

Why EBF?

For manufacturers, exporters, suppliers of Ayurvedic or TCM products, exporting to the EC:

- The imminent implementation of the THMPD (Traditional Herbal Medicinal Products Directive) and the Novel Food regulation will drastically decimate the number of products you can export to the EU.
- The remains of your product range may be scattered into different statutes, most of them unsuitable and all of them financially prohibitive.
- Your costs for quality-safety control will rise exponentially. Analytics from non-PIC countries will not be accepted.
- Your corporate liability will not be clearly defined.
- You will face unfair competition from unregulated and uninspected sources.

For manufactures, importers, distributors inside EC carrying a full catalogue of TCM or Ayurvedic herbs:

- Your registration costs will be financially prohibitive.
- Your product range will be cut down severely.
- Your working costs will rise beyond the financial capacity of companies in this sector.
- Your business is unlikely to survive in 2011.

For professional prescribers:

- Your profession is at stake.
- Your repertory of therapeutic solutions will shrink to a few standardized patents.
- Your customers' options will be reduced significantly and prices of natural health products will skyrocket.

For CAM students interested in traditional healing arts and consumers who choose traditional formulas to maintain healthy balance:

- You will be deprived of your freedom of therapy choice.

Summary

Indeed, the implementation of the THMPD, in its present form, will wipe out most of the traditional herb sector. Why?

While THMPD was created specifically to accommodate traditional systems, it is financially prohibitive for the very companies active in this sector.

Why?

Mainly because of exorbitant registration fees, but also because it tends to enforce unnecessary and expensive quality-safety analytics based on mono-components. This instead of appropriate and more cost-effective control on the total plant, with much better safety guarantees.

Time honored, safe and proven combinations are not accepted when containing more than four ingredients. This means about 90 % of the classical formulas is excluded.

THMPD does not provide any consistent methodological and scientific framework to accommodate complex and tailored formulas and ignores all the tenets of traditional herbalism

Implementation of THMPD in present form will increase the safety risks and multiply inadequate and inappropriate use of traditional plants.

The few substances rightfully forbidden as Food Supplement, will remain restricted as Traditional Medicine as well. There is no added value in the status of TM. You will not be able to use more herbs after THMPD is operational.

The legal and practical execution of the directive is generally experienced by its target sector as an attempt to keep traditional plants out of the Food Supplement statute, rather than to create a workable framework for Traditional Medicinal products. The THMPD negates the essence of a Food Supplement and a Traditional Medicine alike.

Without significant amendments on every level all companies carrying a full catalog of a traditional system will be out of business by 2011.

But there is more ! If the THMPD is not exactly the EU's finest hour, then what to say about the Novel Food regulation? Originally designed to regulate gmo's NF regulation is now coarsely and rashly targeting traditionally used herbs. Novel Food regulation is by far the most intransparent, incoherent and undemocratic piece of legislation the EU ever produced, but today already it is swallowing up important chunks of the traditional pharmacopeias. (e.g. *Scutellaria baicalensis* and *Phyllanthus emblica*) Imagine Ayurveda or TCM without these herbs!

The imminent implementation of both THMPD and NF regulation will only aggravate the already confused legal situation our sector finds itself in, and will make it more difficult for manufacturers and distributors to make sure they are operating legally.

EBF was created by a group of people who are professionally active in the field of traditional phytotherapy. They have been monitoring the technical and scientific interpretation of THMPD and NF by the regulatory and have come to the conclusion that our sector is heading for disaster.

EBF wants to highlight the specific situation of traditional disciplines in the European forum and intends to propose safe and viable alternatives on every level in order to obtain a suitable statute for our sector.