Italian Regulatory Approach to Botanicals:
traditional use, safety and health claims

Bruno Scarpa
Head of Office 4 Directorate General for Hygiene, Food Safety and Nutrition (DGISAN)
Ministry of Health, Italy
• **Botanical Food Supplements: open issues**

• **Traditional use**

• **European Commission:**
  *Roadmap on Regulation (EC) 1924/2006*

• **Italian approach**

• **Conclusions**
BOTANICAL FOOD SUPPLEMENTS (BFS): OPEN ISSUE

since 2010 claims “on hold”
(European Commission asked EFSA to stop the clock)

WHY?
CLAIMS “ON HOLD”

TRADITIONAL USE IS NOT CONSIDERED A PROOF FOR EFFICACY ACCORDING TO FOOD LEGISLATION

REGULATION (EC) 1924/2006
TRADITIONAL USE

DOUBLE STANDARDS IN THE EU LEGISLATION

Traditional Herbal Medicinal Products (THMP) Dir. 2004/24/EC

FOOD LEGISLATION
THMP AND TRADITIONAL USE

TRADITIONAL USE AS PROOF OF EFFICACY: OK
DIRECTIVE 2004/24/EC: RECITAL 4

Having regard to the particular characteristics of these medicinal products, especially their long tradition, it is desirable to provide a special, simplified registration procedure for certain traditional medicinal products. However, this simplified procedure should be used only where no marketing authorisation can be obtained pursuant to Directive 2001/83/EC, in particular because of a lack of sufficient scientific literature demonstrating a well-established medicinal use with recognised efficacy and an acceptable level of safety...
FOOD LEGISLATION AND TRADITIONAL USE (1)

TRADITIONAL USE AS PROOF OF SAFETY: OK
FOOD LEGISLATION AND TRADITIONAL USE

Regulation (EC) 258/97 on novel food
Regulation (EU) 2015/2283

Novel food means food that was not used for human consumption to a significant degree within the EU before 15 May 1997

TRADITIONAL USE AS PROOF OF SAFETY: OK
FOOD LEGISLATION AND TRADITIONAL USE

TRADITIONAL USE AS PROOF OF EFFICACY: NO
Regulation (EC) 1924/2006
Regulation (EC) 353/2008:
The assessment of health claims is done on the basis of studies conducted in healthy subjects

The traditional use is not taken into consideration for botanicals claims evaluation.
TRADITIONAL USE:
IMBALANCE BETWEEN THMP AND BFS

SAME BOTANICAL

SAFETY
THMP: OK
BFS: OK

EFFICACY
THMP: OK
BFS: NOT OK
TRADITIONAL USE:
IMBALANCE BETWEEN THMP AND BFS

SAME BOTANICAL

THMP

BFS

EFFICACY

PLAUSIBLE

PROVEN
EUROPEAN COMMISSION EVALUATION AND FITNESS CHECK (FC) ROADMAP

from 01/ 2016 to 06/ 2017
Evaluation of Reg.(EC) 1924/2006 with regard to:

1) nutrient profiles

2) health claims on botanicals
UPDATE ON ITALIAN LEGISLATION ON FS

DECRETO 27 marzo 2014
Aggiornamento del DM 9 luglio 2012 sulla “Disciplina dell’impiego negli integratori alimentari di sostanze e preparati vegetali”

The decree is been updating
We hope to notify it to the Commission at the beginning of next year

It will have just one list of plants

FS are concentrated sources of nutrients or other substances with a nutritional or physiological effect

LEGISLATIVE DECREE 169/2004
transposing Directive 2002/46/EC

FS containing substances with physiological effects (BFS) MUST bear these effects
COHERENCE WITH LABELLING LEGISLATION

the definition of FS is not consistent with a voluntary claim according to Regulation (EC) 1924/2006

Reg. (EU) 1169/2011 (FIC)

art.4: mandatory food information:
(a) information on the identity and composition, properties or other characteristics of the food

Article 9: list of mandatory particulars:
(j) instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
ITALIAN LEGISLATION ON FS


Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect.

LEGISLATIVE DECREE 169/2004
transposing Directive 2002/46/EC

FS containing substances with physiological effects (BFS) MUST bear these effects.

THE CLAIM REGULATION BLOCKED OUR APPROACH
The separation between **EFFICACY AND SAFETY EVALUATION** can lead to a positive opinion on an health claim for a substance at such a dose, that may be higher of the one traditionally used.
The present opinion does not constitute...an authorisation for the marketing of...a positive assessment of its safety, nor a decision on whether...is, or not, classified as a foodstuff

...such an assessment is not foreseen in the framework of Regulation (EC) 1924/2006
THE MONACOLINE CASE IN FS

In Italy (and in EU) monacoline admitted in FS at a maximum level of 3 mg. NOT NOVEL FOOD ONLY FOR FS

REGULATION (EC) 1924/2006 ON CLAIMS

CLAIM:
Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol levels

The claim may be used only for food which provides a daily intake of **10 mg of monacolin K** from red yeast rice

3-10 mg: SAFETY?
CONCLUSIONS (1)

• The EU harmonisation for botanicals FS is a goal to achieve

• The recognition of tradition of use as proof of efficacy for botanicals FS in a fully harmonized framework in order to:
  - overcome the differences with THMP
  - make consistent the food legislation in the evaluation of safety and efficacy
CONCLUSIONS (2)

AFTER THE ROADMAP

STILL AN OPEN ISSUE
Regulation (EC) 1924/2006, art. 27

The report on the application of Regulation (EC) 1924/2006 that was supposed to be done by January 2013
THANK YOU FOR YOUR KIND ATTENTION