Presentation given by
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Ladies and gentlemen,

It is a great pleasure for me to be here today. I would like to thank the organisers for having invited the European Commission to participate to this important event on Botanicals in Food Supplements. I also would like to send to all of you the regards of my Director General, Ms. Paola Testori Coggi, who unfortunately could not attend today and asked me to give the opening remarks to this conference.

As you know very well, the use of so-called 'botanicals' for their physiological effects has a long tradition in Europe and the rest of the world. In Europe, **products containing botanicals have been marketed in various ways, due to different traditions and different cultures in the Member States**. And the Court of Justice of the EU has recognised the right of Member States to classify such products as medicines or food, without prejudice, of course, to the provisions of the Treaties. Consequently, relevant legislation has developed in parallel, both at national and at EU level. However, today regulation of the market, particularly that of the food products, is only partly harmonised.

Products containing botanicals are in certain cases considered medicinal products and, if this is the case, they have to comply with all the relevant legislation applicable to medicinal products. A specific EU Directive on Traditional Herbal Medicinal Products was adopted in 2004. It established the possibility for these products to obtain a 'simplified traditional use registration'. **This procedure recognises, under certain strict conditions, the importance of evidence of 'traditional use'** when it comes to prove the safety and efficacy of botanicals. This Directive works well and, as of 31 December 2011, 751 THMPs were registered in the different Member States.

Products containing botanicals are in other cases considered food, and in this case are most often sold as food supplements. Italy is maybe the Member State with the most extended tradition in that area, but other Member States have also considerable experience with food products containing botanicals. EU rules do not harmonise which botanicals can be used in food. Therefore Member States have the right to set national rules on the subject. According to EU law, food cannot claim therapeutic properties, but can bear health claims on the beneficial effect that it has on normal body functions.

As you know, in the context of the implementation of the Regulation on claims, **many concerns were brought to the attention of the Commission regarding botanicals**. The Regulation on claims foresees that claims need to be based on scientific evidence of the highest possible standard. The European Food Safety Authority assesses the substantiation of claims and the Commission and Member States decide on their authorisation.

The interpretation of such rules made evidence of 'traditional use' de facto insufficient to prove the substantiation of claims on botanicals. Stakeholders as well as Member States were attracting the attention of the Commission to the fact that this difference of treatment was not justified. In particular, it was being flagged that the same botanicals are sometimes used in both foods and medicines and consumers may sometimes struggle to perceive the difference between certain claims/therapeutic indications (e.g. "relief of minor articular pain" vs. "maintenance of normal joints". "Treatment of common cold vs. "supports immune system"). It was also underlined how implementation of the Regulation on claims with no changes to the rules would result in most, if not all, claims on botanicals being rejected.

The **Commission**, in agreement with Member States, decided to put claims on botanicals 'on hold' and **launched a reflection on the topic**.

This reflection started in 2010 and culminated last year, in a discussion paper that the Commission sent to Member States. Also stakeholders had the opportunity to provide the Commission with comments on this paper.

2 possible options for future action were considered:

- **The first option would uphold the status quo**. It would be based on the consideration that the different treatment of botanicals between foods and medicines is justified. It would therefore require EFSA to resume its assessment of health claims on botanicals with no changes to its approach. A negative opinion from EFSA would then lead the Commission and Member States to reject claims made on botanicals used in foods. In parallel, therapeutic indications on the basis of 'traditional use' for the same botanical ingredients would continue to be given under the THMPs Directive.
- **The second option would on the contrary consider that the difference in treatment would not be justified**. Botanicals would be considered as a particular case in the food area, and new rules would be drafted for the use of botanicals in food that recognise the importance of evidence of 'traditional use'.

The result of this consultation confirmed how different are the views of Member States on the subject:

- 7 Member States were strongly supporting option 1 and
- 5 strongly supporting option 2.
- While 3 Member States had reservations with both options,
- 11 Member States would not oppose either of them, but underlined how option 2 can be very difficult to achieve.

What was very interesting, and very relevant for today's discussions, was that **Member States were clear that if a new legislation were to be undertaken, it should have a global approach**: in other words, not only efficacy of botanicals and claims should be considered, but also issues of quality and safety.

In addition to the Member States, one should be aware that the views of the European Parliament on this issue would be very important. As in most cases, there are different views. Some have been expressed clearly and forcefully in favour of one option but others, representing the opposite view are also coming into the scene. Taking into account of the considerable political significance of the debate, it seems to us of great importance that appropriate and complete information is provided to those MEPs with an interest in the subject.

Last but not least the views of the stakeholders are crucial for the overall consideration of the subject. For manufacturers and other business operators that market products under the different legal regimes the issue is of the utmost importance. There is no surprise therefore that there are fundamentally differing opinions as to the choice of the options under consideration. They both have their valid arguments and the Commission is paying full attention to them. On the other hand the consumer representative organisation has expressed a view in favour of option 1. But this concerns their general attitude towards claims. On the contrary, I believe that consumers would be very pleased with the BELFRIT initiative because it would meet their request for ensuring the safety and quality of these products. In that context I consider that time taken to explain the initiative to them would be time well used.

I just mentioned the BELFRIT project, which will be the subject of the discussions this morning, and I would like, to say a few more words on this initiative**.**

The European Commission follows with great interest the work of BELFRIT, not only for its promising outcomes, which are the result of solid scientific work, and a good cooperation between three Member States. But also for its possible future implications at EU level.

In its report of 2008, the Commission considered that laying down specific rules applicable to substances other than vitamins and minerals for use in food supplements (including botanicals) would not be justified. In that context, and in the absence of harmonised rules, the Commission acknowledges the right of Member States to act on the subject. Full coherence between THMP and food products is desired; it would be inconsistent if a plant ingredient is declared fit for THMP and unfit for food products.

We now see that three Member States with considerable experience and tradition in food products containing botanicals, including food supplements, have joined forces. Their efforts, supported by the scientific expertise of leading scientists in the area, will hopefully facilitate the free circulation of such products among these Member States' territories.

This is clearly a positive result for these three Member States, especially in an area where borderline cases and divergent interpretations are not unusual, and it would be interesting to see the reaction of other Member States to that initiative and their potential interest in joining BELFRIT in the future. We certainly encourage the 3 partners of BELFRIT to inform other MS about this initiative and convince them to join so as to arrive to have the broadest agreement among MS.

But being the European Commission, our main concern is the whole Internal Market of the EU. So the question is, **what can the Commission learn from BELFRIT and what would be the impact for decisions at EU level?**

First of all, **BELFRIT points very clearly to the importance of the quality and safety aspects when dealing with botanicals used in food**. It confirms what it also appeared from the replies to the Commission's discussion paper on botanicals: that there is a growing recognition among Member States of the importance of a global approach on botanicals, which is based on quality, safety and efficacy considerations.

This is also confirmed by the recent letter that six Heads of national Food Safety Agencies addressed to EFSA last February: the Agencies of France, Belgium, Denmark, Germany, Luxembourg and Spain are calling on EFSA to take a leading role in reviewing the safety of botanicals in the EU. As you know EFSA has already taken some steps, as an own initiative, on the subject of the safety of botanicals.

EFSA is now considering its response to that request. In that context one should not forget that **the European Food Safety Authority is the first scientific interlocutor of the European Commission in matters of food safety**. Therefore one reflection from my side today would be that the work of BELFRIT should in no event become antagonist to work that may be carried out by EFSA. Taking into account that two out of three partners of BELFRIT are also co-signatories of the letter to EFSA, I am sure we all agree on this point and on the importance of coherence and cooperation on the matter.

As I already mentioned, one should also not forget that at this stage there are two distinct categories of products containing botanicals that are regulated by distinct legal regimes and measures: THMPs and food products. In that context, one should keep in mind the work being done by the Herbal Medicinal Products Committee within EMA on the subject and the importance to have a clear borderline between foods and medicines.

I am afraid that today I do not have any news to tell you on the outcome of the reflection of the Commission on the two options as to how to go about claims concerning botanicals. **The Commission has taken due note of the position of Member States and of stakeholders and we hope to finalise this reflection as soon as possible.**

Independent of the outcome of that reflection, we consider that the work of BELFRIT is very important. Its effect on attitudes towards relevant future action at EU level is probably too early to predict. It will depend on the critical mass of followers that it may gather among Member states and stakeholders. Also very much will depend on the outcome of the on-going reflection on botanicals, namely whether Option 1 is retained or Option 2 is brought forward.

But either way, we see BELFRIT as a tool with at high potential which should and probably could be shared by many other MS. And I am sure we will be talking about it again in other occasions.

Let me wish you a very fruitful conference today.

Thank you for your time.