The origins of the Belfrit project

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Rome, 18 April 2013

Use of plants in food supplements

DIRECTIVE 2002/46/EC

Harmonization provided just for the use of vitamins and minerals
Conclusions of the Report on the use of substances other than vitamins and minerals in food supplements:

**Specific provisions are not justified, the existents provisions are sufficient**

- Regulation (EC) 178/2002
- Article 8 du Regulation (EC) 1925/2006 on the addition of vitamins and minerals and certain other substances to food
- Regulation (EC) 258/97 concerning novel food and novel food ingredients
- National laws and principle of mutual recognition

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**DRAFT OF THE NATIONAL DECREE ON THE USE OF “BOTANICALS” IN FOOD SUPPLEMENTS**

**NOTIFIED TO THE EU COMMISSION**

October 20, 2011 favorable opinion

**POSITIVE LIST**

of plants and parts of plants allowed

**NOTIFICATION PROCEDURE**

of the label to the Ministry of Health as required for food supplements
Use of substances and herbal preparations in food supplements

(D.M. 9 July 2012)

HEALTH CLAIMS

on botanicals

since 2010

"on hold"

for the out of proportion difference regarding the TRADITIONAL USE as evidence of efficacy between food supplements and traditional herbal medicinals products
The BELFRIT Project

In 2011 the collaboration between Belgium (BEL-gium), France (FR-ance), and Italy (IT-aly) has started in order to define a common positive list, deriving from the comparison of national lists, and to harmonize eventually their approach to the assessment of plants in food supplements.

The BELFRIT Project

WHAT ARE THE REASONS TO DO IT?
Food supplements containing botanicals are widely available on the market of Italy, France and Belgium.

Given the lack of harmonisation, the mutual recognition has to be applied on a case by case basis.

The idea came up during the meeting of the Advisory Board of PlantLIBRA in May 2011 in Brasov (Romania).

PlantLIBRA is a European project that aims to provide data and information useful to the safety and efficacy of “botanicals” in food supplements.
The BELFRIT Project

The “case by case” mutual recognition approach can be avoided if there is a common list of plants allowed in food supplements.

Only the preparations of listed plants that have a traditional history of use can be used in food supplements.

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SHARING OF EXPERIENCES

Increased level of consumers protection
Facilitated mutual recognition application by the other member States
The BELFRIT Project

After one year and a half of working together we define a common list of the three member States:

THE BELFRIT LIST

containing plants considered safe on the basis of the traditional use and of the whole complex of available scientific evidence, and that can be used because of their “physiological effects”

The BELFRIT Project

We are very satisfied with the achieved result, but we are aware that this is only the starting point and not the end
The BELFRIT Project

WHAT ARE THE NEXT STEPS?

ADOPTION of the common list in the three member States legislation

JOINT MANAGEMENT OF THE LIST to keep the common position reached
JOINT MANAGEMENT OF THE BELFRIT LIST (1)

Definition of additional provisions on the basis of development in scientific knowledge and of new data collected through phytovigilance system, such as:

- additional warnings for the labeling
- maximum levels of substances "of concern"
- dosage of the plant or the part used
- type of preparation permitted for use as ingredients

JOINT MANAGEMENT OF THE BELFRIT LIST (2)

Application of the principle of mutual recognition to food supplements that are legally marketed in any other Member States

*It should also be noted that it is very difficult to have a valid proof that the product is legally marketed in an other Member State*
The BELFRIT List: a work in progress

To join the BELFRIT project might be of interest to other Member States sharing a similar approach related to the use of “botanicals” in food supplements.

The BELFRIT List

can serve as a tool for an European harmonization
**EUROPEAN HARMONISATION ON BOTANICALS**

*does not affect the possibility by a Member State to give priority to the pharmaceutical legislation on the basis of the current European legislation*

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**EUROPEAN HARMONISATION**

**HEALTH CLAIMS**

REGULATION (EU) 432/2012 - Recital 17

The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 13(3) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.
The provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use should apply where, taking into account all its characteristics, a product may fall within the definition of “medicinal product” and within the definition of a product covered by other Community legislation. In this respect, a Member State may, if it establishes in accordance with Directive 2001/83/EC that a product in a medicinal product, restrict the placing on the market of such product in accordance with Community law.

EU countries may restrict the marketing of a product through specific legislation.
TRADITIONAL USE

Botanicals:

The traditional use accepted as proof of safety should also be accepted as proof of efficacy

TRADITIONAL USE

According to the Regulation 258/97/EC

a botanical that have been used for human consumption to a significant degree within the Community is allowed for food supplements
Betula pendula

**Status**: not novel food supplement

According to the information available, Betula pendula (Siberian Elm) is not considered to be a novel food in Europe. The uses of this plant are limited to medicinal and nutritional purposes, and its consumption is not considered to be a novel food.
Not NOVEL FOOD: STATUS DEFINITION

The plant is considered not novel food because of the traditional amount ingested... and not through appropriate dose-related studies in humans.

WHY have this amount been used by consumers? in relation to its physiological effects

"detoxifying and draining "

Novel food catalogue

Monascus purpureus - monacoline

Description:
The request concerns the use of so-called "red yeast fermented rice" as food supplements only, and not fermented rice is produced by cultivating the mould Monascus purpureus on rice. The rice is first soaked in water until the grains are fully saturated. The now-soaked rice is then steamed for the purpose of sterilizing and cooking the grains prior to inoculation. Inoculation is done by mixing either M. purpureus spores, or powdered red yeast rice together with the rice that is being treated. The rice is then incubated in an environment at room temperature for 3-5 days. During this period, the rice should be fully infiltrated with M. purpureus, with each rice grain turning bright red in its core and remaining pale at the outside. The fermented rice is then either used as the dried grain, or ground and powderized to be used as a wet paste, or dried and powered to be used as a powder.
Monascus purpureus - monacolin K

STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
SECTION ON GENERAL FOOD LAW
Summary Record of Meeting of 26 January 2010

3. Exchange of views on the consideration of fermented red yeast rice in food supplement as a novel food (requested by Belgium)

ITALY CONFIRMED that food products meeting the definition of food supplements (Directive 2002/46/EC) were on the market in Italy already before the entering into force of the Novel Food Regulation. The Committee therefore concluded, that ‘fermented red yeast rice’ when used in or as food supplement, should not be considered as subject to the novel food Regulation.

Monascus purpureus - monacolin K

Monacolin for physiological purposes:
max 3 mg in Italy

Regulation (EU) 432/2012 on health claims
(art. 13.1 reg 1924/2006)

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

10 mg of monacolin K
Monascus purpureus – monacolin K

EFSA Journal 2013; 11 (2): 3084

The opinion does not constitute ... a positive assessment of its safety, nor a decision on wether red yeast rice is, or not, classified as foodstuff

It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) 1924/2006

Food supplements with 10 mg of monacolin K

Is not applicable ➔ Regulation (EC) 258/97

Is applicable ➔ Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

Article 8
Substances prohibited, restricted or under Community scrutiny
1. The procedure provided for in this Article shall be followed where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

CONCLUSIONS

We hope that the BELFRIT project will be an USEFUL TOOL FOR THE HARMONIZATION AT EUROPEAN LEVEL of botanicals in food supplements

CONCLUSIONS

We also rely on the importance of TRADITIONAL USE as proof to support health claims on botanicals in order to deal proportionally with the “pending” current situation
Grazie
Thank you
Merci