Press release

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Limit and guideline values for THC (tetrahydrocannabinol) in hemp foods

Analysis and evaluation of the opinion of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) from 8 November 2018 "Tetrahydrocannabinol levels are too high in many hemp-containing foods – health impairments are possible" No. 034/2018.

Hemp foods containing different components of the hemp plant in their original or processed form are enjoying increasing popularity worldwide. In North America, China and also Europe hundreds of hemp products are on the market and, with their valuable fatty acids and proteins, belong to the trend products of a healthy nutrition.

Since small amounts of the psychoactive tetrahydrocannabinol (Δ^9-THC), hereinafter briefly referred to as THC, remain in the food even after the most careful processing, limit or guideline values must be defined that reliably protect the consumers from side effects. As we present in this study, a number of countries such as Australia, Canada and Switzerland have set themselves similar limit or guideline values. These allow producers sufficient leeway to supply consumers with a variety of hemp products, while avoiding any side effects from THC. More than ten years of experience in Canada confirm this.

The legal situation in Europe is more complicated and constitutes an obstacle to the further development of the industry. In Europe, there are no uniform limit or guideline values for residual THC contents in food, not even uniform guideline values for consumption. Back in 1997, the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) (formerly BgVV) established THC guideline values that, until today, represent the strictest international values and have been criticised by experts for years as being too restrictive. When the Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, BMEL) commissioned the BfR to clarify some fundamental aspects regarding the assessment of the THC content in food at the request of the monitoring authority of a federal state, many scientists and producers hoped for a comprehensive reassessment and adaptation as well as international harmonisation of the guideline values.

These hopes were severely disappointed by the BfR opinion No. 034/2018 of 8 November 2018 "Tetrahydrocannabinol levels are too high in many hemp-containing foods – health impairments are possible". Instead of a comprehensive reassessment, 40 pages explain why the 1997 established THC guideline values would continue to apply and that, if they were to be amended, they would rather be tightened than loosened. Germany would thus create clear

barriers to the growing hemp industry and make it more difficult for the population to access hemp products as a result of higher prices.

In this situation the European Industrial Hemp Association (www.eiha.org), the industry association of the European hemp industry, asked the independent nova-Institute to analyse and evaluate the BfR statement. In cooperation with representatives of the scientific advisory board and the executive committee of the association, a 29-page-long evaluation was created. In the following, the most important results of this evaluation will be summarised.

In the opinion of the scientists, the BfR has taken the easy way out with its statement and defence of its recommendations from 1997. Much has happened since 1997, new scientific findings have been gained and comprehensive experiences with hemp foods have been made in many countries – both have not been adequately considered. Six important scientific studies published after the year 2000 and the detailed EIHA position paper "Reasonable guidance values for THC (tetrahydrocannabinol) in food products" (September 2017) were not regarded when reviewing their own risk assessment; they were simply ignored, even though they were known to the BfR. If the new scientific findings were to be considered, a defence of the old guideline values would fall short. It becomes apparent that a comprehensive revision of the recommendations is necessary and that the THC guideline values can be significantly increased without any risk when consuming hemp products - and internationally harmonised.

In order to establish guideline values with a sufficient safety distance to undesirable effects, one must know the LOAEL (lowest observed adverse effect level) or the NOAEL (no observed adverse effect level) and then apply a factor that takes into account the different sensitivities of the consumers. The European Food Safety Authority (EFSA) has issued clear recommendations on the methodological approach.

Uncertainty factor

The BfR applies an uncertainty factor of 20-40 to THC, since no NOAEL is known for THC. Therefore, in addition to the usual EFSA uncertainty factor of 10, the BfR uses a further uncertainty factor of 2-4 for interindividual differences, namely for the extrapolation from the known LOAEL of THC to NOAEL. But according to current scientific knowledge, this is no longer tenable. Due to the more recent clinical experience on active THC, we know today where the NOAEL lies for the large majority of patients. An additional factor of 2-4 is therefore no longer justifiable.
Also, the reasoning that there is no sufficient data available on the effects of THC appears to be not very reliable because in the current evaluation of THC twice as many studies are used as in the evaluation of nicotine. In addition, today numerous other studies exist that further support a more differentiated evaluation of THC. If one compares the uncertainty factor of 20-40 with the uncertainty factors the BfR assigns to other psychologically active substances, the procedure and justification does no longer appear scientifically comprehensible.

For nicotine, opium alkaloids, but especially for caffeine and alcohol, very low (or no) uncertainty factors are applied, even lower than the recommended standard uncertainty factor of 10 for interindividual differences. For THC, on the other hand, a strict methodology is followed and then further exacerbated by applying an extra factor on top, which is not scientifically tenable. If, for example, the BfR were to apply comparable standards to alcohol as to THC, bread or orange juice would no longer be marketable. And similarly, there would

be no more poppy-seed cakes or poppy-seed rolls to purchase if opium alkaloids were subject to the same procedure for risk assessment as THC.
The BfR risk assessments for the substances mentioned are inconsistent, inscrutable and hardly comprehensible. This systematic unequal treatment of substances with similar effects will not withstand an overarching risk assessment and is scientifically outdated.

Active THC and patients

There are further errors and inconsistencies in the BfR statement that systematically overestimate THC risks: The studies used by the BfR only use active THC, whereas in reality THC always occurs together with other cannabinoids that can influence the effect of active THC. In addition, all studies used were medical studies and therefore conducted exclusively on patients, sick persons, who are usually more sensitive than healthy people.
But when assessing "health claims" on food, the EU Commission usually only considers studies that were carried out on healthy volunteers. Clinical studies on sick volunteers generally have the disadvantage that possibly relevant physiological parameters of the volunteers are altered. This scientific principle must of course be observed not only in health-related effects, but also in risk assessment.

Total THC and active THC

The biggest error, however, results from the imprecise distinction between total THC and the active form of THC (Δ^9-THC). In most hemp foods, THC is primarily present in its non-active form (up to 90%), which only converts into its active form after prolonged heating. A complete transformation is almost impossible under normal production and preparation conditions of food.
If the guideline values refer to total THC and not only to the active form, the guideline values are systematically set too strict. In other words, the BfR derives much too high active THC contents in food in its approach. This leads to objectively inaccurate results and scientifically completely wrong conclusions for the risk evaluation of THC.

Bottom line

The BfR has once again missed the opportunity to comprehensively revise the THC guideline values, to take account of current scientific findings and to harmonise the German THC guideline values internationally. The attempt to defend the old recommendations fails because the arguments are based on outdated information, systematically ignoring studies and findings from the last 18 years for a differentiated risk assessment. The lack of a clear distinction between total THC and active THC, which has long been the scientific standard, is also a weak point of the BfR statement that cannot be ignored.
Why the BfR shows such, scientifically not justifiable, severity with the THC in food, while the reference values for comparable substances such as alcohol, caffeine, nicotine and opium alkaloids are disproportionately indulgent and generous, can at this point only be speculated. Are there lobby interests behind this? Shall competition for established products on the market be prevented? Or is it still a remnant of the fight against the alleged "devil drug cannabis"?
Whatever the reason, there can be no speculation about the following conclusion: The measurements and methodologies of the BfR are so different that they cannot prevail. The current risk assessment of THC by the BfR is inadequate according to current scientific knowledge, goes against international experiences and potential harmonisation, and should therefore be urgently revised.

The study was conducted by the nova-Institute and commissioned by the European Industrial Hemp Association (EIHA). Please support EIHA and become a member so that further such studies can be financed.

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You can download the full nova study "Evaluation of limit and guideline values of THC (tetrahydrocannabinol) in hemp foods" for free under: www.bio-based.eu/ecology/

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