

Tradition & Botanicals – Combining National Best Practices

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Slide 1

DGV1

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THE USE OF BOTANICALS IN EU (1)

long tradition of use in Europe

**while most of these products have
a long history of use in Europe,
some concerns exist with regard
to safety and quality**

THE USE OF BOTANICALS IN EU (2)

available on the EU market as:
traditional herbal medicinal products
food/ food supplements

USE OF BOTANICALS IN FOOD SUPPLEMENTS IN EU: NOT HARMONIZED

- ▶ **no positive list**
- ▶ **no specific authorization
procedure**
- ▶ **under the general food law:
reg. 178/2002
reg. 258/97**

THE USE OF BOTANICALS IN ITALY (1)

**long tradition of use as “erboristici”=
products, containing plants without
therapeutic effects marketed in Italy under
the food law**

**until the Dir. 2002/46/EC,
when they have been classified, and
consequently marketed,
as food supplements**

THE USE OF BOTANICALS IN ITALY (2)

**Those products contain plants and part of
plants with a significant history of
consumption before the 15 May 1997,
They are not novel food according
Reg. (CE) 258/97**

over 2 millions euro/yr market in Italy

THE ITALIAN POSITIVE LIST OF BOTANICALS

DM 9 OF JULY 2012,

Containing a positive list of plants and their parts that can be used in FS, because of their traditional use

"Linee guida ministeriali sulla documentazione necessaria per l'impiego di botanicals negli integratori alimentari" (www.salute.gov.it):

the use of extracts from any plant in our list, but without a significant history of consumption, is subjected to the Regulation (EC) 258/97 on novel food

THE BELFRIT PROJECT (1)

**Since 2011 cooperation between
BElgium- FRance-ITaly**



**to obtain a common positive list of
plants and their parts to be used in fs**

THE BELFRIT PROJECT (2)

**botanical scientific expert working on
the project:**

BElgium: Luc Delmulle

FRance: Robert Anton

ITaly: Mauro Serafini

THE BELFRIT PROJECT (3)

The experts worked together following the criteria defined by

“Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements”

to define a common list

THE BELFRIT PROJECT IN EU

- ▶ **April 2013 Bruxelles: Official introduction of the project to the European Commission**
- ▶ **April 2013 Rome: Meeting with other member states and Mr Basil Mathioudakis for the Commission**
- ▶ **November 2013 Bruxelles: First draft of the BELFRIT common list**

THE ADOPTION OF THE BELFRIT LIST IN ITALY

27 march 2014 modification of the Annex to DM 9 July of 2012 with the inclusion of the BELFRIT list

a further assessment of plants is still going on, in order to finalize the list, when the process will be finished the only list of plant in Italy will be the BELFRIT one

EU HARMONIZATION FOR BOTANICALS USE IN FOOD SUPPLEMENTS

**The BELFRIT project is the first
step to achieve an European
harmonization in the use of
"botanicals" in food supplements**

THE ISSUE OF CLAIMS FOR BOTANICALS (1)

**the claims for botanicals are
currently on hold**

THE ISSUE OF CLAIMS FOR BOTANICALS (2)

different approach applied to assess botanicals when used as food or as medicine:

Reg.(EC) 1924/2006 did not recognize the tradition of use as a key factor for botanicals in foods/food supplements;

Dir. 2004/24/EC recognized the tradition of use for traditional herbal medicinal products



CONCLUSIONS

- ▶ **THE EU HARMONISATION FOR BOTANICALS IN FOOD SUPPLEMENT IS A GOAL TO ACHIEVE**
- ▶ **WE HOPE FOR THE RECOGNITION OF TRADITION OF USE IN A FULLY HARMONIZED FRAMEWORK**

**THANKS FOR YOUR
ATTENTION**