Position paper of the European Industrial Hemp Association (EIHA) on:

Reasonable guidance values for THC (Tetrahydrocannabinol) in food products

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Executive summary

With this document, the European Industrial Hemp Association (EIHA) publishes a unique position paper on reasonable guidance values for THC in food. It is the result of one year of work and based on the exchange of several international scientists and experts. The scientifically sound new THC guidance values will protect consumers from any undesirable side effects without unnecessarily compromising the market of hemp products. The proposed THC guidance values are in line with the regulations in Canada, USA, Switzerland, Australia and New Zealand. In comparison, the German guidance values from 1999 are far too strict and scientifically outdated, but nevertheless applied in several member states of the European Union.

These costly one-year activities, financed by the European Industrial Hemp Association (EIHA), were necessary because of the unfavourable framework conditions in the European Union: Further investment and growth in Europe are delayed or even in danger because of a patchwork of national regulations. The hemp food sector has grown with considerable speed over the last several years and has reached a volume of 40 Million € in Europe and a global volume of 200 Million €. Reasonable regulations, especially harmonized THC guidance values are crucial for the further development of the domestic hemp food industry and to ensure access to the 'nutritional powerhouse' of hemp nuts containing a wide fatty acid range (including the healthy linolenic acids: alpha-linolenic acid and gamma-linolenic acid) and easy-to-digest proteins.

EIHA asks the European Commission to create a working group in DG Health to develop harmonised guidelines for THC in hemp food products, based on the EIHA proposal, to overcome the existing patchwork of national regulations. Harmonised legislation should be applied in all member states. This will guarantee consumer safety and the further expansion of the hemp food industry, attract direct and indirect investments and create new jobs.

The eleven-page report shows unique in-depth background information on all issues around THC in food, strictly based on scientific evidence. The report can be downloaded for free: www.eiha.org

Background information

The hemp food sector is growing fast and has reached a volume of 40 Million € in Europe and a global volume of 200 Million €. Further investment and growth in Europe are delayed or even in danger, because of a patchwork of regulations and the recent withdrawals of hemp products from the market in almost half of the EU countries (following "RASFF alerts").

For the European producers and market development, this is a very critical situation, which already lead to serious economic damage. The recall of the products from the market – shops, wholesalers, manufacturers of supplements and suppliers of raw material endangers the hemp food industry in the entire EU. It took many years to

establish hemp food products on the market, now their positive image as a 'nutritional powerhouse' is in jeopardy. To avoid long-term negative impacts for the European hemp food operators, urgent actions are required to stop the interdiction of safe hemp food products immediately.

The aim of this position paper is to propose scientifically sound THC[1] guidance values for hemp foods at the European level, that protect the consumer without unnecessarily compromising the market of hemp products. The lack of European-wide guidance values can potentially undermine an industry that is currently growing at a two-digit global growth rate. Furthermore, excessive restrictions may prevent consumer access to what has been dubbed by both scientific minds and diet experts, alike, as a 'nutritional powerhouse' due to its wide fatty acid range (including the rare and valuable linolenic acids: alpha-linolenic acid and gamma-linolenic acid) and easy-to-digest proteins.

In the European Union, only Germany has applied guidance values for THC in food products. The German guidelines are the most commonly used in Europe, due to the fact that other member states lack their own THC regulation. Albeit the first EU member state to pass regulation on the issue and hemp's biggest market, in the continent, the German guidance values are too strict and outdated. They are also commonly misunderstood and misused by authorities, resulting in unnecessary and costly controls.

Canada, on the other hand, with the world's largest hemp food industry, recently revised its testing requirements for in field THC testing. Cultivated industrial hemp crops in Canada grown from pedigreed seed of the List of Approved Cultivars (confirmed by Health Canada with no more than 0.3% THC) are no longer required to be tested for THC percentage in field plant samples. Other changes to the Industrial Hemp Regulations are beneficial in reducing procedures and red tape associated with hemp production, storage and processing. The Canadian Hemp Trade Alliance continues to work with the Canadian government to treat hemp as a crop and not as a drug. This achievement will most certainly lead to additional growth of the hemp sector in Canada.

Meanwhile China, with the world's largest cultivation area of industrial hemp, has also developed a growing domestic market for hemp food products and, in addition, is becoming a global player by exporting processed hemp food ingredients. Traditionally hemp has always been a regular and well respected crop in China.

The EU should create a level playing field to avoid that European cultivators and manufacturers suffer the consequences from this regulatory disadvantage compared to their overseas competitors on the market.

Finally, consumers looking for healthy European food will face problems finding hemp food products "made in Europe" at all and especially at a reasonable price.

Conclusion

For consumer protection and further growth of the European hemp food industry, reasonable and Europe-wide guidelines for THC levels in food products are needed. The European guidance values should guarantee the availability of hemp food products to the consumers while protecting them from any undesirable side effects. This will guarantee the expansion of the industry, attract direct and indirect investments and create new jobs. EIHA asks the European Commission to create a working group in DG Health to develop and propose guidelines for THC in hemp food products to overcome the existing lack of standard regulations and their application within the member states.

The European Industrial Hemp Association (EIHA) points out the following aspects which underline the new EIHA sound scientific guidance values and the urgent need for reasonable Europe-wide guidelines.

Note: This position paper is only dealing with food ingredients and food products derived from hemp seeds and hemp leaves. Hemp extracts and/or oil mixtures (CBD products) are a subject of Position paper published by EIHA on January 2017: **www.eiha.org/cbd-support.**

[1] Please find more information on THC in the appendix.

The German THC guidance values are too strict and outdated

The German THC guidance values in food, created as a non-binding reference, are most widely used within Europe, regardless of their relatively conservative nature. These guidance values were already introduced in the year 1999. In the meantime, a plethora of research on THC has been conducted. Therefore, the German guidelines, unfortunately, must be considered unnecessarily strict and scientifically outdated.

In the year 2015, EIHA asked the experts from nova-Institute to update the THC guidance values on the latest scientific knowledge. The full report "Scientifically Sound Guidelines for THC in Food in Europe" from nova-Institute, published in July 2015, is freely available online at www.eiha.org.

As an outlook on further research topics the report stated: "This report identified important gaps when deriving reasonable guidance values for THC in food. Further research is mainly needed in: Methodology and evaluation of uncertainty factor, realistic consumption patterns of hemp food, and interaction of THC with other Cannabinoids (especially CBD)." As additional topics further research on the "effect of heating on active THC" and "employing appropriate analytical measurements to differentiate between THCA and THC" were mentioned in the report. This position paper uses the term THC to mean the total of Δ9-THC and its natural precursor acid THCA. This is also called total-THC. This definition is most commonly used by authorities and the public alike. If we mean pure THC without THCA, we write Δ9-THC or neutral THC (further details see Appendix).

In the meantime, nova-Institute performed studies on the rationale behind EFSA's use of uncertainty factors (UF) and on the effect of heating on THC (see below). The results strongly justify the implementation of new guidance values.

The European Industrial Hemp Association (EIHA) proposed, after an extensive review of the literature on the topic of THC consumption and effects, a Lowest Observed Effect Level (LOEL) of 2.5 mg of Δ9-THC intake per person twice daily (Sarmento et al. 2015). A total daily intake of 5 mg Δ9-THC (2 x 2.5 mg) results in a LOEL of 0.07 mg Δ9-THC/kg body weight (b.w.) per day assuming a body weight of 70 kg.

This proposal is based on the minimal effective Δ9-THC doses described in the studies by Chesher (1990), Petro & Ellenberger (1981), Beal (1995, 1997), Strasser (2006), and Zajicek (2003, 2005).

According to these scientific studies, a single dose of 2.5 mg of Δ9-THC may usually be regarded as a placebo dose, i.e. minimal effects can also be observed with a placebo. Consequently, these effects are not significant for the active substance. Therefore, we could as well assign the NO(A)EL to this dose.

German guidance values are for ready-to-eat products, not for ingredients

The German guidance values for THC in food products are clearly made for ready-to-eat-products. They were not intended for evaluation of ingredients. Hemp protein powder and hulled hemp seeds are always used in small portions for drinks, muesli or salad. That means the final ready-to-eat product has to fulfil the guidance values – but not the hemp ingredient itself. The same applies for example to coumarin in cinnamon: There are limits for coumarin in ready-to-eat cakes, but not for the coumarin-content of cinnamon as an ingredient.

Nevertheless, some authorities mistakenly apply the German THC guidance values to ingredients such as protein powder. Even the Rapid Alert System for Food & Feed (RASFF) was used to report high THC levels in protein powder. This resulted in withdrawal of hemp protein powder from retailers across Europe.

Conclusion

EIHA urges the German authorities to revise their guidance values. Ideally, Europe should adopt updated and scientifically sound THC guidance values which include detailed and concrete recommendations for the different groups of ingredients and ready-to-eat products such as the EIHA-study proposes (Sarmento et al. 2015), and this update reiterates (see tables 1 and 2).

Adhering to EFSA's own guidelines would mean a total UF of 10 for Δ9-THC

For THC, EFSA does adhere to its own guidelines of using uncertainty factors (UF) of 10 for interindividual and 10 for interspecies differences (see Table 3 in Appendix). Especially striking is the fact, that no risk assessment has been conducted at all for alcohol in food products, and that the EFSA guidance value for caffeine is above the No Observed Adverse Effect Level (NOAEL). Moreover, Δ9-THC is treated unfairly compared to nicotine where no UF was used for the extrapolation of a NOAEL from the LOAEL. If THC were treated the same as nicotine, the UF for the NOAEL-LOAEL-extrapolation of 3 should be disregarded. Following EFSA's guidelines an UF of 10 should be employed for Δ9-THC (EFSA, 2012). EIHA's standpoint is, that Δ9-THC is treated a lot stricter compared to the UFs used for opium alkaloids, nicotine, caffeine, alcohol, and vitamin E. This clearly leads to the discrimination of a whole industry and a more restricted market access.

Conclusion

The uncertainty factor (UF) for Δ9-THC as used by EFSA should be lowered from 30 to 10 in line with e.g. Australian Food Standards[2]. For details please take a look at the report "Comparison of EFSA's rationale behind using uncertainty factors for plant ingredients in food" (Iffland, Kruse and Carus 2016).

Proposal for a proper ARfD derivation for Δ9-THC

With regards to EFSA's own guidelines and advice in practice, an uncertainty factor of 10 for Δ9-THC would apply. Using an UF of 10 and a LOEL (and as well a NOAEL) of 0.07 mg/kg b.w. would lead to an **A**cute **Ref**erence **D**ose (ARfD) of **7 µg Δ9-THC/kg b.w.** (see calculations). This ARfD is EIHA's recommendation for a reasonable and scientifically justified intake of THC from food, in contrast to the ARfD currently used by EFSA.

$$\text{LOEL [mg/kg b.w.]} = \frac{5}{70} = 0.07 \text{ mg } \Delta 9\text{THC / kg b.w.}$$

$$\text{ARfD} = \frac{\text{LOEL}}{\text{UF10}} = \frac{0.07 \text{ mg/kg/day}}{10} = 0.007 \text{ mg } \Delta 9\text{THC/ kg b.w.}$$

$$= 7\mu\text{g } \Delta 9\text{THC / kg b.w.}$$

The derived ARfD of 7 µg/kg b.w. is for pure Δ9-THC and not total THC, because most studies have been performed with Dronabinol (chemically identical with Δ9-THC).

Our proposal is supported for example by FSANZ (2012) which determined a LOEL of 5 mg Δ9-THC/d. Based on this, a TDI of 420 µg Δ9-THC /d (or 6 µg/kg b.w.) can be calculated.

The EIHA recommendation for an ARfD of 7 µg Δ9-THC/kg b.w. is also supported by the assessment of the health risks of THC in foods by the Swiss Federal Office of Public Health (1995). The Swiss authority recognised a lowest observable physiological effect level of orally administered Δ9-THC of 5 mg per adult and applied an UF of 10. This means a provisional tolerable daily intake of 7 µg/kg b.w. (as reported by Zoller et al. 2000).

[2] FSA Supporting document 1 of 23 March, 2017: http://www.foodstandards.gov.au/code/proposals/Documents/P1042%20Low%20THC%20Hemp%20seeds%20as%20food%20AppR%20SD1%20Dietary%20Exposure%20Assess.pdf

Evaluation of total-THC is misleading – THCA has no effect

In the hemp crop and hemp food, Δ9-THC and THCA are present, often in a 1 to 9 ratio. THCA has no psychotropic effect as long as it is not heated. The majority of foods made from hemp seeds are used in cold cuisine to protect the valuable polyunsaturated fatty acids. With heat THCA will transform to Δ9-THC (depending on temperature and time – To fully convert THCA to Δ9-THC at 115 °C it takes ca. 2 hours, figure 1). For example, a cake in the oven has an internal temperature of less than 100 °C (as long as water is present). Using an average baking time of 45 min, this would mean, that only ca. 1/3 of the THCA is converted into Δ9-THC. Therefore, the realistic Δ9-THC proportion in hemp flour is 43% of total-THC after baking (33% Δ9-THC created through THCA-decarboxylation + ca. 10% original Δ9-THC content in hemp flour). Using the total-THC measurement method, currently employed by the authorities, this leads to an overestimation of 57% (Iffland, Carus and Grotenhermen 2016).

Moreover, usually, only up to 15–20% of the total flour mass is hemp flour in baked goods. This further reduces the THC content of the cake (for background information, please refer to appendix).

The small share of Δ9-THC (for example 10–20%) in total-THC could be considered to work as an additional safety factor (= UF).

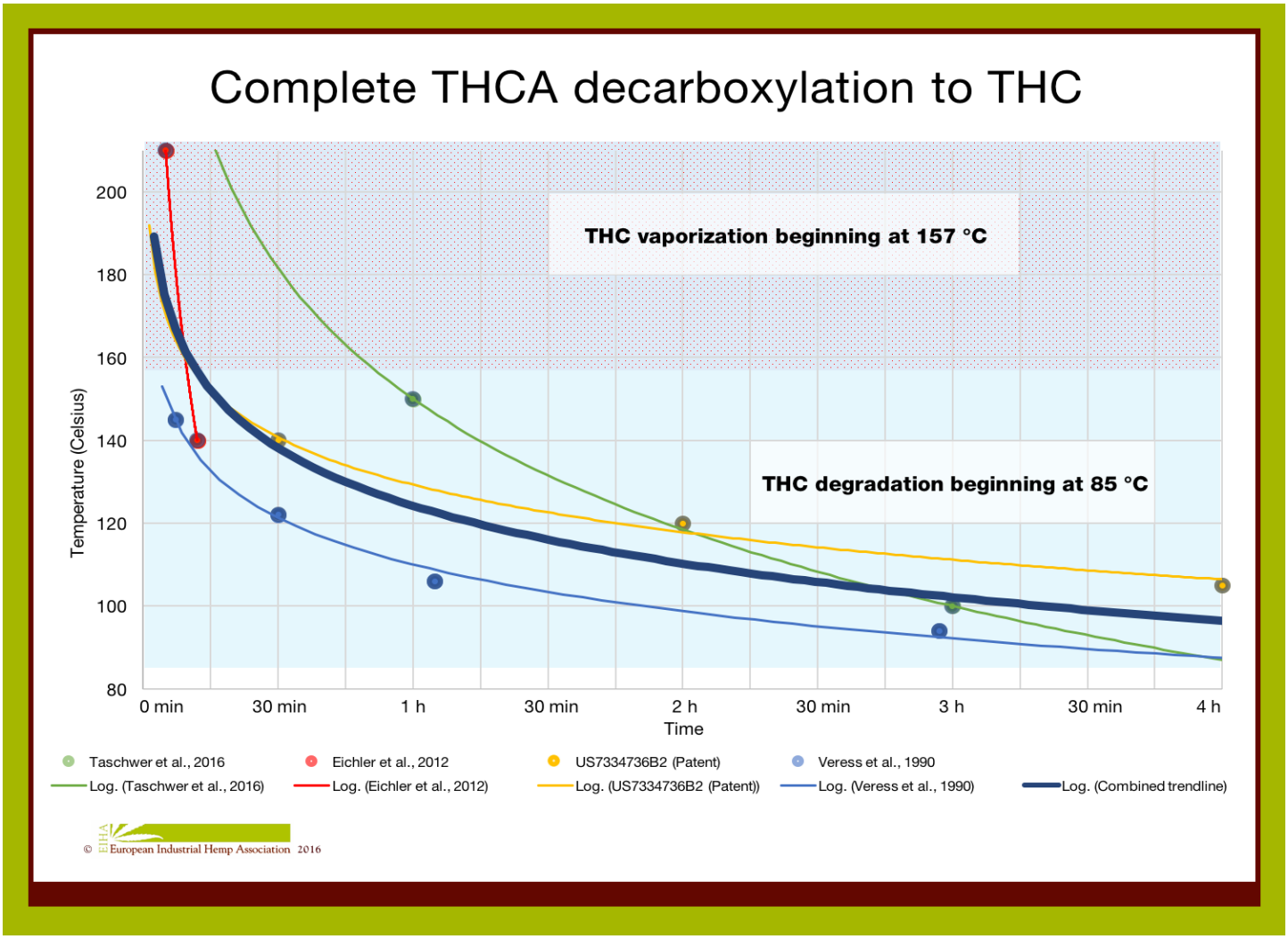

Figure 1: Graph of various experiments measuring the complete THCA-decarboxylation depending on time and temperature. The bold dark blue line represents a combination of the depicted experiments (Iffland, Carus and Grotenhermen, 2016).

Conclusion

Currently, Δ9-THC-content is overestimated to a variable extent in analyses of hemp products. The existing guidance values refer to the total-THC content only, meaning Δ9-THC + THCA. This is only acceptable for food products which are heated leading to complete THCA conversion. All other products which are only gently heated or not heated at all will need an assessment of the Δ9-THC-content (without THCA) which can easily be done by applying an appropriate analytic method (e.g. HPLC[3]) or GC with derivatisation. This is an important and necessary distinction, because only a correct differentiation between Δ9-THC and total-THC makes an accurate evaluation of THC in food products possible.

However, in current practice, it is pragmatic to use a guidance value for total-THC and to measure it in food, that may be heated by the consumer, because at this moment it is impossible to predict to what extent, in terms of time and temperature, hemp food will be heated before consumption.

Proposal for new guidance values based on scientifically sound assessment of THC effects

Tables 1 and 2 give an overview on existing THC guidance values in different countries, and the new EIHA guidance values from 2017 which apply the ARfD suggested above. Average hemp content in circa 50 publicly known recipes and official German consumption patterns have been used for our calculation. Including hemp-leaf or flower infused drinks, the sum total of "Total-THC" daily uptake is just slightly over 500 µg for an average adult, corresponding to 3.50 µg of Δ9-THC per kilogram body weight (0.49*500.55 µg total THC/70kg = 3.5 µg Δ9-THC) with three additional safety factors:

- For our calculations we applied a 49%/51% Δ9-THC/THCA ratio for the THC-contamination on the outer shell of the seeds. Nevertheless, this may be considered very conservative, because long term test report data shows rather an average of 40%/60% Δ9-THC/THCA ratio for this specific THC-contamination. And also EFSA claims that "in fresh plant material, up to 90 % of total Δ9-THC is present as the non-psychoactive precursor Δ9-THC acid." (EFSA Journal 2015;13(6):4141).
- The exposure estimates assume that all foods contain THC at the scenario concentration, the actual THC levels in food most likely will be lower.
- It is not realistic that consumers will eat only hemp-enriched foods with each of their meals. Assuming a daily diet that consists of 50% of hemp food the daily uptake would be further reduced to 1.75 µg Δ9-THC/kg b.w./d.

From the above values and based on the recipes of the different product categories, the following THC guidance values for hemp ingredients were developed (Table 2). EIHA proposes the use of the guidance values for ingredients as means of assuring the safety of all products in the market to be correctly estimated.

In accordance with the three principles presented above, any ingredient that contains THC under the indicated values (Table 2) would result as being safe both as such and in derivatives. This would simplify the safety measurement by simplifying the identification of the products (hemp seed whole or hulled; hemp seed oil; or processed press cake) and reduce the misuse on ingredients of the German guidance values, intended for final food goods (ready-to-eat) only. The approach is also in line with successful and well established hemp market norms such as in Switzerland, Canada or Australia, where national authorities not only followed the same steps, but continuously consulted the industry while setting them up, and this resulted in no complaints by authorities or consumers.

[3] High Performance Liquid Chromatography

Table 1: New EIHA proposal resulting in a daily total THC uptake of 500.55 µg

Food categories	EIHA Guidance value for total THC [µg/kg]	Average Consumption Pattern [g/day/person]	Total THC uptake/day/person (consumption * guidance value = uptake) [µg]	Current Guidance values (Germany – BfR) [µg/kg]
Edible oils	10 000	2.93	29.30	5 000
'High Volume' foods: Protein (e.g. Tofu, hemp based dairy alternatives)	1 000	183.87	183.87	150
'High Volume' foods: Carbohydrates (Bread, Baked Goods, Pasta, Breakfast Cereal)	1 000	230	230	150
'Low Volume' foods (Protein Shakes, Sweets)	1 000	27.01	27.01	150
		[ml/day/person]		
Alcoholic beverages (Beer, Wine, Spirits)	20	180.61	3.61	5
Non-heated Non-alcoholic beverages (Soft Drinks, Fruit Juices)	20	120.03	2.40	5
Heated Non-alcoholic beverages (Tea, Infusions)	80	304.47	24.36	5
Total THC daily uptake			500.55	

Table 2: List of new total-THC-reference values (green box) for hemp ingredients derived from EIHA proposal on ready-to-eat products, selected recipes and consumption patterns; together with guidance values and limits for listed countries.

Ingredients	EIHA proposal 2017 Total THC [µg/kg]	THC Guidelines	THC limits[4]		
		Germany – BfR [µg/kg] (total THC) 2000	Switzerland [µg/kg] 2016	Canada [µg/kg] 1998	Australia and New Zealand [µg/kg] 2017
Hemp Seeds Whole or Hulled	10 000	–	10 000	10 000	5 000
Hemp Seed Oil (Edible oil)	10 000	5 000	20 000	10 000	10 000
Processed Press Cake (Protein powders, Flour)	10 000	–	–	10 000	5 000

Conclusion

EIHA asks the European Commission and the Member States to update their THC guidance values according to the new scientific findings highlighted in this paper and the EIHA proposal based on them. EIHA proposes the use of guidance values on ingredients (Table 2) for several reasons:

- Simplifying identification and categorisation of hemp products;
- Scientifically, it is certain that all products derived from the three main hemp ingredients (hemp seeds whole or hulled; hemp seed oil; or processed press cake) will be safe as they will only partially be made of well-regulated hemp ingredients;
- The approach is commonly and successfully used by other major hemp producing countries such as Switzerland, Canada and Australia.

[4] Health Canada's THC limit values refer to Δ9-THC, however the official testing method uses GC without derivatisation. We assume a similar approach for Switzerland. Therefore, the limits should be interpreted as Total-THC.

Urgent next steps

- To avoid long-term negative impacts for the European hemp food producers, urgent actions are required to stop the blockage of safe hemp food products immediately.
- Create a working group in DG Health to develop and propose guidelines for THC in food products to harmonize its regulation in the EU member states, and protect the consumer without unnecessarily compromising the market of hemp products.
- The first European THC guidance values should reflect the latest scientific results, as shown in the report "Scientifically Sound Guidelines for THC in Food in Europe" and studies mentioned in this and other papers, including Sarmento et al. 2015, Iffland, Carus and Grotenhermen 2016, Iffland, Kruse and Carus 2016, combined with the new findings from studies performed in 2016 (see table 1 and 2), such as:
  - Actual adherence to EFSA's own guidelines and advice in practice would mean a total uncertainty factor (UF) of 10 for THC. This UF takes into account interindividual differences and does not use a LOAEL-NOAEL-UF (similar to nicotine). Considering the better data quality of THC compared to e.g. thujone and THC's mild transient effects, the UF could be further reduced (compare with tocopherol and amygdaline using an UF of 2 and 4.74 respectively).
  - The European THC guidance values should focus on different groups of ingredients, as safe ingredients THC values assure the safety of all types of products derived from said ingredients.
  - For hemp-containing food supplements, there should be a separate set of reasonable limits for the Δ9-THC-content (THCA excluded), that should be set together with the hemp and food industry. None of the above values apply to food supplements.
  - Only analytical methods that can differentiate between THCA and active Δ9-THC should be allowed to measure adherence to the future new EU THC limits. This is in line with the newest recommendation 2016/2115 of the European Commission on the monitoring of Δ9-THC, its precursors and other Cannabinoids in food. This procedure also excludes methods such as simple GC[5], that heats the sample and therefore artificially increases the Δ9-THC level, causing false positives.
  - As a long-term aim EIHA proposes that only Δ9-THC(-content) should be considered for legal and regulatory assessment of hemp food products.
- Further research on up-to-date hemp food consumption patterns is needed to evaluate which higher guidance values will be still safe for the consumer and practicable for the industry. Australian authorities, faced with the same problem, accepted a 10% market penetration of hemp based food goods for all consumption values that they used.

[5] Gas Chromatography

Appendix

Uncertainty Factors

Table 3: Comparison of uncertainty factors (UF) used by EFSA for various inherent plant toxins, food contaminants and vitamins (references can be found in the extensive table 2 in Iffland, Kruse and Carus 2016).

Substance	UF	Comment
THC	30	Factor of 10 was used for interindividual differences and 3 for the extrapolation of NOAEL from LOAEL measuring mood alteration
opium alkaloids	3	Extrapolation of LOEL to NOEL was considered in the UF but neither the interindividual differences nor interactions between the alkaloids or that codeine gets metabolized to morphine
tropanalkaloid	10	UF accounts for interindividual differences in the NOAEL measuring e.g. deceleration of heart rate
vitamin E	2	UF is for interindividual differences for the NOAEL-end-point of blood clotting
caffeine	1	EFSA does not use any UFs for its guidance value of 5.7 mg/kg b.w. even though anxiety and behavioural changes already occur at 3 mg/kg
alcohol	n/a	No EFSA risk assessment. Interestingly alcohol can cause dizziness in children starting from 1,5 g alcohol and apple juice can contain 0.77 g/L and a roll 1.2 g/100 g
coumarin	100	The NOAEL for hepatotoxicity was measured in dogs so according to WHO/EFSA guidelines an UF of 10 was used for interspecies differences and another 10 for interindividual differences
cyanide/amygdaline	4.74	The UF is comprised of a toxicodynamic subfactor and 1.5 for women and children
thujone	500	The NOAEL for convulsions and seizures was measured in mice so according to WHO/EFSA guidelines an UF of 10 was used for interspecies differences and another 10 for interindividual differences. An extra 5 was used for poor data quality (which was not done for e.g. vanillin)
menthol	50	UFs and rationale behind them were not directly mentioned, also different NOAELs (for changes in body weight) were cited, ranging from 200 - 600 mg/kg bw. The UF of 50 is based on 200 mg/kg bw
nicotine	4.4	NO correction for LOAEL to NOAEL extrapolation. Correction factor of 0.44 because they used a study where they injected nicotine even though a 2006 study of smoked nicotine also exists.

Withdrawal of safe hemp food products

The "Chemisches und Veterinäruntersuchungsamt Karlsruhe (CVUA)" conducted a series of inspections on hemp food products (protein powder, nutritional supplement containing protein powder, hulled hemp seeds) in the German market, in summer of 2016.

These products are used as ingredients in the preparation of ready-to-eat meals. The BVL[6] issued reports followed by RASFF alerts, which were distributed through its system to all EU countries. Following the procedures for alerts, some food safety authorities in the EU countries were asking companies in the distribution chain, to recall their products from the market, even if the respective countries have no guidance levels for THC in food. Without sound scientific and legal reasoning, the subject of alerts was "unauthorised substance Tetrahydrocannabinol (THC)" and the risk decision stated as "serious" (for food safety). These actions caused confusion for the retailers, leading to claims from the business operators and consequently high costs for the manufacturers. Additionally, these actions created a high level of uncertainty regarding the legality of the business with industrial hemp seed products.

Further details (for the case described above):

http://www.hempro.de/download/Statement-THC-Foods.pdf

Background information on THC in hemp food

- Application of Article 2, par. (g) of Regulation (EC) 178/2002 is not appropriate in hemp-derived foods since the psychotropic substance Δ9-THC is not added to foods during processing. Rather, Δ9-THC is an unavoidable plant contamination in hemp food.
- About the term „THC": Δ9-THC (shortly named "THC" or "neutral-THC" or "active THC") is the psychoactive substance of total-THC. Another component in hemp food is Δ9-tetrahydrocannabinolic acid (THCA), the

[6] Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety)

natural precursor of Δ9-THC, which itself is non-psychotropic. THCA is neither converted to Δ9-THC in the human body, nor is there an enzymatic pathway from THCA to Δ9-THC. Non-psychoactive THCA can be transformed with heat into the psychoactive Δ9- THC, but a significant time and sufficiently high temperatures are needed. Additionally, Δ9-THC will be partly transformed into a non-psychotropic molecule after prolonged heating (Iffland, Carus and Grotenhermen, 2016).

- Δ9-THC and THCA only occur in the flowers, leaves and the small petals which cover the hemp seeds. The hemp seeds themselves do not contain Δ9-THC and THCA. THC in food is only detected due to a contamination, caused during bloom and harvest from the blooms, the flower petals and the resins of the fresh plant. The proportion of THCA (in relation to Δ9-THC) in fresh hemp plants is up to 90%.
- Various analytical methods for THC determination exist. There are various methods for detection and quantification based on Gas Chromatography (GC), i.e. combining GC with mass spectrometry (MS) or flame ionisation detector (FID). German authorities use the GC-MS method for determination of the "THC value" in food products. Both methods work at temperatures between 260 and 300 °C. Since THCA is fully converted into Δ9-THC at this temperature, the result of the GC-MS method automatically states the total-THC. Consequently, analysis with GC-MS cannot differentiate between Δ9-THC and THCA in the hemp product at such high temperatures. These temperatures cannot be reached under normal (household) conditions, even when using hemp ingredients for baking or cooking. Most hemp ingredients do not get heated at all, but are used as "raw food diet" and "super food" in salads, mueslis or smoothies. EFSA explicitly states in its report "Risks of THC in Milk and other food with animal origin to human health" (2015) that GC-MS and GC-FID are showing a high neutral-THC (in this case total-THC) compared to High Performance Liquid Chromatography (HPLC) method, a test-method which uses ambient temperatures (and therefore can differentiate between Δ9-THC and THCA).
- The German Federal Institute for Risk Assessment (BfR, former BgVV) issued guidelines for THC in hemp foods for Germany, which are based on an Acceptable Daily Intake (ADI) of 1 to 2 **µg** of **total THC** per kg body weight. This was calculated using an uncertainty factor of 20 to 40 for a daily intake of total-THC of 2.5 mg effective dose per day for an average male person weighing 70 kg.
- European Food Safety Authority (EFSA) recommends an Acute Reference Dose (ARfD) of **1 µg** of **Δ9-THC** (not total-THC) per kg body weight.
- With regards to EFSA´s own guidelines and advice in practice, an uncertainty factor of 10 for Δ9-THC would apply. Using an UF of 10 and a LOEL (and as well a NOAEL) of 0.07 mg/kg b.w. would lead to an **A**cute **Ref**erence **D**ose (ARfD) of **7 µg Δ9-THC/kg b.w.** (see calculations). This ARfD is EIHA's recommendation for a reasonable and scientifically justified intake of THC from food, in contrast to the ARfD currently used by EFSA.
- The basic hemp seed products, processed directly from industrial hemp seeds such as protein powder, whole and shelled/hulled hemp seeds, hemp seed oil, are usually not consumed pure, as a single product or staple. On the contrary, these hemp raw materials are used as ingredients. In ready-to-eat meals, quantities of hemp ingredients are equivalent to a teaspoon or tablespoon. Consequently, the content of Δ9-THC in ready-to-eat food is much lower than in the hemp seed and the hemp ingredients themselves. Therefore, it is inappropriate to use the guidance values for ready-to-eat foods in the evaluation of hemp ingredients.
- Legal consumption of hemp products does not interfere with THC drug tests. It has been shown that extended daily ingestion of 450 µg Δ9-THC in hemp oil is not likely to cause positive results of blood or urine tests.

Literature

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