

RE-EVALUATING THE EU THREAT TO NUTRITIONAL PRACTITIONERS

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Practitioners have long felt comforted by scientific evidence which supports the use of particular therapies. We have become accustomed to recognising that it is rare to find, in the published, peer reviewed literature, unanimous support for a particular therapy. We recognise that contradictory findings can often result from huge differences in methodologies between studies. However, when positive research findings coincide with positive clinical experiences, the latter of course being both more realistic and relevant, we breathe a sigh of relief and the practitioner invariably delivers the therapy with confidence. This assumes, of course, that the product is still available on the market, in the appropriate formulation and dosage.

Three particular pieces of EU regulation are set to rock this *status quo*. One of them, the amending EU Human Medicinal Products Directive (Directive 2004/27/EC), as its code name indicates, has now been around for over 3 years. The second, the Nutrition & Health Claims Regulation (Regulation [EC] No 1924/2006), is a newcomer, having just come into force EU-wide on 1 July 2007. As an EC Regulation, unlike a Directive, it does not need to be transposed into the legislative system of Member States before coming into force. The third is the familiar Food Supplements Directive (Directive 2002/46/EC) whose provisions currently only limit vitamin and mineral ingredients.

Clinical nutritionists, nutrition therapists, ecological physicians and others who use nutrition as the primary modality in healthcare by and large rely on food and nutritional products that are legally regarded as foods. The products on which these professions rely could not be supplied at their current diversity and price should they be re-classified as medicinal products. A drugs licensing regime, or a 'medicinal products marketing authorisation procedure' as the EU prefers to refer to it, is prohibitively expensive for the majority of small to medium-sized enterprises (SMEs) that have pioneered therapeutically-active nutritional products. So—it is paramount that the nutritionist's toolbox remains populated with food, rather than medicinal, products. Food supplements, under EU law, are a category of food, in the sub-group food supplements, which are defined as concentrated sources of nutrients, delivered in dose form. Amino acids and even nucleotides, are also categorised under EU law as food, but as sub-group referred to as 'foods for particular nutritional uses' (abbreviated to PARNUTS, and covered by a specific series of Directives¹).

¹ Base Directive 89/398/EEC, amended five times, most recently in 2006. As of 1 April 2004, all PARNUTS products must comply with a positive list (included in amending Directive 2001/15/EC, and appended twice, Directive 2004/5/EC and Directive 2006/34/EC).

How EU regulations could decimate the nutritionist's toolbox

Let's look at each one of the three pieces of offending EU regulation in turn.

Human Medicinal Products Directive

This Directive was originally issued in 1965, ostensibly to protect consumers from disasters such as thalidomide. However, ironically, the definition of what constitutes a 'medicinal product' as laid out in Directive, is so broad that it effectively makes all food products, even water, drugs. The second, so-called *functional* limb of the definition encompasses anything at all which is used "with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

The first limb, the *presentation limb*, is the more familiar no-go area for nutrition, which means any food that is "presented as having properties for treating or preventing disease in human beings" will be classified a medicine by any EU regulator whose attention is drawn to the fact. To be regarded as a 'medicinal product', it is important to recognise that a product need comply with *either*, rather than both, limbs of the definition.

You might be wondering why we are so concerned given the decades that the presentation and functional limbs of this definition have been around in similar forms. There are four answers to this: firstly, only in the most recent amendment of the Directive (2004) has the phrase "exerting a pharmacological, immunological or metabolic action" been added, leaving no doubt that any type of physiological effect in the body could be construed as medicinal; secondly, the original, base, 1965 Directive had exclusions in it for food (and "toiletries" as it happens, later, of course more commonly referred to as cosmetics!); thirdly, although exclusions for such things such as foods and cosmetics still exist, it has been transferred to the preamble section (the recitals) of the *amending* Directive, where it has no firm legal authority;² and fourthly—and, probably most importantly—the most recent amendment now also indicates that "in cases of doubt" and where the definition of a medicine applies even if the product is already covered under other aspects of EU legislation (e.g., foods), medicinal classification has supremacy.³

This paves the way for the arbitrary re-classification of any food product as a medicinal one, by any EU 'competent authority' i.e., those national authorities

² An extract of Recital 7 of amending Directive 2004/27/EC states: "where a given product comes under the definition of a medicinal product but could also fall within the definition of other regulated products, it is necessary, in case of doubt and in order to ensure legal certainty, to state explicitly which provisions have to be complied with." The ANH has secured a legal opinion (14 December 2003) from Brick Court Chambers on the authority of this Recital in relation to Article 2(2), and the Opinion indicates that because, in legal terms, Articles have supremacy over Recitals (particularly in amending directives), Article 2(2) effectively "emasculates the food supplements regime under the FSD and results in the application to those products of a regime designed for an entirely different type of product which is liable to be less suitable."

³ Article 2(2) of amending Directive 2004/27/EC states: "In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply."

responsible for policing medicinal law. In the UK, this means the Medicines and Health products Regulatory Agency (MHRA).

Short of challenging the legal uncertainty brought about by this unacceptably broadly defined law through the courts (one option for the ANH, funding being the limiting factor), we must live in hope that medicine regulators around the EU choose to exercise their extraordinarily far reaching powers in a reasonably responsible way. However, a number of recent cases, in the UK and Germany in particular, would suggest the regulators do not always act reasonably in relation to their legally prescribed powers. Take for example the case of Jim Wright, a Welsh, small-scale supplier of supplements, who was criminalised for selling one pot of vitamin B-17 (regarded as an unlicensed medicine by the MHRA) on 14 December 2007. The fact remains that the MHRA and BBC worked to entrap him, acting covertly as potential clients. They charged him for selling one pot of the vitamin that he had on hand in his office as old stock (prior to it being made illegal as a food supplement in 2001). They urged him to part with the vitamin pot following the covert team's presentation of an emotional story about one of them dying of cancer and their need for the B-17 as a life-saver.

Nutrition & Health Claims Regulation

The Advertising Standards Agency (ASA) has challenged many health claims made on magazine and television advertisements, posters, websites and other marketing materials that they believe either cannot be adequately substantiated or are untruthful. The mechanism for such challenges is the CAP code.⁴ However, the Nutrition and Health Claims Regulation (NHCR) has the power to override everything. It will take several years to come fully into force⁵, but, like the majority of EU laws, operates on principles derived from the Napoleonic Code, which formed the basis of the legal systems of France and most continental European countries, rather than the common law system, the legal system developed among Anglo-Saxon people, especially in England.⁶

In short, one key element of the NHCR is its remit to effectively ban all health claims made on foods and nutritional products, *unless* they are specifically allowed.⁷ Fortunately, the Regulation allows for some degree of national competence (although which Member States will be interested?) and in the Regulation's preamble, it usefully heeds Article 5 of the European Treaty which relates to the principle of

⁴ See http://www.asa.org.uk/asa/codes/cap_code for further information. Particularly relevant to health claims in advertising are CAP Code clauses 3.1 (Substantiation) and 7.1 (Truthfulness). [last accessed 7 September 2007].

⁵ The EU is mandated under the NHCR to enforce permitted claims by 31 December 2010, at the latest.

⁶ The Napoleonic Code was the French civil code, established under Napoléon I in 1804. To take the simplest interpretation of a key difference between the Napoleonic Code and common law, common law assumes that a person is innocent until proven guilty, while the Napoleonic Code dictates that the state can convict a person of a crime unless that person can prove him or herself innocent. Translating this interpretation to food law or health claims, this means that, under certain EU Directives or Regulations (which are in turn based on the Napoleonic Code), a food ingredient or health claim can be banned unless it is specifically demonstrated to be plausible, valid or safe.

⁷ The NHCR states under Article 10: "Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14."

subsidiarity. Recital 34 indicates: “this Regulation does not go beyond what is necessary in order to achieve that objective” (which is stated earlier in the same recital as “to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection”).

Worse than this, the NHCR applies itself not only to health claims made on product labels or in advertising (most practitioners are accustomed to products bearing no health claims), but the Regulation invades all aspects of communication and presentation, including, we would interpret, speech.⁸ The NHCR defines a health claim as: “any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.” This is the central domain within which any nutritional practitioner operates during the course of his or her duties.

A practitioner that recommends or sells a product is likely, under the NHCR, to be characterised as a “food business operator” – and as such, the NHCR applies. Furthermore, the NHCR specifically bars anyone making any claims that are attributable to medical doctors or complementary medical associations (while potentially giving *carte blanche* to orthodox medical associations and pharmaceutically-funded health-related charities).⁹ This regime forces everyone in the natural health arena into the onerous scientific substantiation process established for the Regulation.

So, what sort of health claims will be authorised? There are essentially two sorts of health claims that are in the process of being developed:

1. Generic *function* claims for ingredients in foods and food supplements (under Article 13) e.g., maintains healthy cholesterol *or* helps to control blood pressure.
2. *Disease risk reduction* (and *child health*) claims (under Article 14) e.g., lowers blood cholesterol *or* reduces blood pressure. Such claims will require a considerably higher level of scientific substantiation, and as such, will likely be accessible mainly to large, well funded corporations such as major pharmaceutical or agri-food businesses.

On 20 July 2007, the Standing Committee on the Food Chain and Animal Health released its opinion on certain key areas of interpretation of the Regulation. Some of the key points to emerge were:

⁸ The NHCR applies to any aspect of **presentation** of a claim, in any commercial situation, including where a practitioner is recommending/selling a product. Article 1(2) states: “This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, **presentation** or advertising of foods to be delivered as such to the final consumer, including foods which are placed on the market unpacked or supplied in bulk.” [the term ‘presentation’ has been bolded for emphasis].

⁹ Article 12 of the NHCR states that “claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11” are disallowed, while Article 11 indicates: “In the absence of specific Community rules concerning recommendations of or endorsements by national medical associations and health-related charities, relevant national rules may apply in compliance with the provisions of the Treaty.”

- Clarification on the differentiation between a health claim and a nutrition claim. For example, “source of” [a given nutrient] claims will be allowed as nutrition claims, whereas “contains” claims may be either nutrition claims or health claims, the latter applying if there is any implication of a health effect. Therefore “contains antioxidants” will be regarded as a health claim and will necessitate approval through the claims authorisation procedure. The claim “contains lycopene” on the other hand will be regarded as a nutrition claim.
- The Standing Committee has also provided clarification on the borderline between a functional claim (Article 13) and a health claim (Article 14). Functional claims refer to normal, vital functions of the body whereas reduction of disease risk claims refer to reduction of specific disease risk factors. When the function claims mention a disease risk factor generally recognised by scientific evidence, it is considered as an Article 14 claim if a reduction of this risk factor is mentioned.
- The Standing Committee emphasised that all claims are subject to the general principles laid down in Articles 3 and 5 of the Regulation. In the case of “contains” claims (nutrition or health claims), this means notably that the substance subject to the claim is present in significant quantity *and* has been shown to have a beneficial nutritional or physiological effect.

Any reader will have noted that there is a clear contradiction between the NHCR, which is intended for foods, and the Human Medicinal Products Directive, which deals with medicines. NHCR allows for authorised health claims on foods, which by their very nature, suggest physiological or metabolic effects on the body which force them to fall under the remit of the functional limb of the definition of a medicine. Astute readers will also recall that Article 2(2) of the Human Medicinal Products Directive also provides the supremacy clause for medicinal law, which has power over any other EC law. This merely serves to demonstrate how laws conflict and overlap, and, in practice, means law enforcers will follow precedents set in the wake of legal challenges. This is why the ANH’s targeted legal and scientific strategy is of such key significance to developing the future legal framework for natural health.

The total impact of the NHCR to practitioners is likely, in the course of time, to be considerable, although it will ultimately depend on how businesses progress with authorisation of claims (function and disease risk reduction), how the European Food Safety Authority (EFSA) conducts the evaluation process of such claims, and if any latitude is given in individual Member States, such as the UK, under the principle of subsidiarity. Turning a blind-eye to practitioners is one way forward, but a recent case of a Harley Street practitioner being exposed by a journalist posing as a client, armed with a covert camera, soon to be televised nationally, may provide an incentive to impose tight controls on what practitioners communicate.

Since “nutrition and health claims shall be based on and substantiated by generally accepted scientific data” (Article 6, NHCR), the ANH has been particularly active in highlighting deficiencies in the likely requirements for scientific substantiation. There has been strong inclination by the European Commission and EFSA to support data packages in which evidence from randomised clinical trials is the key requirement (providing what is referred to in the Regulation as “generally accepted scientific

data”). Epidemiological and observational evidence, and supporting biochemical evidence, is typically regarded as being inadequate, if not also supported by randomised clinical trials. On this basis, most foods that are more or less unanimously regarded as ‘healthy’, could not be substantiated as being so. Therefore, it is vital that a more flexible and scientifically meaningful approach is developed towards scientific substantiation, and such an approach is central to ANH’s efforts in this area.

Maximum Permitted Levels of vitamins and minerals in food supplements

Nutritional therapy has long been based on using dosages of vitamins and minerals that are substantially higher than those typically found in the average, contemporary diet. Markos Kyprianou, the (unelected) European Commissioner responsible for health and consumer protection, made clear in January 2007 that the European Commission does not wish to allow sale of therapeutically active food supplements.¹⁰

So, while many countries in Europe have regulated maximum levels of vitamins and minerals via multiples of the Recommended Daily Allowance (RDA), the European Commission and EFSA is in the late stages of planning the methods it will use to develop EU-wide, harmonised, maximum permitted levels for food supplements and fortified foods. This process will be instigated legally through an implementing measure of the Food Supplements Directive.

A harmonised European market for maximum (and minimum) dosages will no doubt be of considerable benefit to large corporations, especially the pharmaceutical companies that dominate the low-dose end of the supplement market, as they will no longer need to reformulate products for specific EU markets. Low doses EU-wide are also regarded by many regulators as a useful end-point for meeting the Food Supplements Directive’s requirements for a “high level of consumer protection”. Nutritional therapists may, of course, take a different view, since they are much more likely to recognise the two-tailed nature of risks associated with nutrients. At very low levels of intake there are risks of inadequacy (that go well beyond simply the risk of developing deficiency diseases, but of course significantly impact the risk of chronic and even infectious diseases). At high or very levels of intake of some nutrient forms, there are, of course, potential risks associated with excessive intake. This may be particularly true of certain fat soluble vitamins, especially synthetic, isolated forms, and also some minerals, that have a somewhat narrow beneficial and therapeutic dose range (e.g. selenium, vanadium). Complicating matters even further, practitioners are also much more cognisant of the differences between short and long-term exposure. Short-term, high dose therapy with certain nutrients may in fact be highly beneficial (e.g., B vitamins), while the risks associated with long-term exposure, which are generally mild, transient and fully reversible, unlike many side effects associated with pharmaceutical drugs, are well recognised.

¹⁰ Collective response made by Commissioner Kyprianou in January 2007 in relation to letters received about the European Commission’s plans to set maximum permitted levels of vitamins and minerals in food supplements. An extract follows: “...it is important to note that food supplements are regulated as food and are intended for supplementing the normal diet rather than having therapeutic effects. In fact, claims as to treatment, cure or prevention of disease would not be allowed for food supplements and would place the product under the legal framework of medicines.” Source: http://ec.europa.eu/food/food/labellingnutrition/supplements/coll_answer_en.htm. [last accessed 7 August 2007].

So how is the EU looking to take into account these differing requirements? An obvious approach, which has never been seriously contemplated by the EU authorities, is to develop a bespoke regime for practitioners—a third category, that exists between food and medicines. Whether the absence of a ‘third category’ has been the result of pressure from the pharmaceutical industry, inadequate pressure from practitioners and their associations, a requirement for simplification of the legal regimes by the regulators, or a combination of these elements, is anybody’s guess. But, all the evidence thus far suggests that a system is in development that utilises the formulaic approach already laid out in Article 5 of the Directive, which is likely to result in extremely low daily levels of many vitamins and minerals.¹¹

The Federal Institute of Risk Assessment in Germany (the Bundesinstitut für Risikobewertung, or BfR) has already employed their interpretation of Article 5 to determine maximum permitted levels (MPLs) and the results emphasise the concerns of many objective scientists.

Some proposed MPLs (daily doses) for food supplements, as determined by the BfR,¹² are listed below:

Vitamins		Minerals	
Vitamin	Max daily dose	Mineral	Max daily dose
Beta-carotene	2 mg	Magnesium	250 mg
Vitamin B1	4 mg	Iron	0
Vitamin B6	5.4 mg	Zinc	2.25 mg
Niacin	17 mg	Selenium	25-30 µg
Vitamin C	225 mg	Copper	0
Vitamin D	5 µg	Chromium	80 µg
Vitamin E	15 mg	Manganese	0

Fortunately, there have been many objections to the BfR approach to risk assessment and management for the determination of MPLs, but other options that are under consideration still, in the main, reveal MPLs, and in several important cases even Safe Upper Levels (SULs) for most vitamins and minerals that are well beneath the therapeutic range. A dramatic reminder of how cock-eyed these risk-based assessments are is given by comparing MPLs with amounts found in our food. For example, and astonishingly, the beta-carotene in two carrots or the selenium in one Brazil nut will typically exceed the MPLs for beta-carotene and selenium respectively.

¹¹ Article 5 of the Food Supplements Directive indicates that: “Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account: (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups; (b) intake of vitamins and minerals from other dietary sources. A common interpretation is that intakes will be subtracted from upper safe levels, which, for many nutrient forms, are already well below the realistic safe level, as established through decades of observational, clinical and even experimental evidence.

¹² Domke A, Großklaus R, Niemann B, Przyrembel H, Richter K, Schmidt E, Weißenborn A, Wörner B, Ziegenhagen R. *Use of Vitamins in Foods: Toxicological and nutritional-physiological aspects*. BfR, Berlin. 222pp.

Maximum Permitted Levels, or even SULs, insinuate that higher levels may expose consumers to risk, so most people assume that therapeutic ranges would typically be risky. Several decades of clinical nutritional practice demonstrates that the therapeutic range, just like the beta-carotene in ten carrots, or a handful of brazil nuts, poses no risk and is, as the term ‘therapeutic’ would imply, beneficial to health.

The ANH has submitted detailed submissions to European Commission, EFSA and the UK Food Standards Agency, drawing attention to some of the limitations of the proposed methodologies and suggesting alternatives, that are based on rational science. It is of paramount importance that, in determining MPLs, due account is given to other factors and processes. These include:

- the speciation of the nutrient (different nutrient forms of the same nutrient [group] often follow distinct pathways in the body, resulting in differing bioavailability, metabolism and toxicology)¹³;
- medical records and other medical or scientific evidence which demonstrates the safety of therapeutic and beneficial dosages of nutrients;
- evidence of safety of high intakes of nutrients ingested in foods by specific population groups;
- determinations must take into account all available and relevant evidence on both risks and benefits and must not ignore relevant studies and case reports;
- Where SULs cannot be established through lack of data, it is not possible to determine MPLs. Guidance Levels, as determined by the Expert Group on Vitamins and Minerals (EVM) should not be used as surrogates for SULs.¹⁴
- MPLs should be waived in situations where there are inadequate data to produce scientifically meaningful SULs or where there is no evidence of toxicity at even very high dosages (e.g., thiamine, riboflavin, vitamin B12, biotin, etc.). As such, regulation needs to be proportionate and should only be applied where genuine risks to the general public can be determined.

The future

Within the big picture of a harmonised Europe and a globalised world, where Codex Alimentarius acts as the vehicle for international harmonisation,¹⁵ practitioners of

¹³ The importance of speciation of the nutrient form was acknowledged at the Sixth Colloquium of the European Food Safety Authority, Risk-Benefit Analysis of Foods: Methods and Approaches, held at Tabiano, Italy, 13-14 July 2006 (see

http://www.efsa.europa.eu/etc/medialib/efsa/science/colloquium_series/risk_benefit_analys_foods/1486.Par.0004.File.dat/SES_summary_report_en.pdf for full report), viz: “the importance of speciation of the nutrient form was stressed: folic acid has 1 glutamic acid moiety, whereas natural folate has two or more glutamic acid moieties” (p. 12 of report).

¹⁴ Expert Group on Vitamins and Minerals. *Safe Upper Levels for Vitamins and Minerals*. May 2003. Food Standards Agency, London. 360 pp.

¹⁵ The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food

nutritional therapy have had barely a look in. The system has been carved out by the most powerful forces in government (i.e. the European Union's executive body, the European Commission, and powerful Member States such as Germany, France and the UK) and the heavy hitters in industry. The natural health industry is extremely fragmented and, for example, in terms of the vitamin and mineral suppliers, the pharmaceutical industry remains easily the dominant supplier, providing around 70% of the total volume of these nutrients used EU-wide.¹⁶ This means that trade associations, through which most of the lobbying in Europe occurs, maintain positions that are beneficial to the majority of their members, or at least the biggest financial contributors. This is how legal regimes for low-dose, synthetic (or partially synthetic), non-therapeutic ingredients and products become the basis of harmonisation. Therapeutics, they might argue, as suggested by Commissioner Byrne, are the domain of the medicinal sector. Yet, if this was the case, how can government's plead over the benefits of 5 A DAY or the Mediterranean diet? The agri-food sector, similarly, has its own trade bodies and these are dominated again by big name companies that are comfortable with a non-therapeutic approach to food.

The ANH has become one of the key standard bearers for the development of a scientific and legal framework for healthcare based on nutrition, taking into account the principles of sustainability, the foundation stone of the now universally familiar 'organic agriculture'. The ANH has developed a new paradigm for this approach, which it calls 'sustainable healthcare'. We define it as follows:

A complex system of interacting approaches to the restoration, management and optimisation of human health that has an ecological base, that is environmentally, economically and socially viable indefinitely, that works harmoniously both with the human body and the non-human environment, and which does not cause any significant unfair or disproportionate effects which may hinder the functioning, development or viability the healthcare system itself.

If practitioners are willing to come together, be proactive, and work with organisations such as the ANH—sustainable healthcare, and a significantly reduced threat from EU legislation, could become the reality and make for a very bright future.

Standards Programme. One of the Codex Committees, the Committee on Nutrition and Food for Special Dietary Uses has produced in 2005 guidelines for vitamin and mineral food supplements, which mirror key elements of the EU Food Supplements Directive, that will form the basis for international harmonisation. For further information see www.codexalimentarius.net and www.anhcampaign.org.

¹⁶ Frost and Sullivan Market Research Report. *European Dietary Supplements and Vitamins Markets*, 1998. Frost & Sullivan, London. 279 pp.