

Health in harmony with Nature

DG Health and Food Safety Madame the Head of Unit for Nutrition, Food Composition and Information

4 Rue Breydel B-1040 Brussels

Elsenborn, November 4th 2015

Object: Preliminary comments on the proposed road map

Dear ,

I am writing in relation to your presentation of the Commission's roadmap at last week EHPM conference and with your request to emit general comments on it if we felt the need to.

I have therefore submitted the road book to the internal working group of my enterprise in charge of regulatory/ quality/ R&D issues. The competences in presence are a Food technology engineer, a biologist, a pharmacist, and our internal legal expert.

They are strongly supporting the road map as presented and explained by you at the EHPM meeting.

They also think -at least on the base of the declarations- that the refit concept offers a pragmatic approach, enabling new regulations to address legitimate consumer needs while taking into account the resources available in an organization as ours.

Reading through the lines, they dream of the future European framework for botanical food supplements - and the corresponding aspects of safety & truthfulness- as a coherent system addressed in the same pragmatic way as their everyday context in Belgium, France and Italy.

For them, the botanical Food Supplements category needs a specific place in European regulations.

Both their safety and the knowledge of what they can be good for (in terms of exerting a beneficial effect by the means of a physiological process) have no

Laboratoires ORTIS PgmbH



Health in harmony with Nature

equivalence, because it is the only category of consumer goods with such a long history of use.

They also drew my attention to the fact that this would be a strong signal for the non-EU world, and would help European SME's to export their excellent products more easily.

One critical point for them is the agency in charge of monitoring the BFS. Its future mission should be defined taking account of the specificities of the products defined in the category.

I do hope that these elements will help you in your efforts to fine-tune the process in course.

My team and I would also be more than happy to be part of the announced market survey.

In the meanwhile, I remain,

Respectfully yours,

Managing Partner

Laboratoires ORTIS PgmbH

- 1