportionate, influence in the CCNFSDU's proceedings. This process is aided by the fact the CCNFSDU's chair is none other than Professor Rolf Grossklaus, who also heads up BfR's research group on 'dietary foods, nutrition and allergies'. Some of you might be aware of another BfR stalwart, Professor Hildegard Przyrembel, who works very closely with Prof Grossklaus. Prof Przyrembel is one of the prime movers behind the European Commission's plans to set maximum permitted levels for vitamins and minerals, following a more or less identical process to that being contemplated by the CCNFSDU. The International Alliance for Dietary Supplement Associations (IADSA), an umbrella organisation for national and regional natural products industry trade associations worldwide, has been busy putting Prof Przyrembel on its conference circuit, presumably in an attempt to get people used to what the BfR has in mind for us.

What's wrong with the BfR model?

We've established thus far the BfR exerts a good deal of control over nutrient risk assessment, both in Codex and in Europe. Let's now take a closer look at how the BfR interprets what is deemed safe or unsafe.

For a biological process that is remarkably complex - namely the interaction of nutrients with which we have evolved over millennia, with a diverse range of genotypes - the overarching model used in conventional risk assessment is remarkably simple. As scientists, we tend to agree you should always use the simplest model that does the job adequately, but using a model that over-simplifies complex interactions can lead to problems - big problems at that.

In essence, the model has two parts: the first part aims to develop an Upper Safe Level (USL), while the second 'dumbs' these down to the maximum amounts permitted in supplements.

The USL is derived for each nutrient group, giving you an output which tells you the highest level of all nutrient forms within that group that can be taken safely by the vast majority of people. This USL (the process by which it is derived now having been endorsed by an Expert Panel of the FAO/WHO)¹, is derived by estimating, with help from existing studies published in the peer reviewed literature, the No Observable Adverse Effect Level (NOAEL) i.e. a level where you are very sure there is no risk of any 'adverse effect' (but of course with no requirement to suggest this level is either close or distant from that which will yield adverse effects in some people), and then 'adjusting' (= lowering) this NOAEL by dividing it by some arbitrary 'uncertainty factor' to give the USL.

In layperson's terms, you are taking a level that is already viewed as safe from the literature and dividing it, to further increase the level of safety, from an already safe level by an arbitrary factor, which might be 3, or 10 or even 100. Using this first part of the model, you end up with USLs such as the 1000 or 2000 mg/day for vitamin C (see Table below). The reason we don't see USL's higher than this for vitamin C is some people are on the cusp of bowel tolerance at these low levels, some of the time - and this is documented in the literature (they of course don't tell you that divided doses would never give rise to such effects, in anyone). Therefore, using this model, it's not possible to consider the *benefits* (and lack of adverse effects) some of us derive from taking 10 or more times these dosages on a daily basis.

The regulatory end-point of this so-called 'scientific risk assessment process' is of course not the first part of the model that gives you the USL. So if you think 1000 or 2000 mg a day is manageable, think again. How about a BfR-friendly 225 mg daily as the maximum allowable amount? It's the second part of the model that gives you these sorts of problematic Maximum Permitted Levels (MPL) for so many nutrient forms - and as consumers or practitioners it's these MPLs we need to worry about more than the USLs, which are simply intermediate points in the MPL determinations (see Figure overleaf).

To derive an MPL using the existing models contemplated by Codex and the EU, you start with the USL and then you subtract the amounts of a given nutrient type people ingest from their normal diet, based on national dietary surveys, which, incidentally, take into account we all consume fortified foods (I can't remember the last time I sampled those vitamin and mineral-enriched breakfast flakes made from corn that are popular with those that like to eat the spoils from those Golden Arches [or was that Starches?] restaurants).

Adding insult to injury, the risk assessment brigade then take into account any further adjustments that might be required for sensitive population sub-groups. You'll remember, for example, the ATBC² and CARET³ trials on beta-carotene that were conducted on smokers and asbestos workers who were dosed with large quantities of synthetic beta-carotene. As irrelevant as these studies are to those of us interested in supplementing with natural forms of mixed carotenoids, we will now be forced to assume we are in fact all smokers or asbestos workers who must in turn feel concerned, despite somewhat flawed or irrelevant experimental designs in the trials, that we might suffer a higher risk of lung cancer if we ingest levels of beta-carotene (regardless of source) in excess of around 7 mg/day. This is, in principle, akin to banning peanuts, dairy and wheat products as a means of protecting those with peanut, dairy or wheat allergies or intolerance! This amount of beta-carotene incidentally equates to the amount of natural beta-carotene you might get in a reasonable side serving of carrots.⁴

¹ Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment WHO Headquarters, Geneva, Switzerland, 2-6 May 2005, *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, FAO/WHO, 11 January 2006 (http://www.who.int/ipcs/highlights/full_report.pdf).

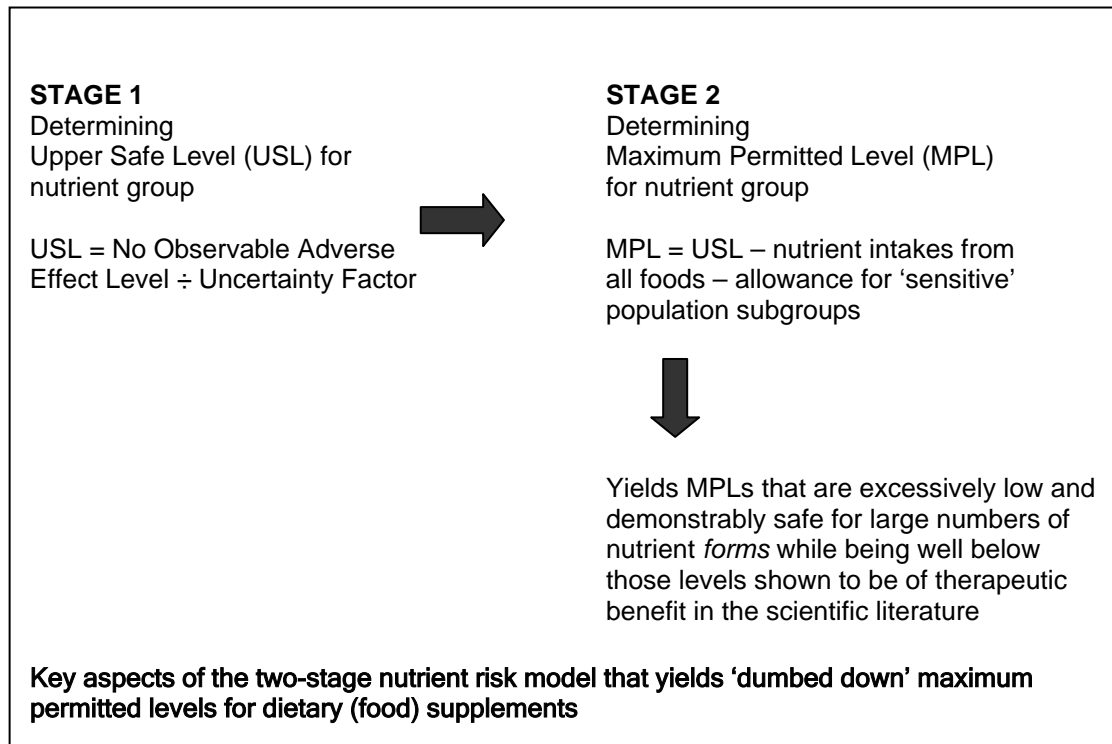
² Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group. The effect of vitamin E and beta-carotene on the incidence of lung cancer and other cancers in male smokers. *New England Journal of Medicine*, 1994; 330: 1029-1035.

³ 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 of Medicine*, 1996; 334: 1150-1155.

⁴ Bulux J, Quan de Serrano J, Perez R, Rivera C, Solomons NW. The plasma beta-carotene response to a single meal of carrots in Guatemalan schoolchildren. *Int J Food Sci Nutr.*, 1998, 49: 173-9.

The results are also at odds with the much more appropriate, longer running and larger Physician's Health Study.⁵

Let's remember then, if we used this same two-stage approach (see below) in other areas of food law, we would see bans on foods as commonplace as peanuts, dairy and wheat products!



From saving seals.....to banning nutrients

At the heart of all this scientific irrationality is a principle that has absolutely nothing whatsoever to do with pure science. It is the ‘precautionary principle’ that first came to the fore, belatedly yet aptly, with the Rio Declaration in 1992 as means of protecting whales, dolphins, seals and rainforests, in the face of scientific uncertainty.

When the European Food Safety Authority was established in 2002 under an EU Regulation, the Rio Declaration, intended for the protection of the environment, was transposed to health policy in the European Union. Unfortunately, its applicability to EU food supplement law was firmly clarified by the European Court of Justice, in its ruling on the Alliance for Natural Health’s case challenging EU-wide bans on food supplements.

The precautionary principle has been misapplied to health policy and food supplement law in Europe and now may provide one of the greatest obstacles to freedom of choice in healthcare. This problem is demonstrated clearly in a recent paper published by Dr Jaap Hanekamp of the HAN Foundation in the peer reviewed journal *Environmental Liability*.⁶

⁵ Hennekens CH, Buring JE, Manson J-A E, Stampfer M, Rosner B, Cook NR, Belanger C, LaMotte F, Gaziano JM, Ridker PM, Willett W, Peto R. Lack of effect of long-term supplementation with beta carotene on the incidence of malignant neoplasms and cardiovascular disease. *New England Journal of Medicine*, 1996; 334: 1145-1149.

⁶ Hanekamp H, The precautionary principle: a critique in the context of the Food Supplements Directive. *Environmental Liability*, 2002, 2: 43-51. The article can be downloaded from: http://www.alliance-natural-health.org/docs/ANHwebsiteDoc_239.pdf.

What does the BfR model do to nutrient 'maximum permitted levels'?

The best way of testing or validating a model is to put real data into it. That's what the BfR did and one of the biggest concerns has to be its enthusiastic response to the result! The BfR was apparently thrilled to be the first to determine what a Codex or European approach to scientific risk assessment would do to maximum levels of vitamins and minerals (these levels are summarised in the right-most column of the following table). If you are either a nutritional therapist or a consumer, I would suggest you study the table carefully to see if you think you could live with these levels as maximum permitted daily amounts for supplements.

Vitamin	Upper Safe Levels			Maximum Permitted Levels
	USA (Food & Nutrition Board)	EU (European Food Safety Authority)	UK (Expert Group on Vitamins and Minerals)	Germany (BfR)
Vitamin A (mcg)	3000	3000	1500	800
Beta carotene (mg)	Not set (for smokers)	Not set (for smokers)	7 mg (0 mg for smokers)	4
Vitamin C (mg)	2000		1000	225
Vitamin D (mcg)	50	50	25	5
Vitamin E (mg)	1000	300	540 (800 IU)	15
Vitamin K (mcg)	Not set	Not set	1000	80
Vitamin B1 (mg)	Not set	Not set	100	1.3
Vitamin B2 (mg)	Not set	Not set	40	4.5
Niacin (B3) (mg)	35	900	500	17
Vitamin B6 (mg)	100	25	10	5.4
Folic acid (B9) (mcg)	1000	1000	1000	400
Vitamin B12 (mcg)	Not set	Not set	2000	9
Pantothenic acid (mg)	Not set	Not set	200	18
Biotin (mcg)	Not set	Not set	900	180

Mineral	Upper Safe Levels			Maximum Permitted Levels
	USA (Food & Nutrition Board)	EU (European Food Safety Authority)	UK (Expert Group on Vitamins and Minerals)	Germany (BfR)
Potassium (mg)	Not set	Not set	3700 (suppl)	2000
Calcium (mg)	2500 (total)	2500 (total)	1500 (suppl)	1200
Phosphorus (mg)	4000	Not set	250 (suppl)	1250
Magnesium (mg)	350	250	400	400
Iron (mg)	45	Not set	17	15
Iodine (mcg)	1100	600	500	200
Fluoride (mg)	10	Not set	Not set	3.8
Zinc (mg)	40	25	25	10
Selenium (mcg)	400	300	200	70
Copper (mg)	10	5	10	1.5
Manganese (mg)	11	Not set	4	5
Chromium (mcg)	Not set	Not set	10,000	100
Molybdenum (mcg)	2,000	600	0 (suppl) 230 (diet)	100

Only a very brave, or misinformed, person would argue the BfR levels, or levels close to them, applied in law wouldn't decimate nutritional therapy.

What's all this got to do with the TGA?

In principle, exactly the same two-stage procedure for setting upper and maximum levels that has been adopted in Europe (under Article 5 of the Food Supplements Directive) has now been adopted by the CCNSFDU (November 2004), with rather a lot of help from the BfR and their friends in the European Commission.

If the BfR maximum levels, or similar, are adopted by Codex and implemented through an international guideline (the notional end game of this part of the CCNFSDU's terms of reference), it is then almost inconceivable the TGA won't take any notice of these levels. How can they ignore them? The procedures were, after all, developed following international scientific consultation and the Australian authorities were involved in the process every step of the way. The Australians even oversaw all the work on risk assessment and rubber stamped it! Perhaps even more tellingly, the Australian government delegation has not attempted to alter the course of the procedure during the last 10 or so years of its development. The same argument can of course also be applied to the United States – the US regulators have been following and have been involved with this process from the year dot and are therefore party to it. Full stop.

What now?

The ANH's work on risk/benefit assessment is one of our highest priorities. We were the first to identify major flaws in the key models being adopted to evaluate the safety of nutrients by US and European regulators, in December 2004.⁷ Presently, major submissions are being prepared by us for presentation to the European Commission by the end of September and we have also made key contributions to the Australian-led Electronic Working Group on Risk Assessment for the CCNFSDU to be held in Thailand this November. Our submission was made via the only health freedom organization with delegate status at the CCNFSDU, namely the US-based National Health Federation.

We are also working closely with the Netherlands-based HAN Foundation (a risk assessment institute) on a range of peer reviewed papers in this area which critique the existing models, and crucially, given ANH's resolve to always find a solution to an identified problem, we are in the process of building an academic team that can work to build a new risk/benefit assessment model specifically designed for nutrients. This model will be one of 'intermediate complexity' that much better deals with the intricacies of interactions between different nutrient forms and human genotypes.

How can you help save nutritional therapy?

If your house was on fire, would you just stand by and watch it burn without doing anything? The ANH is fighting fires on many fronts, for the consumer, for the practitioner and for the innovative food supplement manufacturers, to name a few. But we can't do it alone. We are a not-for-profit organisation set up by a small, concerned group of scientists, doctors and lawyers, to promote and protect natural healthcare worldwide using good science and good law and we are funded solely by donations.

Please spend a moment or two thinking about how all of this, if unchallenged, could impact on the future of nutritional therapy – worldwide. Please also take the time to visit our website at www.anhcampaign.org or our new funding site at www.fundan.org and make a donation. By so doing, amongst other things, you will be contributing to a new model of risk/benefit assessment – a model that will stand scientific scrutiny and help build nutritional healthcare as the default healthcare approach for the future.

⁷ Alliance for Natural Health submission to the FAO/WHO Nutrient Risk Assessment Project, December 2004 (http://www.alliance-natural-health.org/_docs/ANHwebsiteDoc_121.pdf).

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