



# **GLÓWNY INSPEKTOR SANITARNY**

GIS-ŻP-SD-4272-00023/AW/17

Warszawa, dnia ..... 2017 -04- 14

**European Commission DG SANTE**  
**Directorate – General For Health and Food Safety**  
**Directorate E – Food and Feed Safety, Innovation**  
**Unit E2: Food processing technologies and novel foods**  
**Rue Breydel 4**  
**1049 Bruxelles**  
**Belgium**

Dear Madam,

With reference to notifications concerning placing on the Polish market food supplements containing hemp extracts (*Cannabis sativa*) produced from flowers, I would like to kindly ask for your opinion whether these extracts are allowed to use in food supplements.

In Poland till now only seeds and oil from *Cannabis sativa* seeds could be used as ingredients in food, including food supplements. Other parts of hemp plant and their extracts should be considered as novel food/ novel food ingredients.

During the process of notification to the Chief Sanitary Inspector concerning placing on the Polish market food supplements containing extracts from hemp flowers, food business operator (FBO) as evidence that other parts of hemp plant (apart from hemp seeds) are not novel food ingredients and therefore in its opinion, they can be used in the production of food, including food supplements, submitted European Commission document dated on 3 February 1998, stating that “it was decided that foods containing parts of the hemp do not fall under the scope of the Regulation (EC) 258/97” (attachment). I would like to kindly ask if that document is still valid.

Simultaneously I would like to bring to your attention that *Cannabis sativa* in Belgian regulation: *ARRETE ROYAL du 29 AOUT 1997 relatif à la fabrication et au commerce de denrées alimentaires composées ou contenant des plantes ou préparations de plantes* (M.B. 21.XI.1997, last amendment 24.01.2017) was placed on the list 1. "*Dangerous plants that can't be used as food or food ingredient*".

Taking into account French regulation: *Arrêté du 24 juin 2014 établissant la liste des plantes, autres que les champignons, autorisées dans les compléments alimentaires et les conditions de leur emploi* (consolidated version - 16 January 2017) *Cannabis sativa* was not mentioned as ingredient which can be used in food supplements.

According to Italian regulations: *DECRETO 9 luglio 2012 Disciplina dell'impiego negli integratori alimentari di sostanze e preparati vegetali (ALLEGATO 1 aggiornato con Decreto 27 marzo 2014)*, MINISTERO DELLA SALUTE, and *DECRETO 9 luglio 2012 Disciplina dell'impiego negli integratori alimentari di sostanze e preparati vegetali (ALLEGATO 1.bis - ATTUALE LISTA BELFRIT)*, MINISTERO DELLA SALUTE, respectively seeds, oleum and seeds are listed as ingredients which are allowed to use in food supplements.

Moreover I would like to note that in the German monograph entitled: *List of Substances of the Competent Federal Government and Federal State Authorities Category „Plant and plant parts”*, published by Federal Office of Consumer Protection and Food Safety in Germany, 2014, only seeds from *Cannabis sativa* are listed as ingredient which can be used in food.

On the other hand it must be underlined that in the Novel Food Catalogue cannabidiol (CBD) which means enriched *Cannabis sativa* extracts was indicated according to the information available to Member States' competent authorities, that "*this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required*".

I would like to add that food supplements which were notified to the Chief Sanitary Inspector in the light of information provided by the FBO, contain naturally occurring CBD (extracts are standardized for CBD content) and they are not enriched in CBD.

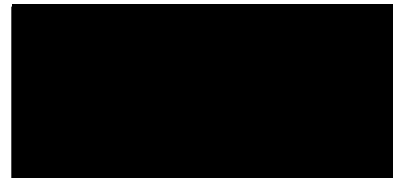
Taking into account the above mentioned information, therefore doubts arise in the context of the history of consumption of flowers hemp and their extracts in the EU Member States before 15<sup>th</sup> May 1997<sup>th</sup>.

Because of the ongoing administrative procedure in Poland conducted by the State Sanitary Inspection concerning food supplements which contain extract from hemp flowers, we need your opinion if parts of hemp plant (other than seeds) and their extracts can be used in food supplements, especially taking into account EC document from 1998 or should be considered as novel food/ novel food ingredients.

I would be very glad for you answer in that issues. Due to the urgency of that matter I am looking forward to hearing from you as soon as possible.

Please be so kind and give us the response also by e-mail to the secretariat of the Department of Functional Foods – sekretariat.zp@gis.gov.pl.

Yours faithfully,



Annex:

- European Commission document dated on 3 February 1998

Attn.:

- SANTE-NOVELFOODS@ec.europa.eu.