

22nd of January 2009.

From:

O.P.P.AS vzw, c/o Chris Dhaenens, Collegebaan 55, 9090, Melle. Belgium.

To:

European Commission. Directorate General for 'Health and Consumers'
B-1049, Brussels. Belgium.

Concerning: Novel Food regulation.

Dear Sirs,

We are writing on behalf of O.P.P.AS., a Belgian professional association representing Belgian and Dutch companies, involved in marketing and distribution of traditional herbal products as occurring in traditions like TCM and Ayurveda, a.o.

By this letter we wish to express our deep concern with respect to the imminent implementation of Novel Food regulation in the EEC. The draft lists of substances considered (or those already decided upon) involve a serious curtailing, if not, the total termination of our activities in the EEC market.

In attachment please find a list of TCM and Ayurvedic substances for which our records show consumption history as food and food supplement prior to 1997. The lists are exhaustive but in no way conclusive. It is our firm conviction that none of the plants/substances listed here should ever be attributed Novel Food status, regardless of what their final status may end up to be. This claim is substantiated by the following arguments:

-Evidence of consumption history can be produced on request.

-We renounce the term "significant use" as a reference since it is vague, intangible and arbitrary. As traditional systems are mainly based on complex formulas quite a few substances may be qualitatively significant, whereas the imported volumes may not be on the high end. Significant use is, from our perspective, rather a quality than a quantity reference.

Moreover, considering the epidemiological, toxicological and all other scientific aspects, it is obvious that the safety and quality of

the full-spectrum (totum) plant is best met in its traditional context (specific plant parts, specific preparation methods, specific formulation, etc...). Hence we conclude that no traditionally used herb should ever be considered a Novel Food, and that NF regulation should focus on supercritical extracts, improved species crops, etc..., thus filling in the designation "novel" and serving its initial purpose .

-Items in draft list contain mistakes, anomalies and sometimes lack taxonomical specification.

-Furthermore, we have questions regarding the legitimacy and practicability of the "retroactive burden of proof". Firstly because plenty of evidence from "tempore non suspecto" has vanished and companies are no longer in existence. Companies still in business have not always assigned a date to their catalogues/publications, and invoices are generally kept for no longer than ten years.

Secondly, we have questions regarding the way concept and content of NF regulation has been communicated in the course of the past ten years. In order to verify consumption history of some plants our association has contacted every professional association in every member state and every known herbal company in every member state. We did not find any record of any attempt whatsoever to contact stakeholders in this field . Unlike the assertions made in the Explanatory Memorandum 14.01.2008 there is no record of any inquiries or inventory requests from local EC authorities for our sector. Draft lists were not officially accessible and unofficial lists were changed inadvertently. In Belgium, an official communication was made in 2006, without revealing draft list content. In some countries companies were repressively informed about the existence of NF regulation and in the vast majority of the member states there has not been any communication to our sector at all.

Our conclusion is that NF regulation displays a disturbing lack of transparency, a lack of consistency and a democratic deficiency, which may be in conflict with several general principles of justice. (e.g. free movement of goods, unfair competition, adequate motivation of necessity and appropriateness , a.o.)

Therefore we shall consequently challenge NF status for all items mentioned in attachment 1 and 2 (but not limited to these). We fully encourage the propositions made in the Explanatory

Memorandum (Proposal 14.01.2008) as to exclude from NF status all items that have a sufficiently long consumption history outside EEC, evidently without putting food safety at stake. We hope a constructive dialogue with our sector can avert a call upon external discretionary judgment.

Yours sincerely

Chris
O.P.P.AS. vzw.

Dhaenens