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# BOTANICAL FOOD SUPPLEMENTS: TOWARDS A WORKABLE REGULATORY FRAMEWORK – EUROPEAN PARLIAMENT, BRUSSELS – 9 NOVEMBER 2016

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Ladies and Gentlemen,

Honourable Mr Arimont,

It is a great pleasure to join you today and to have this opportunity to discuss the EU's work on botanicals in foods, as well as the use of health claims in product marketing. Thank you for the invitation.

I want to start by highlighting two important pillars:

- firstly, the need to promote good health, healthy lifestyles and preventive healthcare, and
- secondly, the need to provide consumers with safe, high quality products – and accurate, non-misleading and helpful information.

It is well-recognised that these two elements are essential to protect consumers and to ensure that they can trust foodstuffs that reach them.

Health claims on botanicals used in food is a complex issue based on the simple principle that no misleading claim should be permitted on foods.

As consumers, this principle is a question of confidence in the safety and quality of the product; for businesses and entrepreneurs it is a question of selling a product fairly.

However, whilst this principle is paramount, it is also undermined by the apparent discrepancy in the rules for health claims on botanicals used in food and those for therapeutic indications used on traditional herbal medicinal products:

- on the one hand, under the Nutrition and Health Claims Regulation, clinical studies are required to allow health claims for botanicals used in food.
- on the other hand, therapeutic indications for traditional herbal medicinal products can be solely based on a demonstration of traditional use.

This poses questions about the fairness and coherent treatment of botanical substances and it is an issue I believe should be addressed as a matter of priority.

Certain Member States already have national legislation to regulate the use of botanicals in food supplements. For such measures to be put in place, they have to fulfil certain criteria:

1. they must be justified on one of the grounds of public interest listed in the Treaty – for example, protection of human health and life;
2. they must be proportionate; and
3. they must comply with the “Mutual Recognition” principle, the principle that any good which is lawfully marketed in one Member State should

be authorised in others.

In this context, I would like to stress that Belgium, Italy and France have taken the initiative to develop a common approach for the safety evaluation of botanicals – a project called "BELFRIT".

This is a very interesting example of how voluntary cooperation between Member States can be used to address common concerns.

At EU level, you will also be aware that the Commission is working on the botanicals issue as part of its Better Regulation agenda. The preparatory work for a Regulatory Fitness Evaluation – the so-called “REFIT” – of the Health Claims Regulation has already started.

This evaluation will examine a range of important issues including whether the current rules for health claims on botanicals used in foods are adequate.

It will also investigate whether the safety, quality and free circulation of these products should be further examined – and, in response to stakeholder feedback that the mutual recognition principle does not work properly, how this situation could be improved.

To give you an example, under current EU rules, it is possible for Member States to classify a product, on a case-by-case basis, either as food or as medicine depending on its presentation and the claimed effect.

In practice, this means that different Member States can classify the same product in different categories: what is treated as a food in one, can be treated as a medicinal product in another as EU law stands.

For that reason, the evaluation will also look into whether the general food safety rules in place are sufficient to ensure the safety of botanicals used in foods and how relevant they are in the context of today’s market situation and tomorrow’s potential.

This will give us a clearer picture to enable the Commission to clarify whether – and to what extent – there is a need to harmonise the use of botanicals in the EU. It will also take into account Member States current regulatory activities.

The external study that will feed into the REFIT evaluation was launched in May 2016.

Discussions were then held with the Member States' experts and members of the Advisory Group on the Food Chain and Animal and Plant Health in two workshops last June.

Once the targeted consultations are launched – which will be by the end of this year – the Commission is looking forward to receiving position papers and input from Member States, stakeholders and SMEs.

An open public consultation on the issue will also be carried out to gather the views of citizens and other interested stakeholders.

Ladies and Gentlemen,

This REFIT Evaluation is a very important step and the Commission is committed to conducting it in full transparency, with all interested parties involved in the process.

It is a key tool to assess the efficiency of the legislation and to develop the necessary evidence base to feed into any decision on whether or not it should be adjusted.

In particular, it will allow the Commission to take a fully informed decision on the use of health claims on botanicals – and clarify whether there is a need to harmonise the use of botanicals in the EU, and to what extent this needs to happen.

The evaluation process and the steps that follow are expected to be lengthy.

However, I anticipate completing the reflection process on possible

changes to the regulatory framework before the end of my mandate.

I encourage you to actively participate in this process and to continue the open and constructive communication that we have benefited from to date.

Thank you.

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