

EHPM Members Meeting – 5 July 2018

Update from National Association – FederSalus



ONLINE NOTIFICATION

From July 1, 2018 an online notification system entered into force (to replace current «paper» system).

With the new system the following actions are possible:

- New notification
- Variation of notification
- Request of Free Sale Certificate
- End of marketing notification

Available both an online access specific for Italian FBOs and one for foreign FBOs.

A manual of use is available, FAQ and demo are expected.

The Ministry of Health maintains the Registro of positively food supplements, as presently

ITALIAN LIST OF PLANTS

The draft of «Belfrit» Decree was notified by the Italian Ministry of Health to the UE Commission under TRIS rules (Directive 2015/1535) on 28 of June 2017. Comments period ended end June 2018.

The Decree includes two Annexes: the first one lists the plants and parts of plants admitted in food supplements, with relevant warnings or limitations, if applicable. The second one sets out the rules to address the quality and safety management of botanicals.

The Ministry of Health maintains the National Guideline that establishes the physiological indications for botanicals

EUROPEAN /ITALIAN PROCEDURES – some items of interest

- Article 8 procedure – reg 1925/2006

Hydroxyanthracene Derivatives (HAD); following EFSA opinion, the Commission is evaluating with the Member States for a regulatory decision. The first draft of regulation (which text is not available) would establish a prohibition on the use of **aloe** only for food supplements with laxative claim (or for all food supplements ? Or for all food ?) while **senna, rhubarb and cascara** would be under scrutiny. MoH has expressed its opposition to the prohibition of aloe, proposing scrutiny. (the plant has a status of not novel food in Europe), the ban only in food supplements could generate conflicts with the general food regulatory framework. MSs and EC to re-discuss (presumably in October) to draw up a final draft regulation.

Monacolin K: EFSA's opinion is expected (MoH had in the past a max intake / has warning)

Lipoic acid ?: MoH maintains the intention to set a maximum intake and to propose a supplementary warning to the current of no association with hypoglycemic drugs

- **Titanium dioxide**: concern on the French proposal of ban. Waiting EFSA evaluation

- **Fermented maltodextrin enzymes**: MoH is evaluating a more precise definition and might be possible a request of proving the not novel food status for those enzymes used for some time for "digestive" purposes.

- **GMP**: MoH should publish the standards (Recommendations) on good manufacturing practices

BOTANICAL DATABASE

The WG on botanicals is working on a botanicals DATABASE to gather information and evidences on plants to support tradition of use of plants used in food supplements, their safety and claims.

A set of plants has been chosen. These plants are used in the most important categories of food supplements of the Italian market.

The Universities of Roma and Pavia are involved in this project.

The database is expected to be finalized in 2018 as a first step. To be then extended to other plants.

GUIDELINES

- Quality of products – **Guideline for the development of food supplements**

Describes the quality and safety process for developing a food supplement

- Quality of products – **Guideline for the analysis of red yeast rice**

Developed with Fondazione E. Mach - SifitLab - Università degli Studi di Siena

- Use of food supplements – **The role of food supplements in the pharmacy and medical practice, i.e. to pharmacists and general practitioners**

Describe the scientific evidences of the benefits of food supplements in the diet and in terms of primary prevention

- Communication – **Guideline on communication of food supplements**

Aims to provide regulatory framework and directives for a correct commercial communication and scientific information on food supplements

FederSalus activities - 3

- TRAINING FOR GENERAL PRACTITIONERS

IntegrInforma project for the general practitioner structured as follows:

- **FAD ECM course** on the role of food supplements in the main areas of wellbeing and health (online from 27 April 2018 to 26 April 2019)

- **digital magazine**

The project is realized with a non-conditioning contribution by FederSalus and Integratori Italia - AIIPA

- **THIRD INDUSTRY SURVEY 2017 – the Italian food supplements industry**

Confirms results of former surveys, showing a strong and growing industry