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08. Dezember 2016
B/sm
PR-Nr. 261/16

Legal Opinion legal marketability of foodstuff with Tetrahydracannabinol (THC)

Dear Mr. Carus,

The European Industrial Hemp Association (EIHA) has asked me to provide for a legal opinion concerning the legal marketability of hemp products. One of the reasons is that currently there are several complaints of the competent authorities denying the legal marketability of foodstuff, partly within so called RASFF-Notifications.

Therefore the Association EIHA itself as well as individual members of the Association would like to provide for a legal opinion clarifying the legal basis and to evaluate the legality of the actions of the competent authorities.

1. Legal basis

Primarily it has to be considered that according to Article 14 section 1 of Regulation 178/2002/EC food shall not be placed on the market if it is unsafe. According to Article 14 section 2 food shall be deemed to be unsafe if it is considered to be

a) injurious to health;
b) unfit for human consumption.

According to Article 14 section 3 in determining whether any food is unsafe, regard shall be head to

a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution and
b) to the information provided to the consumer, including information of the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

It has to be considered as well that according to Article 5 section 1 food law has to pursue as general objective the high level of protection of human life and health and the protection of consumers.

According to Article 6 section 1 food law should be based on risk analysis in order to achieve the general objective of a high level of protection of human health and life.

According to Article 6 risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

According to Article 6 section 3 risk assessment shall take into account the precautionary principle.

The precautionary principle in Article 7 section 1 means that in specific circumstances were, following an assessment of available information, the possibility of harmful effects and health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the community, may be adapted, pending further scientific information for a more comprehensive risk assessment.

Measures adapted on the basis of Article 7 section 1, shall be proportioned and no more restrictive of trade then is required to achieve the high level on health protection chosen in the Community, regard being head to technical and economic feasibility and other factors regarded as limited in the matter under consideration.

According to Article 17 section 1 food business operators at all stages of production, processing and distribution within the business under the control shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

Therefore all operators of hemp products have to ensure that products distributed by them can be qualified after performed risk analysis and under consideration of the precautional principle to be appropriate for human ingestion, and as safe for the human health.

2.

Besides the question of the legal marketability as safe and for the human ingestion appropriate foodstuff, there can be further aspects with regard to the separation line between medicinal products requiring marketing authorization and/or not allowed narcotics.

a)

According to § 2 section 1 No. 1 AMG medicinal products are any substances or combination of substances presented as having properties for treating or preventing disease in human beings (medicinal product by presentation).

Here it has to be ensured, that the products are not marketed and/or advertised with any therapeutical purpose.

b)

Moreover the product shall be no medicinal product by function requiring a marketing authorization according § 2 section 1 No. 2 a AMG.

These are any substances or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting pharmacological, immunological or metabolic action.

In the past there have been repeated considerations, whether products causing a narcotic effect could fall under the marketing authorization of medicinal products.

By judgement of July 10, 2014 – C-358/13 (Legal Highs) – however, the European Court of Justice has clarified that a qualification as medicinal product by presentation is excluded, if the effects are limited to produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or on the long term, on the human health and are therefore consumed solely to induce a state of intoxication and are, as such, harmful to human health.

Is it therefore not possible to prove scientifically a therapeutical effect of the products, a qualification as medicinal product by function is not possible anymore according to this current case law of the EUC.

c)
Moreover the product shall not be a narcotics requiring a marketing authorization. According to Annex I of the German Betäubungsmittelgesetz in principle Tetrahydracannabinol (THC) falls under the Betäubungsmittelgesetz. However, this is not valid for preparations of the substances in the Annex, if they do nit extend 0,01%.

Foodstuff containing hemp in natural form are in principle allowed in Germany. However, it is "recommended", that their consumption shall not exceed 5 µg/kg for non-alcoholic and alcoholic beverages, 5.000 µg/kg for eatable oil and 250 µg/kg for all other foodstuff.

3.
Currently some hemp products in the market are deemed to be non legal foodstuff according to Article 14 of Regulation 178/2002/EC.

a) Legal basis

For the product "Hanfsaat geschält 100% roh Bio" by Unimedica in the Narayana-Verlag there is an existing complaint of the Untersuchungsamt Karlsruhe dated 12.08.2016. The product was qualified as unsafe according to Article 14 section 1 and 2 b and section 5 of Regulation 178/2002/EC and summarized that it is not allowed to distribute the product in the market.

As well there is a further complaint to the product "Hanfprotein 300 g" by the Untersuchungsamt Karlsruhe dated 24.06.2016 as well with the evaluation that it is prohibited to distribute the product in the market according to Article 14 section 1 and 2 b and section 5 of Regulation 178/2002/EC.

Moreover there exists a complaint of the Untersuchunsamt Karlsruhe dated June 24, 2016 for the product "Hanfprotein plus Ashwaganda", distributed at Fitnessworld24 by the manufacturer "Feinstoff".

Here as well the product was qualified as not legally on the market according to Article 14 section 1 and 2 b, section 5 VO 178/2002/EC.

As result of the complaints there has been a notification within the Rapid Safety Warning System RASFF.

The concerned retail companies have stopped voluntarily the distribution of the products after receiving the complaints of the authorities, although the authorities have not ordered to stop the distribution.

b) Publications of health authorities

aa)
The BgVV in Germany published in July 2000 the so called "Guidance" for THC in foodstuff containing hemp.

For the evaluation of health risks of the products the content of the multifunctional an intoxication generating Delta-9-THC respectively its precursor Delta-9-Tetrahydrocannabinolcarbonacid is decisive.

The BgVV recommended that the daily intake of THC with foodstuff containing hemp shall not exceed 1 – 2 µg/kg bodyweight. Under the assumption that daily several hemp containing products would be ingested in an average amount, the following THC-Guidance levels for foodstuff were established:

- 5 µg/kf for non alcoholic and alcoholic beverages
- 5.000 µg/kg for cooking oils
- 150 µg/kg for all other foodstuff.

These Guidance levels refer to the foodstuff ready for consumption and apply for the total THC-content including Delta-9-Tetrahydrocannabinolcarbonacid. This dosage was according to the at this time relevant knowledge qualified as harmless for human health.

Since the dosage dependency of some of the effects of THC are not clarified completely, these are only preliminary Guidelines. There are only intended for an orientation of the foodstuff authorities and manufacturers.

In the meantime these Guidance levels have been confirmed in deliberations of the Senate Commission of the Deutsche Forschungsgemeinschaft zur Beurteilung der gesundheitlichen Unbedenklichkeit von Lebensmitteln (SKLM). Moreover it is pointed out there, that a working group at the BgVV shall evaluate the current development of appropriate standardized analysis methods for the determination of total THC in several foodstuff.

It has to be clarified here that these "Guidances" are qualified as pure recommendation which is not legally binding.

We quote from the commentary Zipfel/Rathke, Lebensmittelrecht, Band II, C 102, § 11 Rdnr. 287 as follows:

> *"According to the decision OLG Köln, LMRR 2011, 86, the Guidances are no legally binding statutes, nor in each case reliable copies of the current consumer understanding (as well OLG Hamm, LMRR 2012, 3)."*

This is confirmed by the current case law of the VG Osnabrück in the judgement dated 23.08.2007, Az. 4 A 119/06 with the following quote:

> *"There is no justification for another decision although the courts opinion would be in contradiction with the Guidances of the German foodstuff book, which were accepted by the German foodstuff book-commission according to § 33 LMPG (now § 15 LFGB). These may establish an important help for interpretation of the evaluation of the market expectance involved with the name of a foodstuff ... They are no generally binding statutes and therefore not binding for the court ...*
>
> *This complies with the legal opinion of the Ministry for Nutrition, agriculture and consumer protection, references for the application or the guidances of the German foodstuff book ... The guidances of the German foodstuff book are no statutes and therefore not legally binding. They do not have the character of administrative Regulations. In any decisions and opinions these guidances are an interpretation help, but not quotable as legal statute. They do not restrict the legality of actions based on national or European law."*

This confirms that the corresponding Guidelines are not binding for the courts and authorities.

Moreover the BgVV is accepting that there is no generally accepted standardized analysis method, which means that in case of specific complaints it is possible to deny the correctness of the analysis method.

As well the BgVV is open for a further development of the scientific state of knowledge.

bb)

Moreover we provide for a publication of the European Authority for Food Safety (EFSA) on the "Risks for human health related to the presence of Tetrahydrocannbinol (THC) in milk and other food of animal origin, 2015.

The EFSA is recommending an ARfD of 1 Mikrogramm pure Delta-9-THC per kg bodyweight.

In other countries the thresholds respectively Guideline levels are significantly higher. In Switzerland there is a binding threshold of Delta-9-THC in foodstuff. In Canada, which provides for a particular great experience with the production of hemp food commodity, exists a threshold for Delta-9-THC of 10 mg/kg for hemp food commodities.

5. Current problems in the risk evaluation

a)

In the current practice of the competent authorities in Germany obviously it is referred for the risk evaluation on the total THC content. There is no differentiation which amount of the psychoactive substance Delta-9-THC is ingested with the specific foodstuff by recommended daily ingestion and how much of the not psychoactive precursor Delta-9-Tetrahydrocannbinonacid (THC-A).

It seems to be the state of the science – as the case may be this could be proven by a scientific expert opinion – that in fresh hemp plants the not psychoactive THC-A-content is contained in relation to the active Delta-9-THC up to 90% and on the outer shell of hempseeds (even after natural or industrial drying) the proportion is still ca. 50%.

If however the total THC-content is consisting out of the psychoactive Delta-9-THC and the not psychoactive precursor Delta-9-Tetrahydrocannabinolcarbonacid (THC-A), for the risk evaluation of the specific product it needs to be determined which specific effects it indeed provides.

If in the evaluations of the competent authorities only the total THC-content is considered and contains the product according to the specific recommendation for ingestion and the purpose of the product a high content of not psychoactive THC-A, therefore the competent authority would make assumptions based on wrong facts and would come therefore compulsory to a wrong risk evaluation.

Depending on the question, which THC-A-content is ingested with the specific product based on the recommended daily dosage, the risk evaluation may change.

According to the relevant case law it needs to be considered the specific intake recommendation and the specific purpose of the individual product. It is not legal to consider a misuse or an overdosage of the consumer contrary to the purpose of the manufacturer.

We quote from the literature e.g. in the Medicinal Product Law, Kloesel/Cyran, Arzneimittelrecht, § 5 Rdnr. 17

> *"For the evaluation of medicinal product as "risky" it needs to be determined the intended usage. Any harmful effects which are caused by a not intended purpose can not be considered for the benefit risk analysis. Which kind of usage is normally intended is determined primarily by the pharmaceutical operator used indications, the proposed manner of usage, contraindications, in general the claims on the label, advertising information.*
>
> *... Harmful effects which are the result of non-intended usage are not relevant. "*

Moreover we quote from the Handbook Pharma Law, Dieners/Reese, page 805 as follows:

> *"The assessment of a harmful effect as not justifiable needs to refer to the intended usage. Only in this scope for which the medicinal product is determined, the benefit risk assessment needs to come to a justification. Without the scope of this area there is no benefit of the medicinal product claimed, therefore such an assessment is not reasonable. Relevant for the intended usage usually are the indications, the dosage and the usage information. Contraindications exclude an intended usage in principle, even if in practice a certain violation of this contraindication has creeped in."*

For the risk evaluation therefore it has to be considered the specific product in its specific actual composition.

If therefore the risk evaluation considers only total-THC and a certain psychoactive effect is based on the total THC-content, whereas the product indeed provides a significant part of THC-A, which is indeed not psychoactive, this is for the corresponding risk evaluation and resulting for the legality of the product of essential importance.

In particular it is not sufficient according to the relevant case law to assume speculative a health risk hypothetically, because possibly the product may provide for a high part of psychoactive Delta-9-THC, whereas the actual psychoactive part of Delta-9-THC was not actually evaluated.

In this case the risk evaluation would be based on pure speculation.

b)
According to the relevant case law, risk evaluations and any on that relying decisions of the competent authorities shall not be based on pure speculation.

The case law, e.g. of the EUC or the OVG Nordrhein-Westfalen is using strict criteria and is not accepting pure speculation for the assumption of health risks (EUC, judgement dated 11.09.2002, T-13/99, Rdnr. 145 – „Pfizer", EuGH, Slg. 1998 I-2265 – „BSE", EFTA-Gerichtshof Surveillance Authority / Kingdom of Norway, E-3/00; EUC, Commission ./. Kingdom Denmark, 23.09.2003, Recital 49; Allpharma/Rat, T-70/99, Slg. 2002, II-0000, Recital 152).

In the judgement European Commssion / Kingdom Denmark as of 23.09.2003, 650, the EUC has clarified, that only the specific effects of the distribution of a specific product, that contains a specific amount of nutrients, can be relevant for the decision.

The EUC has in the Treaty violation procedure European Commssion / Germany in its judgement of 29.04.2004 clarified that it is the obligation of the national authorities to prove a real risk for the health of the population. I quote from the judgement as follows:

> *"Since Article 36 EV-treaty is an exemption which has to be narrowly interpreted from the principle of the free movement of goods within the European Union, it is the obligation of the national authorities, which claim that, in each single case in light of the national nutrition habits and under consideration of the results of the international scientific research to substantiate, that their Regulations are necessary for the effective protection of the interests covered by this Regulation, in particular, that the distribution of the products in question provide for a real risk for the health of the population (judgement Sandoz Rdnr. 22, van Bennekom, Rdnr. 40, Commission ./. Kingdom Denmark, Rdnr. 46 as of 05. Februar 2004 Commission / France, Rdnr. 53).".*

Additionally we refer to the case law of the OVG Nordrhein-Westfalen in the judgement dated 17.03.2006 (Az. 13 A 1977/02). We quote as follows:

> *"It is not possible to determine here health risks by the usage of the product. Independently of the question, which kind of prediction criteria have to be used within this evaluation, it is not possible to refer to hypothetical speculations in foodstuff law, scientifically uncertain claims,*
>
> compare for the probability according to Article 14 *section 4 VO (EC) 178/2002 Gorny, Grundlagen des europäischen Lebensmittelrechts, Rdnr. 297,*
>
> *the pure suspicion or the pure (abstract) possibility of characteristics, which may have potential for a health risk,*
>
> *vgl. Zipfel/Rathke, Lebensmittelrecht, Stand: Juli 2005, Bd. II, C 100, § 8 LMBG Rdnr. 6 and C 101, Artikel 14 VO (EG) 178/2002, Rdnr. 39*
>
> *There are no concrete indications for the assumption that in case of a regular (additional) ingestion of the bacteria contained in the product this shall cause specific health disturbances to the consumers."*

Even more clear was the OVG Nordrhein-Westfalen in the judgement OPC as of 17. March 2006 (13 A 2095/02) from which we quote as follows:

> *"There are no specific indications for the assumption that by regular, additional daily intake of 50 mg OPC this could result into specific health disturbances for the consumers. As far as the defendant has in its letter of 16.12.2005 under the heading "Health risks" quoted literature quotations do not justify significant health risks and in particular not a specific possibility of a health risk. It seems to be strange that the defendant is referring to "newest scientific findings", but in the following it is referred with regard to alleged carcinogenic effects on scientific publications on animal trials, e.g. from the years 1960, 1968 and 1974, without showing that there are new these old research confirming publications. With regard to humans and with regard to Tannine it is only unclear referred to the option that there may be possible relations. In summary this can not be deemed to be a qualified risk analysis (compare for the foodstuff area Article 3 No. 11, section 2 VO 178/2002/E) since – similar like the pharmacological effects – all possible publications which have at the farthest something to do with Flavonoids (OPC) all effects, risks, are added without evaluation and*

weighing, although they belong to different decades, very different questions with different scientific approaches – in-vitro-tests, animals trials and epidemiological studies up to pure literature interpretations – and the results as far as they refer to OPC from grape seeds and their effects on humans do not go beyond assumptions and speculations."

Moreover we refer to the vote of the General Advocate Trstenjak dated June 21, 2007 in case C-319/05 (European Commission / Germany) with regard to garlic preparations in capsule form and quote as follows from recital 44:

"Consequently for the particular risks as well as for the effect of a medicinal product this has to be evaluated based on information which has to be based on solid scientific research."

In particular the legislator presupposes that any recommendations for the preparation and the recommendation for the daily usage of the products have to be considered. According to Article 14 section 3 of Regulation 178/2002/EC in determining whether any food is unsafe the normal conditions of use of the food by the consumer and the information provided to the consumer on the label have to be considered as well.

c)
Moreover it needs to be considered that there needs to be differentiated between the commodity as such and the final prepared foodstuff.

In my view it is reasonable that for the risk evaluation it is not sufficient to refer abstract on the commodity itself, but of the specific final product with a specific recommendation of ingestion and the resulting daily dosage of a specific substance.

Therefore one can not generally assume e.g. for cinnamon that it is not safe for human consumption, but that this may be dependent on the variety of cinnamon and besides that dependent on the daily amount of the specific foodstuff. This would apply for plenty of substances, e.g. garlic, ginkgo or even vitamins and minerals. In general for foodstuff and medicinal products the dosage and concentration is the decisive factor for the risk evaluation.

This applies as well for the remark that it needs to be differentiated between the total THC-content on the one hand and THC-A on the other side. Is it scientifically proven that single components of THC have to be scientifically evaluated differently because they cause other

effects in the human body, this needs to be considered at the risk evaluation correspondingly.

This applies as well for any preparation instructions, e.g. heating instructions. According to Article 14 section 3 a of Regulation 178/2002/EC in determining whether any food is unsafe the normal conditions of use and the information provided to the consumer needs to be considered.

Moreover it needs to be clarified whether the used analysis method (modified extraction by Holler, GC/MS, standard addition) is scientifically generally accepted or whether there can be objections against these analysis methods?

b)
Moreover it can be disputed whether a single analysis can provide a representative statement at all with regard to the THC-content of a product. First of all it needs to be determined that for a product there is the requirement that at least analysis results of two independent examinations have to exist, what is not the case up to now for the products in dispute.

In this context we refer to the decision of the OLG Lüneburg dated 14.06.2013, Az. 13 ME 18/13 and quote as follows:

> *"The predominant arguments prevail that the intended publication can not be based on an effective legal basis. The only relevant § 40 section 1 a No. 1 LFGB is not complying based on the in the fast track procedure only possible summarized evaluation not with the requirements of the constitution, since there is no time limit for the intended information of the public. According to the permanent case law of the Bundesverfassungsgericht any interventions in the right of self-determination require a sufficient specific statutory authorization.*
>
> *Independent from that in this case the requirements of § 40 section 1 a) No. 1 LFGB are not given. A publication is according to this Regulation only possible if it is based on facts, in case product samples (§ 39 section 1 s. 2) on the basis of at least two independent examinations of institutions according to Article 12 section 2 of VO 882/2004 reasonable suspicion existing, that the Regulations in the scope of this law determined thresholds, maximum amounts are exceeded.*
>
> *This Regulation presupposes therefore by an reasonable interpretation independent examinations of different laboratories (compare VG Hannover, decision as of*

29.01.2013, – 9 B 264/13 … Grube/Immel, ZLR 2012, 109, 113; Kühne/Preuss, ZLR 2012, 284, 294 ff. (…).

According to a scientific expert hearing the Committee for Nutrition, Agriculture and Consumer Protection recommended on application of the fraction of the CDU/CSU and FDP the amendment of the draft of a statute and added for the case of samples according to § 39 section 1 s. 2 LFGB as basis for a reasonable suspicion the requirement of at least two independent examinations of institutions according to Article 12 section 2 of Regulation 882/2004 into the wording of the statute. This version became law. This amendment had the purpose "to specify the reasonable suspicion based on facts" on the basis that the facts have to be represented from at least two independent analysis results of accredited institutions (compare BT-DRS. 17/993, p. 18).

The use of the plural form supposes the requirement of an examination by two laboratories (…). Moreover it can be argued by the sense and purpose of the Regulation that there needs to be an examination by different laboratories. The normative requirement for at least two examinations shall guarantee that the examination result is sufficiently safe before it is published. The legislator has therefore made clear that a single examination is not sufficient. Moreover only accredited laboratories within the meaning of Article 12 section 2 VO 882/2004 are allowed to do the relevant examinations. Examinations by two different laboratories guarantee in this context a higher possibility for correctness since the repetition of a possible examination mistake by a repeated examination through the same laboratory is significantly reduced."

Since at this time there are not two analysis results from independent laboratories for the products existing, in my view therefore there is no scientifically valid proof.

d)

In summary it can be concluded, that each product needs to be examined individually. In particular it needs to be evaluated what is the actual psychoactive THC-A-content. If it is scientifically proven that the THC-A-content of a product is not psychoactive, this has decisive importance for the evaluation of the possible health risks of the product. If this would lead for the specific product to the fact that the psychoactive Delta-9-THC-content would be under the anyway not legally binding Guidance level, these products then need to be qualified as indisputably legally on the market according to Article 14 of Regulation 178/2002/EC.

In our view it is important to establish a scientific standard procedure, accepting that the THC-A-content needs to be considered for the risk evaluation, leading to another risk assessment compared to the pure evaluation of the total THC-content.

Please do not hesitate to contact me in case of any further questions.

Yours sincerely

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