

# Reasonable Guidance Values for THC (Tetrahydro- cannabinol) in Food Products and Feed

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Maternushaus, Cologne, Germany

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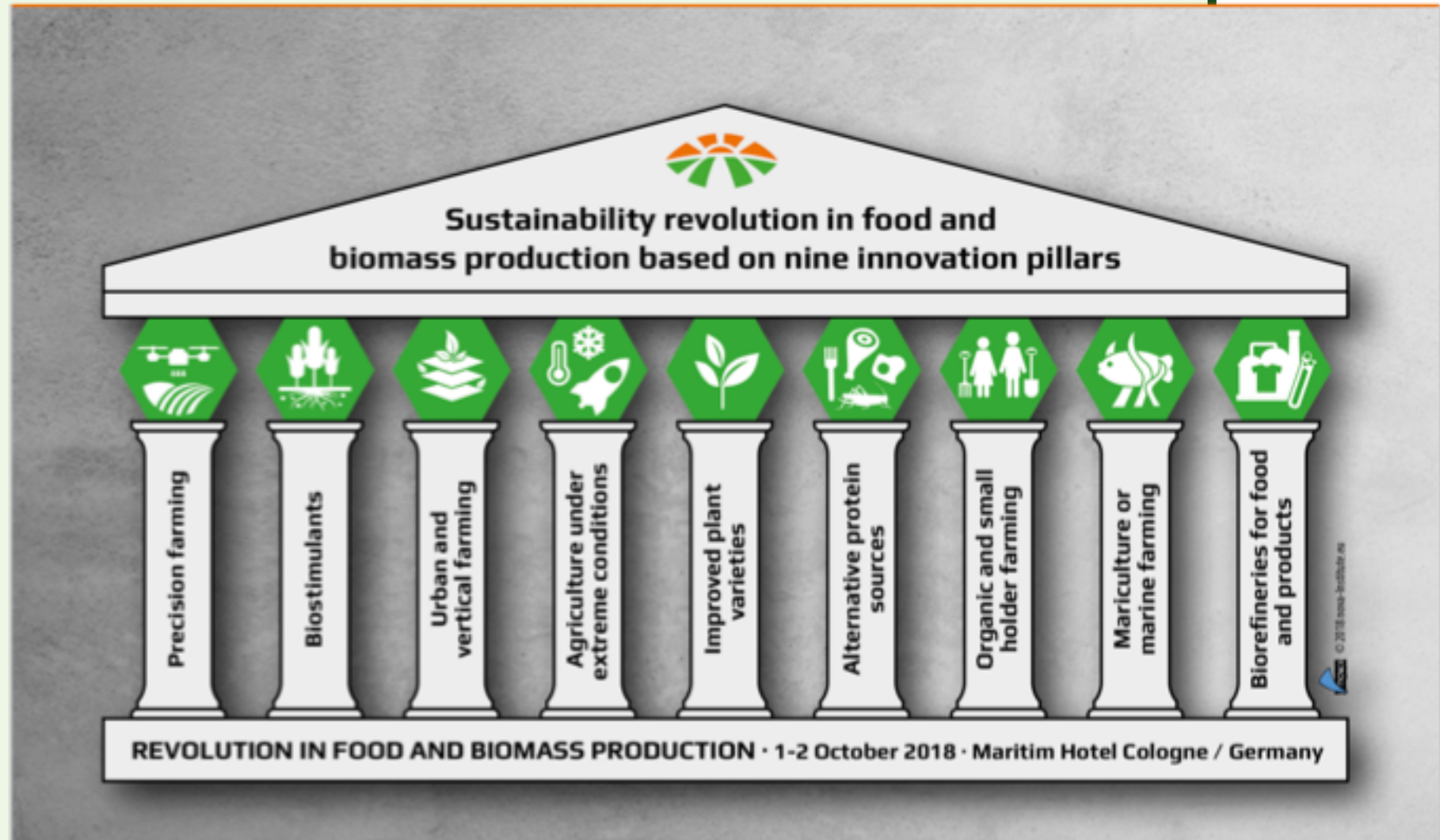
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## Reports and position papers

### Latest activities and publications on CBD

- 18-01-17 Press Release: Pre-review of CBD by the World Health Organization (WHO) with favorable results – next step in May
- 17-12-07-Joint EIHA – FAAAT contribution to the 39th ECDD evaluation of Cannabidiol
- 17-03-29 Press Release: Patchwork of regulations on Cannabidiol (CBD) endangering use as a food supplement to the detriment of consumers and food industry
- 17-01 Position paper of EIHA on CBD, update January 2017 (support page)
- 16-10-24-Review on: Safety and Side Effects of CBD
- 16-09-01-Even high doses of oral cannabidiol do not cause THC-like effects in humans
- 16-11-11-Legal-Opinion-CBD-Novel-Food
- 16-12-07-Legal-opinion-CBD-Medicinal-product
- 16-10-26\_Rechtsgutachten\_CDB-Arznei
- 16-10-26\_Rechtsgutachten\_CBD\_Novel Food

### Latest activities and publications on THC

- **NEW: 18-03-07 Press release: The European Industrial Hemp Association (EIHA) demands rational THC limits for industrial hemp in accordance with international regulations**
- 17-09-18 Reasonable guidance values for THC (Tetrahydrocannabinol) in food products
- 17-09-18 Press Release: Reasonable guidance values for THC (Tetrahydrocannabinol) in food products
- 16-10-25-Decarboxylation of Tetrahydrocannabinolic acid (THCA) to active THC
- 16-12-19-Comparison of EFSA's rationale behind using uncertainty factors for plant ingredients in food
- 16-12-08-Legal-Opinion-legal marketability of food with THC
- 16-10-27\_Rechtsgutachten\_Verkehrsfähigkeit\_von\_Lebensmitteln\_mit\_THC

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

# **Reasonable guidance values for THC (Tetrahydrocannabinol) in food products**

**Main authors of the report: Boris Bañas, Dr. Bernhard Beitzke, Michael Carus, Kerstin Iffland, Daniel Kruse, Luis Sarmento, Daniela Sfrija and many other EIHA members and related experts**

**Hürth (Germany), September 2017**

Download this paper and further documents at: [www.eiha.org](http://www.eiha.org)

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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.

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.

**EIHA will have two meetings with DG Health (European Commission) in July and August 2018, and additional meetings in autumn with the German authorities to discuss the proposal.**

## Step 1 – LOEL and daily intake

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  $\Delta$ 9-THC intake per person twice daily (Sarmiento et al. 2015). A total daily intake of 5 mg  $\Delta$ 9-THC (2 x 2.5 mg) results in a LOEL of 0.07 mg  $\Delta$ 9-THC/kg body weight (b.w.) per day assuming a body weight of 70 kg.

## Step 2 – uncertainty factor

The uncertainty factor (UF) for  $\Delta 9$ -THC as used by EFSA should be lowered from 30 to 10 in line with e.g. Australian Food Standards<sup>2</sup>. 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).

With regards to EFSA's own guidelines and advice in practice, an uncertainty factor of 10 for  $\Delta 9$ -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 **Acute Reference Dose (ARfD)** of **7  $\mu$ g  $\Delta 9$ -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.

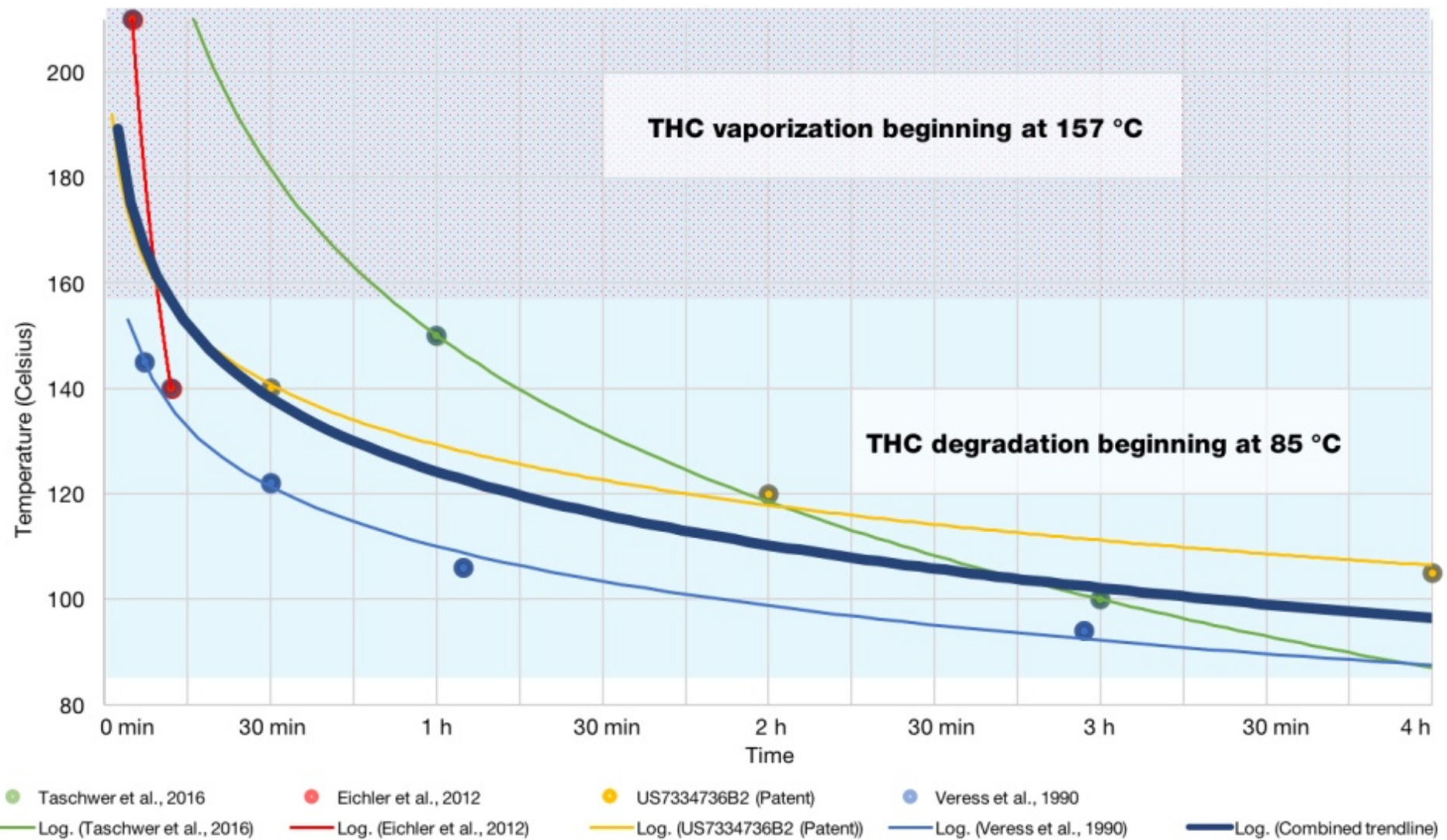
$$\text{LOEL [mg/kg b.w.]} = \frac{5}{70} = 0.07 \text{ mg } \Delta 9\text{THC} / \text{kg b.w.}$$

$$\begin{aligned} \text{ARfD} &= \frac{\text{LOEL}}{\text{UF}_{10}} = \frac{0.07 \text{ mg/kg/day}}{10} = 0.007 \text{ mg } \Delta 9\text{THC} / \text{kg b.w.} \\ &= 7 \mu\text{g } \Delta 9\text{THC} / \text{kg b.w.} \end{aligned}$$

## Step 3

### ARfD

## Step 4 Complete THCA decarboxylation to THC



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 ( $0.49 \times 500.55 \text{ µg total THC} / 70\text{kg} = 3.5 \text{ µg } \Delta 9\text{-THC}$ ) with three additional safety factors:

## Step 5

## Total-THC daily uptake

**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 <sup>4</sup> |                |                                   |
|-----------------------------------------------|--------------------------------------|-----------------------------------|-------------------------|----------------|-----------------------------------|
|                                               |                                      | Germany – BfR [µg/kg] (total THC) | Switzerland [µg/kg]     | Canada [µg/kg] | Australia and New Zealand [µg/kg] |
|                                               |                                      | 2000                              | 2016                    | 1998           | 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                             |

**The EIHA proposal has already strong impacts on the legislation in some European countries such as Greece.**

**EIHA is in discussions with hemp associations in the USA, Canada and China – and in the future also India and Australia – to harmonise the THC guidelines for hemp foods worldwide and thus speak with a strong voice in all regions and at international level.**

## **One last thing ... before CBD**

**Boris Bañas (EIHA board) and Bernhard Beitzke (EIHA advisory committee) have done so much in the field of CBD in the last 12 months in cooperation with FAAAT at international level (WHO) that they deserve special thanks from all of us.**