

Brussels, 28 September 2017

**Comments on the Italian Decree regulating the use of vegetable substances and preparations in food supplements, replacing the Decree of the Minister for Health of 9 July 2012
(TRIS notification number 2017/276/I (Italy))**

Dear Madam, Sir,

Food supplements Europe represents the sector of Food Supplements in the European Union.

Food Supplements Europe welcomes the establishment of this law as an important step in the mutual recognition of botanicals permitted for use in food supplements for health maintenance purposes. It is the result of an intense collaboration between three Member States (Belgium, France and Italy) and helps companies to market their products in the same way in each of these Member States. We urge the Commission to support this initiative in the same way as the previous publication of the Belgian Royal Decree (TRIS No 2015/157/B).

We have one remark relating to the warning statements included. While, on the basis of scientific risk assessment certain warning statements may be justified, we note that in a number of cases the warning statements are based on the proposition that the product contains certain substances at certain levels that warrant the presence of such statement. However, there is no provision exempting products in which these compounds have been removed or reduced to minimal levels, thus taking away the cause for the concern. We believe that blank warning statements without criteria are unjustified and would like to ask the Commission to request the Italian authorities to better specify under which conditions of use such warning statements are valid and when not.

As an example, the warning statements required on food supplements containing Aloe vera (Not to be given to children under 12 years old. Consult your doctor if you are pregnant or breast-feeding. Not to be used for prolonged periods without consulting your doctor) are obviously justified because of the presence of aloin in the plant. However, in many food and food supplement products aloe gel, decolorised aloe gel or decolorised aloe whole leaf is used. In these preparations the aloin content is minimal (<10 ppm) and this warning statement is not warranted, even misinforming consumers. The setting of a criterion based on aloin content could solve this issue.

We would ask the Commission to take this on board in its comments.

We remain at your disposal for any clarification or questions you may have.

Yours sincerely,



Patrick Coppens
Director Scientific and Regulatory Affairs