alliance for
natural health
good science and good law

THE GOOD, THE BAD AND THE UGLY OF EU NATURAL HEALTH LEGISLATION

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You might think that getting your head around the tsunami of regulation set to bombard the natural health shores over the next decade, is more than you can, or want, to get your head around. But in this guide, the Alliance for Natural Health has taken the mystery out of the legal jargon and condensed the potential ramifications of key pieces of European legislation into succinct points. We give the key take-home points on the good, the bad and the ugly of the Big Four EU laws on natural health that are in the process of impacting the natural health sector.

We also offer key action points to help you become part of the campaign to protect your ability to choose what natural products you use to manage your own health. Be part of the the sustainable healthcare paradigm shift that the ANH is heading. Find out more at **www.anhcampaign.org.**

Over the last few years the European Union has seen fit to introduce a wide array of legislation affecting natural health, which is in the process of largely replacing relevant national laws.

Harmonisation

The underlying feature of this legislation is the harmonisation of laws across the EU. This means that Member States that once had more liberal regimes (e.g. UK, Netherlands, Sweden), might have to accept a more restrictive regime, while the market in other Member States (e.g. Germany, Denmark, Greece) might be made more liberal.

Most EU laws affecting natural health generally have two stated aims:

1) To facilitate the **free movement of goods or services between Member States** by removing technical barriers to trade (as per Article 95 of the Treaty of the European Union), and,

2) To provide a **high level of consumer protection**.

The Alliance for Natural Health (ANH) argues that these two requirements often conflict with one another and that, in the case of nutrients, their unnecessary or unjustified limitation leads to risks to consumers through enforced legal restriction of nutrients.

Directives and Regulations

EU laws come in two main forms: Directives and Regulations. Both are generated initially as proposals by unelected bureaucrats within the European Commission who generally respond to input from Member States, stakeholders, consumer groups and other non-governmental organisations.

They are finalised through what is known as a Co-Decision Procedure, where approval is given both by the Council of Ministers, which represent the governments of individual EU Member States, and the European Parliament, which aims to represent the people of the EU.

In practice, the demands of large corporations can be disproportionately over-represented and the requirements of health-conscious consumers and small businesses are frequently under-represented. Additionally, the one democratic element in the rule-making process, the European Parliament, is not uncommonly over-ruled and 'compromise packages' are agreed which are not always in the interest of health-conscious consumers.

Directives only come into effect once they are transposed into Member State laws via statutory instruments. Regulations, on the other hand, come into force immediately across all EU Member States once they are signed off in Brussels.

Food vs medicinal law

Food law across the EU is controlled by the General Food Law Regulation EC 178/2002, while medicinal law is contolled by the Human Medicinal Products Directive 2001/83/EC, most recently amended in 2004, by amending Directive 2004/27/EC (p. 4 of this guide).

In order for natural health products to be freely available, cost effective and widely used for the purpose of preventative healthcare, it is important that the vast majority remain as foods, rather than as medicines (see Box 2).

Food Supplements Directive (Directive 2002/46/EC)

The good

When some countries in Europe regarded any food supplement containing more than the Recommended Daily Allowance (RDA) of vitamins or minerals as a medicine, the Food Supplements Directive (FSD) could be considered a breakthrough, given that it considers food supplements as a sub-category of food. Presently it applies only to food supplements containing vitamins and minerals, but it will in future be applied to supplements containing other groups of nutrients such as essential fatty acids, amino acids, herbal products, etc. Using the elements of the European Court of Justice's ruling on the ANH's legal challenge of the FSD (Box 1), the ANH has received confirmation that a diverse range of natural sources of vitamins and minerals are considered by the European Commission to be outside the scope of the FSD, and will be regarded as foods.

The bad

The FSD relies on a positive list, so that, effectively, if an ingredient is not on the list, it is banned. The positive list presently contains primarily synthetic forms of vitamins and inorganic forms of minerals, but a temporary EU list of derogated vitamin and mineral forms can still be used and it is hoped that the majority of these will be added to the positive list by the end of 2009. The ANH is concerned that future positive lists for botanical, herbal and other products might be very limited.

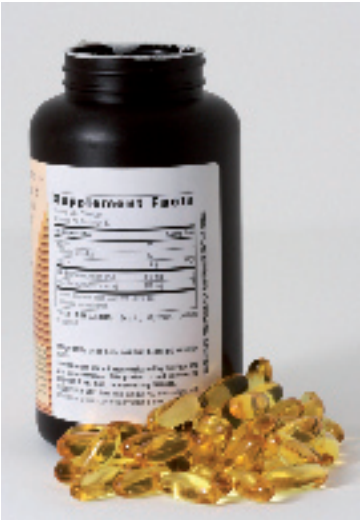
The ugly

Not only does the FSD control what nutrients you can put in food supplements, it will in the near future be applied to both maximum and minimum allowable dosages, at least for vitamins and minerals. The 'maximum permitted levels' (MPLs) of vitamins and mineral food supplements will be set EU-wide using methods of risk assessment/management that seem likely to be unnecessarily restrictive for a wide range of vitamin and mineral forms. The ANH argues that these methods are scientifically flawed. If this approach is not altered, it is possible that some of the levels will be so low that they will be much less than that which might be consumed in the conventional diet, which is known to be already nutrient-depleted in many areas. For example, the MPL for beta-carotene that is being considered might be less than that which you might consume in two carrots, while that for selenium could be less than that found in just two or three brazil nuts.

If the European authorities were so convinced these levels in food supplements are harmful, why are they not recommending limits on the number of carrots or brazil nuts being sold, or at least requiring warning labels? The reason for this is that they know perfectly well that the natural forms of nutrients, that are being restricted on the basis of some, sometimes spurious, safety concerns with synthetic forms, are not only very safe, but are also beneficial at dosages well above the proposed MPL. The MPL will likely be used as the borderline between products considered as food supplements and those considered as drugs (see Box 2).

What to do

- Support the ANH in its work to demonstrate that the risk assessment and management methods being used to impose dosage restrictions are flawed scientifically.
- Write to your MEP and national parliamentarian and let them know of your concerns about proposed, unnecessary restrictions on forms and dosages of nutrients that are clearly beneficial.



BOX 1 - The ANH legal challenge of the Food Supplements Directive (2003-5)

In October 2003, the ANH launched a legal challenge to the FSD in the High Court in London. The case was referred to the European Court of Justice (ECJ) in January 2004, where it was joined by a parallel case initiated by two UK trade associations, and a year later oral hearings were heard in Luxembourg. Although the Advocate General in the case, in April 2005, recommended the Directive be overturned owing to fatal flaws within it, when the ruling was handed down in July 2005, the Directive was left standing. However, very important and helpful clarifications were made by the Court relating to the exclusion of natural sources from the Directive, simplifying the process of application to the positive list and making clear that the primary burden of responsibility on proof of safety is on the governmental authorities, not the industry. In August 2007, the European Commission confirmed that a range of applications submitted by the ANH were outside the scope of the FSD, confirming the ANH's interpretation of the ECJ ruling.

The Nutrition and Health Claims Regulation (Regulation (EC) No 1924/2006)

The good

Before 1 July 2007, when this Regulation came into effect, many European Member States, regarded any health claim for a food as a medicinal claim, this resulting in bans and prosecutions. However, the Nutrition and Health Claims Regulation (NHCR) will allow particular claims to be made for foods and food ingredients, including ingredients in food supplements. Two types of health claim will be allowed: generic claims (under Article 13) and disease risk reduction (and childrens' health) claims (under Article 14).

The bad

Only claims that are approved by European authorities, notably the European Food Safety Authority (EFSA), will be allowed. Hundreds of generic claims submitted by manufacturers, associations and other bodies, including the ANH, are presently being considered by EFSA. Evaluations will be complete in 2009/10 and from that time only approved claims will be allowed to be used—all other claims from that point being banned.

The ugly

For the all-important category of disease risk reduction claims (Article 14), there will be a very onerous data requirement which will be beyond the reach of many small to medium-sized businesses that have been the key pioneers and innovators within the natural health field. Approvals for these claims will be product-specific, so human clinical studies for given products will be required to gain approval of a claim. This pathway has effectively created a passport system for big business which will undoubtedly gain claims for products such as phytosterol or plant stanol ester containing margarines, which, in our view, are hardly at the cutting-edge of health foods.

What to do

- Support ANH and other parties in filing generic applications for health claims, under Article 13.
- Support the ANH's campaign efforts to reduce the scientific data requirements for disease risk reduction claims, making them more accessible to small to medium-sized businesses.

BOX 2 - Why the ANH is campaigning to stop Regulators turning natural health products into drugs

Natural health products have been part of our heritage for millennia and it has been widely accepted for many years that their long history of safe use precludes the need for safety evaluation. Here are some of the main reasons why the ANH is campaigning to prevent the 'medicalisation' of natural health products:

Inevitable price rises would make products less accessible to the public. Medicines law requires that products be extensively evaluated both for safety and effectiveness. This can cost millions and the cost must be passed on to consumers, forcing products to increase significantly in price, making them less accessible to the public.

Medicines law poses a barrier to companies. The recent expansion of the natural health industry has been pioneered by small to medium sized companies. However, many of these companies are not be able to afford the cost of obtaining a drugs license so many products would be lost from the market.

Medicines are not generally consumed by healthy people. Medicines are generally taken by those who are sick and not those who are healthy. Natural products are extremely useful tools for the maintenance and promotion of health and people would be much less likely to use them for 'preventative healthcare' if they had to buy them as medicines.

Higher doses of nutrients are not medicines. Many regulators around the world are contemplating making higher dose nutrients medicines. In Europe, there is a serious risk that the amount of beta-carotene present in two carrots or the selenium in two or three Brazil nuts would be regarded as medicinal when included in a food supplement. Just because a particular meal or food supplement is healthy and has beneficial effects on the body that might preclude the need for conventional pharmaceuticals, does not mean it should be classified as medicinal. Setting low borderlines between foods and medicines is clearly a political, not scientific, agenda.

The Human Medicinal Products Directive (Directive 2001/83/EC, amending Directive 2004/27/EC)

The good
This Human Medicinal Products Directive (HMPD) proposes a relatively tight regulatory regime for pharmaceuticals, although, it has been amply demonstrated that this does not necessarily mean that pharmaceuticals are either safe or effective. The Directive imposes specific regulation on advertising and generic drugs. Most natural health products are presently not considered as drugs (although there is pressure from certain quarters to change this).

The bad
The Directive has swallowed up homoeopathic remedies and is at grave risk of subsuming other groups of 'therapeutic' or effective natural health product, owing to its very broad definition and scope. The HMPD's definition of a medicinal product effectively makes all foods technically drugs as it indicates that any substance or combination of substances "which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" should be classified as a medicinal product. It is only a weak paragraph in the preamble of the HMPD (Recital 7) that excludes products which are "clearly foods and food supplements" from the onerous imposition of a full drugs regime. However, a legal Opinion commissioned by the ANH suggests that this Recital has little legal weight.

The ugly
Not only is the exclusion under Recital 7 weak, the amended Directive of 2004 includes a supremacy clause (Article 2(2)) which gives this Directive ultimate power, in cases of "doubt", over any other EC law, even if another law applied previously. This clause effectively provides the European regulators with a 'loaded gun' to enforce a full drugs regime on any product, arbitrarily.

What to do
- The ANH legal team believe that the overly wide ranging power of this Directive should be challenged legally, given that it creates excessive 'legal uncertainty'. The ANH is presently inviting financial support to mount this challenge.

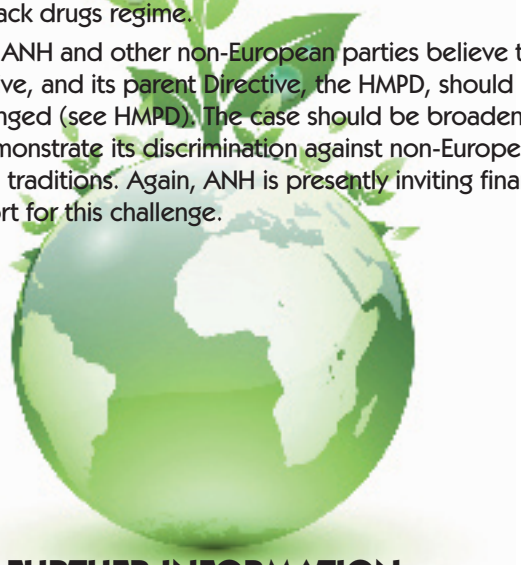
The Traditional Herbal Medicinal Products Directive (amending Directive 2004/24/EC)

The good
The Traditional Herbal Medicinal Products Directive (THMPD) is a sub-Directive of the all-encompassing HMPD and it is effectively a fast-track drugs licensing regime. The fast track means that the onerous safety and efficacy testing required for conventional drugs licensing is avoided for eligible products, on the basis that there is evidence of 30 years safe use (the '30-year rule'), of which 15 years must be in Europe. Apart from the fact that it turns licensed herbal products into 'medicinal product' and therefore allows 'medicinal claims' to be made, there is little else positive to say about the THMPD.

The bad
Apart from the eligibility criteria of the 30-year rule, there are stringent pharmaceutical requirements, including pharmaceutical stability tests that are wholly inappropriate for herbal products. These tests exclude most polyherbal mixtures, especially polyherbal tinctures, given that these are organic, reactive products which contrast markedly from the stable, toxic, new-to-nature molecules which characterise most drugs. Although medicinal claims can be made, these are limited to products treating minor ailments only, which "are intended and designed for use without the supervision of a medical practitioner". Combinations with significant amounts of nutrients such as vitamins and minerals are also disallowed.

The ugly
The 30-year rule, requiring 15 years of EU use, discriminates against non-European herbal traditions, such as Ayurveda, Traditional Chinese Medicine, Amazonian, southern African and numerous other traditions, which are among the longest and most developed worldwide. The traditional use criterion must be for an individual herb or specific combination of herbs, thus preventing use of new or innovative combinations that might be supported by emerging science. There is a real risk that more and more botanicals will be pushed away from the food/food supplement category and towards the THMPD/HMPD. Of course, if they are then not eligible, or the cost of obtaining the drugs license is prohibitive for the applicant, the use of such products will be lost forever.

What to do
- Support the ANH's lobbying efforts to ensure that European authorities and Member States do not wrongly force food and food supplement products through this fast-track drugs regime.
- The ANH and other non-European parties believe this Directive, and its parent Directive, the HMPD, should be challenged (see HMPD). The case should be broadened to demonstrate its discrimination against non-European herbal traditions. Again, ANH is presently inviting financial support for this challenge.



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