Dear Mr. Prats Monné,

Since its enactment, the Nutrition and Health Claims Regulation (NHCR) has been the cause of a lot of discussion. In October 2015 the Commission announced an Evaluation and Fitness Check of Nutrition and Health Claims Regulation. One of the two subjects presented in the Fitness Check has previously been described by the Commission as “the current different legal treatment of botanicals in foods and medicines legislation with respect to health claims / therapeutic indications.” (i)

NPN takes the liberty of suggesting a clear and simple resolution of what is - in essence - no more than the different legal treatment of health claims and medicinal claims based on traditional use.

NPN respectfully proposes that in checking the fitness of the NHCR on the point of the different legal treatment of claims based on traditional use, the Commission shall take account of the following proposition:

The least onerous and least restrictive legislative measure to resolve the problems arising from the “different treatment” of traditional health claims and traditional therapeutic/medicinal claims should be found in the creation of:

- a separate Union Regulation that organizes the market entry of traditional health claims via
a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, having regard specifically to information regarding traditional medicinal use, or

- an amendment of Regulation 1924/2006/EC that specifically addresses the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, having regard specifically to information regarding traditional medicinal use.

With regard to the category of “other substances” identified as “botanicals,” the NPN holds the view that the current “Article 8” procedure laid down in Regulation 1925/2006/EC and Commission Implementing Regulation 307/2012 is the least onerous and least restrictive harmonized measure required to sufficiently secure and procure public safety in the field of “other substances” in the European Union. There is no need to change this procedure.

This proposed resolution fits the goals of the European Commission for smart regulation. It gives many benefits to people and business in a very effective way.

A detailed substantiation of our proposition can be found in the Position Paper Solving the current different legal treatment of health claims and medical claims based on traditional use, a copy of which you find herewith.

We remain open for further contact and exchange of viewpoints.

Respectfully yours,

NPN

Mischa Strijder
Chairman


Feedback file: