

## **Discussion paper from the United Kingdom:**

### **Consideration of the novel food status of CBD extracts of hemp**

#### **Background**

In the UK managing products of hemp and in particular CBD containing extracts has become a complicated and key issue for both producers and enforcement authorities. The novel food catalogue entries make clear that hemp products are not novel but highly refined extracts are novel. However, in practice there is a continuum of products on the market and we think it is important to explore the circumstances in which extracts are no longer consistent with the history of consumption for hemp and would therefore require authorisation under the Novel Food Regulation.

We are reaching a point in the UK where we need to be in a position to provide clear guidance for operators in order to ensure a level playing field. We therefore welcome the opportunity to discuss the issue and have identified some areas we feel are important to discuss in reaching a decision on how these products should be managed in relation to the EU novel foods framework.

We recognise that on this novel food issue, there is interaction with other legal frameworks, including medicines and drugs. However, as these aspects are outside the scope of consideration of this group and arrangements under these frameworks differ from Member State to Member State, they should not be the focus of the debate.

#### **Key Questions**

**In considering the novel food status of hemp extracts we have identified the following key questions we think need to be given consideration when making decisions on hemp extract products, on which we would welcome discussion with the Commission and working group colleagues:**

- What influences the higher level of CBD (the selling point of the product)?
- Is this a selective extraction which increases the intake of CBD by consumers compared to the non novel extracts?
- Does the production process make the product novel?

#### **Consideration of the Key Questions**

##### ***What influences the higher level of CBD (the selling point for the product)?***

We are aware from the information from industry that there can be a number of reasons for the CBD in a product to be higher than traditional hemp oils. For example, there may be naturally higher levels of CBD in the plant starting material where a higher CBD-containing strain produced by traditional plant breeding techniques is used, or where parts of the plant higher in CBD such as leaves, stalk

and flowers is used. It is unclear that if these naturally higher CBD levels in the plant would be consistent with the history of consumption for hemp products and, if so, whether this would affect the novel food status of the product.

***Is this a selective extraction that alters the intake of CBD by consumers compared to the non novel extracts?***

There are cases where foods ordinarily considered to be non novel can be considered to be novel foods when they have been obtained by a selective extraction process e.g. green tea extract. These have largely been highly purified extracts, but the level of purification has varied and could, at least in principle, apply to any extract where selective extraction significantly alters consumers' intake of the material extracted in comparison to the non-novel version of the food.

Extracts, including seed oils, fall within the existing history of consumption for hemp products. In products with higher levels of CBD, careful consideration needs to be given to the techniques and level of purification required to obtain the product and whether this may mean that the product is no longer consistent with the history of consumption and should therefore be considered to be novel.

Some products are simple alcohol extracts of the plant subjected to a rotor evaporation process which leads to an increased concentration of CBD. If this process is repeated, extracts with greater concentrations can be obtained as other components of the oil such as terpenes and flavanoids are removed. Further advanced processes can be carried out to produce highly purified isolates of between 60% and 99% pure CBD. The key questions are: (a) At what point is the extract considered selective? and (b) At what level of purification is a product no longer considered consistent with the existing history of consumption?

The European Industrial Hemp Association (EIHA) have argued that the distinction between foods, food supplements and medicinal uses should be based on daily dosage. However, for managing these potentially novel foods a purity criterion would be more consistent with categorising a food within the novel food framework.

Equally, if the terpene and flavonoid components are removed in the process and then reintroduced to the product would this result in a change to its novel food status? And would a more concentrated ingredient that is standardised to a lower concentration of CBD through use of Hemp oil for use by consumers be treated differently?

***Would the production process in itself be novel?***

Processes not used in the food industry prior to 1997 that give rise to significant changes in a food are considered novel. Would the use of processes to remove undesirable substances such as THC etc. for safety reasons or in order to be compliant with national drugs legislation mean that a product should be considered to be novel?

**Summary**

In conclusion, the UK feels there is a need to consider these issues in order to facilitate the provision of consistent advice on which hemp products should be subject to the provisions of the Novel Foods Regulation. We are aware that in some Member States, highly purified extracts are considered medicinal. Given the case-by-case approach to classifying medicines, we think it is necessary to understand how these products should be managed if they are marketed as foods. This work could perhaps also be used to develop a framework for considering extracts ahead of the new Article 4 process on establishing novel food status under which these issues could be raised more regularly.