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## Guidance levels for tetrahydrocannabinol content in foodstuffs from industrial hemp

The DVFA has set guidance levels indicating which contents of tetrahydrocannabinol (THC) are acceptable in food based on industrial hemp, without the food being in conflict with [Article 14 of the Food Regulation](#) according to which food must not be unsafe.

[Regulation 2015/2283 on novel food](#) says that a food which has not been used for human consumption to a significant degree in the Union before 15 May 1997 shall be subject to risk assessment and authorisation prior to the placing on the market. The novel food list of the EU ([‘Novel Food Catalogue’](#)) sets out the status of a number of products, including hemp. The following products from hemp are not considered novel food: Seed, seed flour, protein powder from seeds and seed oil from varieties of the hemp plant (*Cannabis sativa* L.) which are listed in the EU catalogue of varieties and which are free from or have low THC content.

Hemp extracts with concentrated levels of cannabinoids including THC may be covered by the novel food regulation provided that the extract has not been used for human consumption to a significant degree within the Union before 15 May 1997.

The indicative guidance levels are set out on the basis of the Danish National Food Institute (NFI)’s assessment of the risks related to hemp-based food. The values are defined in such a way that the general adult population is protected from excessive intakes of THC.

Indicative guidance level means that the placing on the market of a food containing THC at the specified level will be possible without the company having to demonstrate that it is not unsafe for the consumer. If an undertaking wishes to place a food on the market with quantities higher than those specified, the company must be able to provide evidence of the safety of the food. If the Veterinary and Food Administration finds, in control, that food products with higher levels than indicated are placed on the market, a specific decision will be taken as to whether the product may continue to be placed on the market. In addition, if unsafe food is placed on the market, sanctions could be imposed e.g. in the form of a fine.

The indicative limit values are an instrument to ensure that unsafe food is not placed on the market. Whether a food is unsafe shall be established by means of Article 14 of Regulation 178/2002 laying down the general principles and requirements of food law.

### Establishment of indicative guidance levels

In relation to the risk associated with the consumption of hemp-based food, the NFI has assessed the impact of the psychoactive substances  $\Delta^9$ -tetrahydrocannabinol and  $\Delta^8$ -tetrahydrocannabinol ( $\Delta^9$ -THC and  $\Delta^8$ -THC), the latter being normally present only in small quantities. In addition, the content of  $\Delta^9$ -tetrahydrocannabinol (THC) acid content is relevant since, for example, in the case of food preparation, this substance could potentially be converted to the psychoactive substance  $\Delta^9$ -THC. The THC acid content in hemp is usually 2-10 times higher than the THC content. Since it is not known to what extent THC acid is converted to THC in food, the Veterinary and Food Administration's guidance levels should take into account both the active substances  $\Delta^9$ -THC and  $\Delta^8$ -THC and the total THC, including THC acid content.

The indicative guidance levels are based on the fact that the intake of THC should not exceed the acute Reference Dose level set by the European Food Safety Authority (EFSA) at 1  $\mu\text{g}/\text{body weight}/\text{day}$  as well as the fact that children and adolescents should not exceed the temporary maximum tolerable daily intake for THC of 0,4  $\mu\text{g}/\text{kg bw}/\text{day}$ . At higher consumption levels, there is a risk of influence on the person's mood, responsiveness, and ability to operate machinery and drive vehicles. Inhibition of working memory and learning ability have also been identified. Data indicate that the brain is more sensitive to the effects of  $\Delta^9$ -THC, while it is developing than in adults. This is of particular concern in the case of a chronic intake.

It should be noted that the THC guidance level does not cover possible adverse effects caused by other cannabinoids, including cannabidiol (CBD), as well as possible combination effects of the intake of THC and CBD-containing products.

In the case of small children (< 4 years), THC guidance levels will not provide a sufficient degree of protection. As a result, children under 4 will be discouraged from taking hemp food. The DVFA will provide information on this in information material for parents etc.

### Indicative guidance levels for THC and THC content

Foodstuff	Seeds	Flour*	Oil	Beer	Tea**	Bread and other foods***
<b>Guidance level (mg/kg)</b>						
<b>THC<sup>1</sup></b>	2,0	2,0	4,0	0,25	0,25	0,25
<b>Total THC<sup>2</sup></b>	5,0	5,0	10,0	0,5	0,5	0,50

\* Covers also protein powder

\*\* Content in the ready drink.

\*\*\* Compound food containing hemp products allowed under the novel food rules.

<sup>1</sup>THC = the total content of the substances  $\Delta^9$ -THC and  $\Delta^8$ -THC.

<sup>2</sup>Total THC = the total THC content of the substances  $\Delta^9$ -THC,  $\Delta^8$ -THC and THC content.

### *Food supplements*

The recommended daily dose of a food supplement may contain a maximum of 80 µg THC and not more than 200 µg of total THC. Children and young people under the age of 18 years, and pregnant and lactating women should, for health reasons, not consume hemp-based food supplements. Hemp-based food supplements and other hemp-based food should not be consumed at the same time.

Both the THC and the total THC content must be within the specified limits.

The above thresholds for contents in food, including food supplements, are to be considered at the finished product level. That is, the content of foods placed on the market for the final consumer has to comply with the respective guidance values. This is due to the fact that the aim of the guidance levels is to protect consumers from excessive intakes. Semi-finished products which are not marketed to the final consumer do not need to comply with the indicative operating limits.

However, attention is drawn to the fact that semi-finished products should not be in conflict with, for example, the legislation on narcotics, which may be the case if the THC content exceeds 0.2 %. The Danish Medicines Agency administer the rules on narcotics in Denmark.

The above guidance levels are established on the basis of the DVFA's current knowledge of the harmful effects of THC. Indicative guidance levels for THC in beer, tea and other foods are set at 0.25 mg/kg, which is the limit of quantification. The guidance levels may be updated to take into account new information or a refinement of the analytical method.