CONTRIBUTION
to the TRIS Notification 2022/0514/LT regarding the Draft Order of the Minister of Health and the Minister of Agriculture of the Republic of Lithuania
"On approving the list of maximum permitted levels of tetrahydrocannabinol in hemp grown for fibre products or categories intended for final consumption"

October 19, 2022
Vilnius

We, the undersigned organizations (hereinafter – the **Organizations**), operate in the field of hemp growing, production of hemp products for final consumption and production of intermediate products, as well as conducting the science and research on hemp products. Our teams include botanists, hemp growers, technical engineers, chemists, and quality control specialists.

Our areas of focus and expertise include:
- Research and applicability of natural hemp-derived remedies to cosmetics, food supplements, functional food;
- Development of cannabinoids as a promising novel treatment strategy targeting numerous diseases affecting human health;
- Development of sustainable hemp growing and processing methods.

The publication of the Draft Order of the Minister of Health and the Minister of Agriculture of the Republic of Lithuania "*On approving the list of maximum permitted levels of tetrahydrocannabinol in hemp grown for fibre products or categories intended for final consumption*" (hereinafter – the **Draft Order**) has raised numerous concerns about its overly restrictive nature that could not only adversely affect the producers of goods derived from hemp, but also contribute to the artificial partition of European single market. In particular, the Draft Order sets out the maximum permitted level of tetrahydrocannabinol in food supplements at 2 mg/kg, and the maximum permitted level of tetrahydrocannabinol in non-alcoholic beverages in at 0.02 mg/kg.

The Organizations note that on June 29, 2022 CJSC "Biosyyd" (company code 304741925, address A. Juozapavičiaus ave. 7, LT-45251 Kaunas, Republic of Lithuania, hereinafter - **Biosyyd**), a company actively working in hemp research and hemp product development sector, has submitted an appeal to the Ministry of Health of the Republic of Lithuania and Ministry of Agriculture of the Republic of Lithuania (hereinafter – the **Ministries**) regarding the restrictions provided for in the Draft Order (Annex No. 1, hereinafter - the **Appeal**), in which it raised concerns regarding the reasoning behind the Draft Order and provided a scientific substantiation for setting higher maximum permitted levels of tetrahydrocannabinol in hemp products or categories intended for final consumption than those indicated in the Draft Order. However, the Ministries did not provide an answer to the Appeal and did not amend the Draft Order.

For these reasons the Organizations submit this Contribution in which the Organizations:
i. **Detail the insufficiencies in the process of adoption of the Draft Order;**
ii. **Outline the errors in the scientific reasoning behind the Draft Order;**
iii. **Detail the obstacles to the free movement of goods within the internal market created by the Draft Order;**
iv. **Urge the European Commission to deliver a detailed opinion to the responsible institutions in the Republic of Lithuania to the effect that the measure envisaged in the Draft Order may create obstacles to the free movement of goods within the internal market in accordance with Article 6(2) of Directive (EU) 2015/1535.**

I. THE PROCESS OF ADOPTION OF THE DRAFT ORDER

On June 6, 2022 the Ministries published the Draft Order in the electronic Legal Acts Information System of the Republic of Lithuania and set a term of 5 calendar days for its coordination with other governmental institutions and interested parties.

The aforementioned step and the setting of a very short coordination period seemingly contradicted the provisions of laws of the Republic of Lithuania which detail the process of legislation and coordination of legislation projects, attaching particular importance to processes when the legislative acts need to be coordinated with European Union legislation:

- Article 9(2) of the Law on Legislative Frameworks of the Republic of Lithuania (hereinafter – the **Law on Legislative Frameworks**) states that "*In the period of legal act project preparation, when the Lithuanian national law is coordinated with European Union law or international law, all possible alternatives must be taken into an account, and the alternative that satisfies the Lithuanian interests the most, shall be selected*";
- Article 9(5) of the Law on Legislative Frameworks states that „*All persons have the right to submit proposals regarding the draft legal act published in the Legal Acts Information System. Upon receipt of proposals that have not been submitted in the Legal Acts Information System, entities preparing draft legal acts must also transfer and publish them in the Legal Acts Information System. The entity drafting the legal act evaluates all submitted proposals*";
- In addition, article 17(3) of the Law on Legislative Frameworks states that „*When drafting legal acts electronically, the institutions with which the draft legal act is expected to be coordinated usually participate. Other persons or groups of persons may also participate in the drafting of legal acts electronically by submitting proposals for the draft legal act being prepared*".

These provisions mean that, according to the Law on Legislative Frameworks, every Lithuanian citizen and entity has a right to be involved in law-making progress.

Biosyyd, acting in accordance with the provisions of the Law on Legislative Frameworks, submitted the Appeal to the Ministries on June 29, 2022. The Appeal contained Biosyyd's concerns regarding the content of the Draft Order with detailed notes and suggestions, in it Biosyyd asked for a deeper cooperation regarding the matter.

However, in spite of the fact that the Appeal contained substantiated argumentation regarding the inadequacy of limits set forth in the Draft Order, the contents of the Appeal were not taken into account by the Ministries and the provisions of the Draft Order were not changed without providing any substantiation as to the reasons of disregarding the arguments set forth in the Appeal.

On July 21, 2022 Lithuania submitted the notification (hereinafter – the **Notification**) regarding the Draft Order to the Technical Regulation Information System (hereinafter – **TRIS**) platform for the Commission and other Members States to examine. At this point, in accordance with the provisions of Article 5(1) of the Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services. On that date the Draft Order entered the stand-still period, where it cannot be adopted, and can receive comments and contributions from the Commission and Member States.

It shall be noted that on August 11, 2022 Commission Regulation (EU) 2022/1393 of 11 August 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ9-THC) in hemp seeds and products derived therefrom (hereinafter – the **THC Regulation**) was

adopted. The THC Regulation covers the matter that is regulated in the Draft Order – the THC Regulation sets forth the maximum levels for delta-9-tetrahydrocannabinol (Δ9-THC) equivalents in foods. The THC Regulation will come into force on January 1, 2023.

Thus the following conclusions can be made about the Draft Order's adoption process:

i. **The Draft Order was not properly coordinated within the Republic of Lithuania as the Ministries did not take into account the information and arguments presented in the Appeal;**
ii. **After the submission of the Draft Order to the TRIS, the THC Regulation was adopted. The THC Regulation covers the matter of setting maximum levels for delta-9-tetrahydrocannabinol (Δ9-THC) equivalents in foods – the same issue that is covered by the Draft Order.**

II. SHORTCOMINGS IN THE JUSTIFICATION OF THE BASIS FOR ADOPTING THE DRAFT ORDER

It is important to note that the Ministries have provided severous erroneous assumptions and conclusions in the substantiation of the provisions of the Draft Order, which contributed to the maximum levels for delta-9-tetrahydrocannabinol (Δ9-THC) equivalents in foods set in the Draft Order being set unjustifiably low.

A detailed analysis of the erroneous methods used to determine the maximum levels for delta-9-tetrahydrocannabinol (Δ9-THC) equivalents in foods in the Draft Order is provided in the Appeal (Annex No. 1). In the Contribution herein the Organizations shall present a summary of the arguments detailed in the Appeal as well as additional comments regarding the Brief Statement of Grounds presented by the Member State in its TRIS Notification.

1.1. Erroneous statements presented in the Brief Statement of Grounds

The Brief Statement of Grounds is a part of the Notification. In accordance with Article 5(1) of the Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (hereinafter – the **TRIS Regulation**), „*Subject to Article 7, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice;* ***they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary****, where those grounds have not already been made clear in the draft*". Thus the Brief Statement of Grounds is supposed to contain the justification of the need to adopt the Draft Order.

However, there are errors and fallacies presented in the Brief Statement of Grounds that give reason to doubt whether the limits set forth in the Draft Order are based on objective scientific data, and fail to substantiate the need for the adoption of the Draft Order.

Firstly, the Brief Statement of Grounds states that „*In 2020, the European Commission prepared a comprehensive opinion on the Draft Law on Hemp Grown for Fibre, where it indicated that in the view of the European Food Safety Authority's THC toxicity and impact assessment, foodstuffs containing 0.2% of THC pose a public health risk and therefore cannot be placed on the EU market. The European Food Safety Authority has determined* ***acute toxicity at 1 µg THC per 1 kg of human body weight***". This statement is verifiably false, as the European Food Safety Authority (hereinafter - the

EFSA) in its 2020 January 7 publication *„Acute human exposure assessment to tetrahydrocannabinol (Δ9-THC)"* has set forth an **acute reference dose** (hereinafter - **ARfD**) of 1 µg/kg body weight (bw) for Δ9-THC.

It must be noted that these two concepts – *„acute toxicity"* and *„acute reference dose"* - are very different: while the former implies a toxic effect to the human body, the latter has been clarified by the European Chemicals Agency[1] as meaning *„an estimate of the amount of a substance in food or drinking water that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer"*, that is, the **ARfD of 1 µg/kg bw for Δ9-THC means that 1 µg of Δ9-THC per kilogram of bodyweight can be safely consumed without the consumer experiencing any adverse effects**.

This means that the Ministries adopted the Draft Order under the assumption that the consumption of 1 µg Δ9-THC per 1 kilogram of bodyweight causes adverse effects, while in reality it is an acceptable limit for safe consumption.

Secondly, the Brief Grounds Statement details that *„Having examined regulatory practices in other EU countries and in line with the precautionary principle, as well as **taking the potential risks to human health into account**, in the Draft Order the working group decided to propose the levels of THC within the range of **0.02** to 7.5 **mg** for the following food categories: hemp grown for fibre seed oil; ground hemp seeds, hemp seeds partially defatted and other products produced or processed from hemp seeds; food supplements (excluding food supplements intended for use by infants, children under 18, pregnant and lactating women); non-alcoholic drinks; other foodstuffs"*.

The lower range of 0.02 mg per 1 kg of product is not further substantiated. Taking into account the fact that 0.02 mg amounts to 20 µg, and that the ARfD for Δ9-THC is 1 µg/kg bw, this lower limit means that a **person with a lower than average bodyweight of 60 kg would have to consume 3 kg of the product in a short period of time to approach the ARfD**. Bearing in mind that the average adult is awake for 16 hours per day, and that the scientific literature details that the effects of THC wear off within 8 hours when taken orally, the ‚short period of time' in this case should not exceed 8 hours, thus such a low limit is unjustifiable, unreasonable and unnecessary.

These statements presented in the Brief Statement of Grounds clearly demonstrate the Draft Order's authors' fundamental misunderstanding of the significance and meaning of the ARfD limit and failure to estimate the likely real-world usage of hemp-derived products. This means that the Draft Order was likely based on erroneus assumptions and faulty premises, thus making the limits set forth in the Draft Order not justified by objective risks.

1.2. Summary of the arguments detailed in the Appeal

Detail arguments and scientific data were presented in the Appeal, which demonstrated the methods used for calculation of Δ9-THC ARfD and acceptable daily intake (hereinafter - **ADI**).

Firstly, the maximum permitted levels of Δ9-THC in products intended for final consumption must be set taking into account the average and maximum consumption of the products in the specific category of products intended for final consumption, as well as the average and maximum duration of the effects of THC on the human body after consumption.

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[1] European Chemicals Agency, *ADI and ARfD derivation for biocidal active substances*, 9 December 2016. Online access: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-health

This means that while setting different maximum levels for different groups of products intended for final consumption is reasonable and necessary, the levels should be determined by evaluating the real-world data on the factual consumption of a certain product.

In practical terms this means that the limits for products that are usually consumed in small quantities (such as food supplements) should in principle be higher than limits for products which are usually consumed in larger quantities (such as non-alcoholic drinks). However, the Draft Order details that the maximum permitted tetrahydrocannabinol quantity for food supplements (excluding food supplements intended for use by infants, children under 18, pregnant and lactating women) – 2 mg/kg – is lower than the maximum permitted quantity for hemp seed oil – 7.5 mg/kg, even though the food supplements are usually consumed in small doses, such as pills or capsules that can contain merely 1-2 grams of the hemp-derived substance. The Draft Order also fails to take into account the fact that the ARfD is a time-dependent indicator, meaning that it should be taken into account that the average amount of a certain product group is likely distributed throughout the day.

Secondly, setting maximum limits for Δ9-THC lower than the limits set forth by the European Union Regulations under the pretenses of „public health protection" is unreasonable as the maximum allowed limits for Δ9-THC are already calculated using stricter parameters than those used in the calculation of ADIs of other psychoactive substances in foodstuffs, such as opium alkaloids, alcohol, nicotine or caffeine.

The main parameter that influences the limit of the ADI is the uncertainty coefficient (hereinafter – **UC**; it is used to compensate for the lack of knowledge of the precision of the test results and the difficulty of assessing effects in different individuals and/or under different exposure conditions), and the higher the UC is, the lower the ADI determined. The UC for Δ9-THC, chosen by the EFSA, was 30, while EFSA's UC for opium alkaloids is 3, for nicotine – 4.4, while UCs for alcohol and caffeine are not determined at all. Bearing in mind the fact that the negative effects of opium alkaloids and nicotine on human health are severe, the setting of an extraordinarily high UC for Δ9-THC demonstrates that the ADI for Δ9-THC is disproportionately lower than respective ADIs of nicotine or opium alkaloids.

Thus it can be concluded that the Draft Order fails to take into the account the factors and calculation methods that are used by the scientific community to evaluate possible effects of psychoactive substances to the human body, and thus the limits set forth in the Draft Regulation are unreasonably low.

III. OBSTACLES TO THE FREE MOVEMENT OF GOODS WITHIN THE INTERNAL MARKET CREATED BY THE DRAFT ORDER

The Draft Order, as a technical regulation, sets forth maximum limits for Δ9-THC in hemp-derived products that differ from the limits set forth in the THC Regulation and thus will affect the free movement of hemp-derived products and to create obstacles to the proper functioning of the internal European Union market.

Since 6 out of the 9 maximum permitted tetrahydrocannabinol quantity limits set forth in the Draft Order for products intender for final consumption by humans are lower than those set forth in the THC Regulation, entry of the Draft Order into force would mean that producers and importers operating in other Member Countries would be unable to distribute and sell many of their products that comply with the THC Regulation in the Republic of Lithuania. This is a clear impediment of the free movement of goods in the Single Market.

Exceptions to the free movement of goods are to be interpreted narrowly in the European Union legislation. Barriers are justified only if the national measures are necessary to satisfy mandatory requirements or any of the interests listed in Article 36 of the Treaty on the Functioning of the European Union (hereinafter – **TFEU**) "*on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States*" and are proportionate to the legitimate objective pursued.

National legislations which aim to restrict the access to the market of the importing Member State are regarded as having an equivalent effect to a quantitative restriction within Article 34 TFEU "*Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.*" Whilst common EU-wide type-approval requirements normally facilitate the marketing of products in the internal market, national type approval in non-harmonized areas may create barriers to trade of goods. In addition, diverging national product standards make it difficult for manufacturers to market the same product in different Member States and may well lead to higher compliance costs. Obligations requiring national type approval prior to the placing of products on the market are therefore to be seen as measures having equivalent effect. Only on the basis of health or safety justifications may a Member State be entitled to require a product which has already received approval in another Member State to undergo a fresh procedure of examination and approval.

The European Court of Justice (hereinafter - the **ECJ**) has issued judgements in several cases pertaining to the artificial partitions within the Single market. In Judgment of 11 January 1996, Commission v Netherlands, Case C-273/94, EU:C:1996:4, paragraphs 13 to 15 the ECJ stated that the national act applying to a specific product a derogation from another technical regulation already in existence concerning the same product constitutes a technical regulation within the meaning of Directive 83/189 since it establishes alternative technical specifications the observance of which is compulsory, *de jure* or *de facto*, when that product is marketed or used. Anyone who wishes to derogate from the existing rule is under an obligation to comply with the alternative specifications in order to produce or place on the market the product in question. The notification obligation does not depend on the presumed effects of the technical regulation in question on trade between Member States. Instead, the objective of the procedure is to establish whether there is any risk of creating a barrier and whether it could be justified in the light of EU legislation. Consequently, even rules liberalizing the arrangements for the products concerned must be notified.

The principle of mutual recognition, which was established by the ECJ in its interpretation of Articles 28-30 of the TFEU and applied in areas that are not harmonized at European Union level. The principle was set by the ECJ in the Cassis de Dijon judgement (Case 120/78, Judgment of the Court of 20 February 1979, ECLI:EU:C:1979:42) in relation to the free movement of goods. According to it, a product lawfully produced and marketed in one Member State must be accepted in another given that the legislation of another Member State is equivalent in its effects to the domestic legislation. In this specific case, Germany refused the placement on the German market of a French liqueur on the ground that it did not correspond to the minimum alcohol percentage required by German law for beverages to be marketed as "liqueur". The ECJ ruled that Germany breached Article 34 of the TFEU. The ECJ also referred to the "rule of reason" regarding the national mandatory requirements that Member States could invoke in order to protect public interests such as health and safety. **On the basis of this rule, Member States must acknowledge that if products are manufactured in accordance with other Member States' national regulations, standards or procedures, they cannot be denied access to their market if these other norms guarantee a comparable level of safety.**

These provisions and case law clearly demonstrate that technical regulations that set out restrictions for certain products groups (when these restrictions are not justified by reasonable public health or safety concerns) constitute artificial partitions of the Single Market. Thus, since the Draft Order sets out arbitrary maximum permitted tetrahydrocannabinol quantities, its adoption would constitute a violation of the TFEU and negatively affect the free movement of hemp-derived products within the Single market.

IV. ORGANIZATIONS' PROPOSALS

On the basis of the information provided above, the Organizations urge the government institutions of the Republic of Lithuania not to adopt the Draft Order.

The Organizations also ask the European Commission to investigate the artificial restrictions on the free circulation of goods created by the Draft Order and oppose the entry of this legal act into force.

ANNEXES:

Annex No. 1 - Biosyyd's appeal to the Ministries.

Best regards,

Association of Industrial Hemp Growers, Processors and Business Innovators (KAPVIA)
Director Rimantas ČIŪTAS

(signature)

Company Biosyyd
Director

Vida Audra BUDRIENĖ

(signature)

Biosyyd, UAB
Įmonės kodas 304741925, PVM mokėtojo kodas LT100011778216
adresas A. Juozapavičiaus pr. 7, LT-45251 Kaunas

Teikiama el. paštu.
Originalas siunčiamas nebus.
Pasirašyta saugiu el. parašu.

Lietuvos Respublikos sveikatos apsaugos ministerijai
ministerija@sam.lt

Lietuvos Respublikos žemės ūkio ministerijai
zum@zum.lt

KREIPIMASIS
Dėl Lietuvos Respublikos sveikatos apsaugos ministro ir Lietuvos Respublikos žemės ūkio ministro įsakymo „Dėl Didžiausių leistinų tetrahidrokanabinolio kiekių galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose ar jų kategorijose sąrašo patvirtinimo“ projekto

2022 m. birželio 23 d.
Kaunas

Gerbiamieji,

Biosyyd, UAB (toliau - **Bendrovė**) veikia galutiniam vartojimui skirtų produktų iš pluoštinių kanapių gamybos bei tarpinių produktų gamybos srityje, taip pat Bendrovė vykdo pluoštinių kanapių produktų tyrimus. Bendrovė, susipažinusi su Lietuvos Respublikos sveikatos apsaugos ministro ir Lietuvos Respublikos žemės ūkio ministro įsakymo „Dėl Didžiausių leistinų tetrahidrokanabinolio kiekių galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose ar jų kategorijose sąrašo patvirtinimo“ projektu, 2022 m. birželio 6 d. paskelbtu Teisės aktų projektų duomenų bazėje (projekto registracijos Nr. 22-8495, interaktyvi prieiga: https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/fa7dbd70e55811ec896de0b71e988500?positionInSearchResults=0&searchModelUUID=45ad0dd0-1002-440f-8f52-7dce0adf9ca7) (toliau - **Projektas**) bei Lietuvos Respublikos sveikatos apsaugos ministerijos parengtu Projekto derinimo lydraščiu (Nr. (1.1.9E-413)10-, toliau - **Lydraštis**), teikia šias pastabas ir pasiūlymus dėl Projekto turinio.

Bendrovė maloniai atkreipia dėmesį, jog Projekte nustatyti didžiausi leistini tetrahidrokanabinolio (toliau – **THC**) kiekiai galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose ar jų kategorijose yra itin žemi. Projekte pateiktos normos yra tokios mažos, kad tai apriboja pluoštinių kanapių gaminių gamintojų galimybes gaminti šiuos gaminius, nes gamyboje naudojami procesai bei įrenginiai negali patikimai ir nuosekliai pasiekti reikiamų rodiklių. Kita vertus, nustatytos ribos nėra pagrįstos objektyviais moksliniais įrodymais, nėra atsižvelgiama į konkrečių produktų rekomenduojamo bei tikėtino suvartojimo kiekius, kurie daro įtaką galutiniam vartotojų suvartojamam THC kiekiui.

Todėl šiame Kreipimesi toliau pateikiami mokslinių tyrimų duomenys bei informacija apie kitų valstybių taikomus apribojimus didžiausiam leistinam THC kiekiui, kuriais remdamasi

Bendrovė prašo padidinti Projekte nustatytus didžiausius leistinus THC kiekius galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose.

SĄVOKOS

BgVV	Vokietijos federalinis vartotojų sveikatos apsaugos ir veterinarinės medicinos institutas;
EMST	Europos Sąjungos maisto saugos tarnyba;
Komisija	Europos Sąjungos Komisija;
LOEL	mažiausias pastebėto neigiamo poveikio lygis, angl. *lowest observed adverse effect level* - mažiausia dozė, kai tiriamoje grupėje pastebėtas efektas rodo neigiamą poveikį tiriamajam;
LPD	leistina paros dozė;
NK	neapibrėžtumo koeficientas, naudojamas siekiant kompensuoti žinių apie bandymų rezultatų tikslumą trūkumą ir sunkumus įvertinant poveikį skirtingiems individams ir (arba) skirtingomis poveikio sąlygomis;
NOAEL	nenustatyto žalingo poveikio lygis, angl. *no-observed-adverse-effect level* - eksperimento būdu nustatytas poveikio organizmui lygis, kuriam esant biologiškai ar statistiškai reikšmingai nepadidėja bet kokio neigiamo poveikio pagal bandomąjį protokolą dažnis ar sunkumas;
THC	tetrahidrokanabinolis;
ŪPED	ūmaus poveikio etaloninė dozė, angl. *acute reference dose* - apytikslis medžiagos kiekis maiste ar geriamajame vandenyje, išreikštas proporcija kūno svoriui, kurį galima suvartoti per trumpą laiką, paprastai vieno valgio metu arba per vieną dieną, nesukeliant pastebimo pavojaus vartotojo sveikatai, remiantis visais vertinimo metu žinomais faktais. Paprastai jis išreiškiamas miligramais kilogramui kūno svorio;

I. MOKSLINIŲ ORGANIZACIJŲ REKOMENDACIJOS

Nova-Institute – tai nepriklausomas institutas, įkurtas 1994 m., kuris vykdo mokslinius tyrimus ir konsultacijas. Nova-Institute vykdo tyrimų ir konsultacinę veiklą šiose srityse: biologinės kilmės medžiagos ir cheminės medžiagos, biotechnologijos, natūralūs pluoštai, kompozitai. Nova-Institute yra Europos Sąjungos Komisijos platformos Knowledge4Policy (liet. „*Žinios politikai*“), skirtos įrodymais pagrįstam politikos formavimui, narė[1].

Nova-Institute specialistai, biomedicinos mokslų daktarai M.D. PhD Gerhard Nahler (Clinical Investigation Support GmbH, Austrija), M.D. Eberhard Pirich, Prof. Dr. Rudolf Brenneisen (Berno universitetas, Šveicarija) ir Prof. Giampaolo Grassi (CRA-CIN, Italija) 2015 m. liepą publikavo gaires „Moksliškai pagrįstos THC maisto produktuose gairės Europoje“[2] (toliau - **Gairės**), kurioje pateikė informaciją, aktualią leidžiamo THC kiekio galutiniam vartojimui galutiniam vartojimui skirtuose produktuose nustatymui.

Gairėse pateiktose rekomendacijose buvo vadovaujamasi moksliškai pagrįstomis THC LOEL vertėmis: apibendrinus daugeto mokslinių tyrimų duomenis, buvo identifikuota, jog THC LOEL sudaro 2,5 mg asmeniui du kartus per dieną (nustačius, jog 5-15 mg THC dozė sukelia lengvą psichotropinį poveikį, o 2,5 mg THC dozės poveikis prilyginamas placebo poveikiui ir retais atvejais gali sukelti nedidelį psichotropinį ar psichomotorinį poveikį žmonėms, pvz. apsvaigimo pojūtį, taip pat įvertinus tai, jog vienos THC dozės poveikis

[1] https://knowledge4policy.ec.europa.eu/organisation/nova-institute_en

[2] Prieiga internetu: https://silo.tips/download/scientifically-sound-guidelines-for-thc-in-food-in-europe

paprastai tęsiasi apie 4-6 valandas, išskirtiniais atvejais – iki 8 valandų, o vidutiniškai per parą žmonės 16 valandų praleidžia nemiegant).

Gairėse, išsamiai išnagrinėjus literatūrą THC vartojimo ir poveikio tema, buvo nustatytas LOEL – 2,5 mg THC suvartojimo vienam asmeniui du kartus per dieną (nustačius, jog 5-15 mg THC dozė sukelia lengvą psichotropinį poveikį, o 2,5 mg THC dozės poveikis prilyginamas placebo poveikiui ir retais atvejais gali sukelti nedidelį psichotropinį ar psichomotorinį poveikį žmonėms, pvz. apsvaigimo pojūtį). Atsižvelgiant į tai, kad, vartojant per burną, THC poveikis išnyksta per 8 valandas, buvo identifikuotas vartojimas du kartus per dieną, atsižvelgiant į tai, vidutiniškai per parą žmonės 16 valandų praleidžia nemiegant. Taikant 20 NK, išvestą iš skirtingų individų skirtumų (5), didesnio vaisiaus ir naujagimių pažeidžiamumo (2) ir galimos sąveikos su kitoms medžiagoms (2), buvo išvestas LPD po 0,120 mg THC vienam asmeniui buvo du kartus per dieną. Nors tyrimų su žmonėmis duomenimis, naudojant NOAEL, vertės gali būti mažesnės, šiame dokumente siūlomas 20 NK, nes NOAEL dar nėra žinoma. Šiuo metu, remiantis mokslinių tyrimų duomenimis, galima nustatyti tik LOEL. Toliau pateiktoje lentelėje Nr. 1 parodyta LOEL raida ir neapibrėžtumo veiksniai, susiję su THC kanapių maisto produktuose.

Lentelė Nr. 1 – THC LOEL ir NK palyginimas kanapių maisto produktuose, remiantis BgVV 1998, EMST 2011 ir 2015 ir Nova-Institute 2015 m. pasiūlytomis vertėmis

	BgVV 1998	EMST 2011	EMST 2015	Nova-Institute 2015
LOEL (mg/kg)	2.5	2.5	2.5	5*
NK	20-40	100	30	20**

** 2.5 mg du kartus per dieną*
*** Siūloma vertė gauta iš duomenų, gautų iš klinikinių tyrimų su kanapių ekstraktais ir THC su žmonėmis. Papildomi neapibrėžtumo veiksniai nėra pagrįsti. Gali būti taikomas ir mažesnis NK; tačiau dėl metodologinio neapibrėžtumo nustatant pagrįstą NK, siūloma vertė gali būti vertinama ateityje.*

Nustačius saugiai leistinas per burną suvartojamo THC dozes ir NK, atitinkamos didžiausios leistinos THC koncentracijos maiste buvo nustatytos naudojant atitinkamų kanapių maisto produktų vartojimo modelius. Nors tipiniai vartojimo įpročiai (nustatyti remiantis 2012 m. Vokietijos federalinės maisto, žemės ūkio ir vartotojų apsaugos ministerijos duomenimis) buvo atskaitos taškas, buvo atsižvelgiama ir į didesnių nei vidutinių kiekių suvartojimą. Kadangi kanapių pagrindu pagaminti maisto produktai gali būti vartojami labai skirtingais kiekiais, buvo nustatytos kelios kategorijos ir atitinkamos jų ribos. Kiekvienos kategorijos riba yra vidutinio suvartojimo vienai kategorijai ir visų THC suvartojimų vienoje maisto prekėje sumos funkcija. Visų kategorijų suma neturėtų viršyti LPD 0,120 mg THC du kartus per parą. Lentelėje Nr. 2 apibendrinamos Nova-Institute siūlomos orientacinės vertės, gautos remiantis moksliškai pagrįstais THC poveikio vertinimais. Kaip palyginimo priemonė pateikiami ir duomenys apie leidžiamo THC kiekio reguliavimą visame pasaulyje rezultatai.

Lentelė Nr. 2 – Nova-Institute pasiūlymas dėl THC reguliavimo tarpiniuose ir galutiniuose maisto produktuose pagal kategorijas ir lygiavertės vertės išvardytose šalyse (mg/kg)

Galutiniam vartojimui skirti produktai	Nova-Institute siūlomos vertės	Gairės	Leidžiamos THC normos			Pramonės susitarimai	
		BgVV	Šveicarija	Belgija	Kanada	Australija ir Naujoji	Jungtinės Ameriko

						Zelandija	s Valstijos
Aliejai: kanapių aliejus	10	5	20	10	10	10	5
„Didelio tūrio“ produktai (baltymai): kanapių tofu	0.15	0.15	1	0.2	-	-	-
kanapių pieno analogas	0.15	0.005	0.2	0.2	-	0.2	-
„Didelio tūrio“ produktai (angliavandeniai): duona, kepiniai, makaronai, sausi pusryčiai	0.1	0.15	2	0.2	-	-	-
„Mažo tūrio“ produktai: saldumynai, užkandžiai	0.35	0.15	-	0.2	-	-	-
Alkoholiniai gėrimai Stiprieji	0.1	0.005	5	0.2	-	0.2	-
Alūs	0.1	0.005	0.2	0.2	-	0.2	-
Nekaitinami nealkoholiniai gėrimai: gaivieji gėrimai	0.1	0.005	0.2	0.2	-	0.2	-
Kaitinamieji nealkoholiniai gėrimai: žolelių ir vaisių arbatos	0.1	0.005	0.2	0.2	-	0.2	-

Vadovaujantis aukščiau pateiktais rekomenduojamomis didžiausiais leidžiamais THC kiekiais galutiniam skirtuose produktuose, buvo išvesti ir didžiausi leistini THC kiekiai kanapių žaliavoms ir tarpiniams produktams (lentelė Nr. 3).

Lentelė Nr. 3 – Nova-Institute siūlomi didžiausi THC kiekiai kanapių žaliavose ir tarpiniuose produktuose, išvesti iš Nova-Institute pasiūlymo THC kiekių galutiniam vartojimui skirtuose vartoti produktuose, pagrįsti pasirinktais receptais ir vartojimo būdais, bei orientacinės vertės bei ribos pasirinktoms šalims (mg/kg)

Žaliavos ir tarpiniai produktai	Nova-Institute siūlomos vertės	Gairės	Leidžiamos THC normos			Pramonės susitarimai	
		BgVV	Šveicarija	Belgija	Kanada	Australija ir Naujoji Zelandija	Jungtinės Amerikos Valstijos
Nelukštentos kanapių sėklos	5.0	-	10	5	10	5	-
Lukštentos kanapių sėklos	2.5	-	10	5	-	5	1.5
Kanapių aliejus	10	5	20	10	10	10	5
Kanapių miltai/kanapių miltai	3.5	-	-	5	-	5	-

Nova-Institute yra pasisakęs ir dėl EMST taikomo NK – 30 – kuris naudojamas nustatant didžiausią leistiną kiekį tam tikrose galutiniam vartojimui skirtuose kanapių produktuose pagal LOEL. 2019 m. gegužės mėn. publikuotame dokumente „THC

(tetrahidrokanabinolio) ribinės ir orientacinės vertės maiste iš kanapių“[3] Nova-Institute pažymėjo, jog, skaičiuojant didžiausius leidžiamus THC kiekius, EMST ir BgVV pasirinko neproporcingai ir nepateisinamai didesnį NK, nei skaičiuojant kitų psichoaktyviųjų medžiagų kiekius, pavyzdžiui, opijaus alkaloidų (EMST NK 3), nikotino (EMST ir BgVV NK 4.4), alkoholio (nei EMST, nei BgVV nėra atlikusios rizikos vertinimo ar nustačiusios LPD maiste) ar kofeino (EMST LPD nustatyta tik energetiniams gėrimams ir dviems naujiems maisto produktas).

Todėl itin aukšto THC NK nustatymas nulemia, jog nustatoma itin žema THC LPD (kadangi LPD yra apskaičiuojama LOEL padalinus iš NK).

Nova-Institute svarbiausios išvados yra šios:

i. **Didžiausi leidžiami THC kiekiai galutiniam vartojimui skirtuose produktuose turi būti nustatomi atsižvelgiant į vidutinį ir didžiausią konkrečios galutiniam vartojimui skirtų produktų kategorijos produktų suvartojimą, taip pat – į vidutinį ir ilgiausią THC poveikio žmogaus organizmui trukmę po suvartojimo;**

ii. **EMST taikomas THC NK (30) yra neproporcingai aukštas, neatitinkantis kitoms psichoaktyviosioms medžiagoms taikomų NK, todėl THC nustatoma LPD yra proporcingai daug mažesnė, nei kitų psichoaktyviųjų medžiagų LPD.**

II. EUROPOS SĄJUNGOS TEISINIS REGULIAVIMAS

Komisija bei EMST yra pateikusios moksliniais tyrimais pagrįstas rekomendacijas dėl didžiausių leistinų THC kiekių galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose. Atkreiptinas dėmesys, jog rekomendacijose didžiausias leistinas THC kiekis yra nustatomas vadovaujantis duomenimis apie vidutinį suvartojamą kanapių produktų kiekį bei vidutinę šių produktų vartotojų kūno masę.

II.1. EMST rekomendacijos

EMST 2015 m. birželio 26 d. mokslinėje nuomonėje dėl pavojaus žmonių sveikatai, susijusio su tetrahidrokanabinolio (THC) buvimu piene ir kituose gyvūninės kilmės maisto produktuose yra nustačiusi **ŪPED – 1 µg (0,001 mg) Δ^9-THC kilogramui kūno masės**[4].

Ši rekomendacija buvo pateikta remiantis duomenimis apie THC kiekius, kurių suvartojimas gali turėti neigiamą poveikį žmogaus organizmui:

i. 2002 m. Australijos Naujosios Zelandijos maisto standartų agentūra FSANZ įvertino THC saugą maisto produktuose. FSANZ laikėsi nuomonės, kad tikslinga nustatyti parametru, t.y., žmonių gebėjimais atlikti užduotis. FSANZ nustatė LPD pagal su žmonėmis atlikto tyrimo rezultatų interpretaciją. Tyrimo metu buvo tiriamas geriamojo THC poveikis gebėjimams, kognityvinėms funkcijoms ir nuotaikai, kai buvo skiriamos 0, 5, 10, 15 ir 20 mg dozės vienam asmeniui[5]. Nustatyta, kad **LOEL yra 5 mg vienam asmeniui** (tai atitiko 60 µg/kg kūno svorio dozės lygį). FSANZ

[3] Prieiga internetu: https://eiha.org/media/2019/06/19-06-18_Limit-and-guideline-values-for-THC-in-hemp-foods.pdf

[4] EMST CONTAM grupė (EMST Teršalų maisto grandinėje reikalų grupė), 2015 m. Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EMST Journal 2015;13(6):4141, 125 p. doi:10.2903/j. EMST.2015.4141. Prieiga internetu: https://EMST.onlinelibrary.wiley.com/doi/epdf/10.2903/j.EMST.2015.4141

padarė išvadą, kad šios dozės poveikis buvo minimalus ir grįžtamas, o psichotropinio poveikio nepastebėta. FSANZ atsižvelgdama į galimą atsako skirtumą žmonių populiacijoje, nustatė **LPD 6 µg/kg** kūno svorio.

ii. 2011 m. Kroatijos maisto agentūra paskelbė mokslinę nuomonę dėl vartojamų kanapių produktų (kanapių aliejaus ir kanapių sėklų) poveikio sveikatai. Nuomonėje nurodyta **500 µg (0,5 mg) LPD**. Tai buvo nustatyta pagal **NOAEL** psichotropiniam poveikiui - **10** (2 × 5) **mg THC asmeniui** (70 kg kūno svorio);

iii. 2011 m. EMST gyvūnų pašaruose naudojamų priedų ir produktų arba substratų grupė (FEEDAP grupė) paskelbė mokslinę nuomonę dėl kanapių (Cannabis genties) naudojimo gyvūnų pašaruose saugos (EMST FEEDAP grupė, 2011). **2,5 mg THC dozė, atitinkanti 0,04 mg THC/kg kūno svorio** (60 kg kūno svorio) buvo nustatyta atlikus tyrimus su žmonėmis[6] [7] [8] kaip **LOEL** psichotropiniam poveikiui (įskaitant euforiją, galvos svaigimą, mąstymo sutrikimus ir mieguistumą, darbingumo sumažėjimą, įskaitant reakcijos laiką ir atminties funkciją) po vienkartinio arba pakartotinio poveikio.

EMST, apibendrindama mokslinių tyrimų rezultatus, pateikė išvadą, jog **2,5 mg Δ^9-THC dozė, atitinkanti 0,036 mg Δ^9-THC/kg kūno svorio per parą asmeniui, sveriančiam 70 kg, gali būti laikoma LOEL**, kurią suvartojant ne tik sužadinamas apetitas, bet ir gali pasireikšti neigiamas neigiamas poveikis centrinei nervų sistemai. Tai taip pat yra mažiausia dozė, turinti vidutinį nepageidaujamą poveikį vienkartinės dozės tyrimų su sveikais savanoriais metu.

Nuo LOEL 0,036 mg/kg kūno svorio per dieną, naudojant NK 30, buvo išvesta ŪPED 1 µg Δ^9-THC/kg kūno svorio. Išvedant šią dozę buvo atsižvelgiama į galimas poveikio variacijas populiacijoje bei tikimybę, jog gali egzistuoti nepastebėtas poveikis. LPD nustatymas nebuvo laikomas būtinu, nes užtikrinus, kad poveikis būtų mažesnis už ŪPED, taip pat būtų apsaugoma ir nuo galimo pakartotinio poveikio poveikio.

Tai reiškia, jog 1 µg Δ9-THC/kg kūno svorio limitas buvo nustatytas atsargiai, t.y., ne vien vadovaujantis mokslinių tyrimų duomenimis apie žemiausią dozę, sukeliančių išmatuojamą poveikį žmogaus organizmui, bet ir šią LOEL dozę, siekiant apsaugoti vartotojus, papildomai sumažinant 36 kartus (1 µg = 0.001 mg).

Pažymėtina, jog minėtasis kiekis (1 µg Δ9-THC/kg kūno svorio) yra minimas ir 2016 m. gruodžio 1 d. Komisijos rekomendacijoje 2016/2115 dėl Δ9-tetrahidrokanabinolio, jo pirmtakų ir kitų kanabinoidų stebėsenos maiste: „*Tetrahidrokanabinolis, tiksliau delta-9-*

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[5] Chesher GB, Bird KD, Jackson DM, Perrignon A and Starmer GA, 1990. The effects of orally administered Δ9-tetrahydrocannabinol in man on mood and performance measures: A dose-response study. Pharmacology Biochemistry and Behavior,35, 861–864.

[6] Beal JE, Olson R, Lefkowitz L, Larenstein L, Bellman P, Yangco B, Morales JO, Murphy R, Powderly W, Plasse TF, Mosdell KW and Shepard KV, 1997. Long-term efficacy and safety of dronabinol for acquired immunodeficiency syndrome-associated anorexia. Journal of Pain and Symptom Management,14, 7–14.

[7] BgVV (German Federal Institute for Consumer Health Protection and Veterinary Medicine), 1997. Einsatz von hanf in lebensmitteln kann gesundheitlich problematisch sein. BgVV Pressedienst (Press Release) 026/97, 22.10.1997.
BgVV (German Federal Institute for Consumer Health Protection and Veterinary Medicine), 2000. BgVV empfiehlt richtewerte für THC (tetrahydrocannabinol) in hanfhaltigen lebensmitteln. BgVV Pressedienst (Press Release) 07/2000, 16.03.2000.

[8] Ramaekers JG, Berghaus G, van Laar M and Drummer OH, 2004. Dose related risk of motor vehicle crashes after cannabis use. Drug and Alcohol Dependence,73, 109–119.

tetrahidrokanabinolis (Δ9-THC) yra reikšmingiausia kanapių augalo Cannabis sativa sudedamoji dalis. EMST nustatė ūmią referencinę dozę (ŪPED) – 1 µg Δ9-THC/kg kūno svorio“.

Vadovaujantis šiomis EMST rekomendacijomis, nustatant didžiausius leistinus THC kiekius galutiniam vartojimui skirtuose produktuose, būtina atsižvelgti į šių produktų rekomenduojamą ir realų suvartojimą (pavyzdžiui, įgyvendinus siūlomus Koncentracijų reglamento pakeitimus pluoštinių kanapių sėklų aliejui nustatomas didžiausias leidžiamas THC kiekis, kuris daugiau, nei du kartus viršija šį leidžiamą kiekį kanapių sėklose bei kituose iš jų pagamintuose ar perdirbtuose produktuose – šis skirtumas nustatytas atsižvelgiant į faktą, jog vartotojai kanapių sėklų aliejaus suvartoja mažiau, nei kitų pavidalų produktų).

Pavyzdžiui, suaugusiam vartotojui, kurio kūno svoris yra 60 kg, ŪPED sudarytų 60 µg arba 0,06 mg, vadinasi, tokiam vartotojui reikėtų suvartoti 8 gramus pluoštinių kanapių sėklų aliejaus arba 20 g pluoštinių kanapių sėklų, kad būtų pasiekta EMST nustatyta ŪPED.

Šie medžiagų kiekiai atitinka maisto produktų kiekius, kuriuos vartotojas gali suvartoti vieno valgio metu – pavyzdžiui, vienas valgomasis šaukštas augalinio aliejaus sveria apytiksliai 20 g[9], vadinasi, vienam patiekalui pagardinti naudojama pusė šaukšto kanapių sėklų aliejaus sudarytų EMST nustatytą ŪPED.

Tai papildomai įrodo, jog EMST nustatyta ŪPED orientuota į vieno valgio metu galimą suvartoti galutiniam vartojimui skirtų produktų kiekį.

Todėl, atsižvelgiant į faktą, jog THC ŪPED yra nustatyta orientuojantis į per trumpą laiką galimą suvartoti maisto produkto kiekį bei tai, jog ŪPED yra daug žemesnė už LOEL normą, akivaizdu, jog, nustatant didžiausią leidžiamą THC kiekį konkrečiose galutiniam vartojimui skirtų produktų kategorijose, būtina įvertinti, kiek atitinkamos kategorijos produkto vartotojai tikėtinai gali suvartoti per trumpą laiko tarpą.

Remiantis aukščiau pateikta informacija, skaičiuojant didžiausią THC kiekį, leidžiamą maisto papildų kategorijos produktuose, taip pat turėtų būti įvertinamas per trumpą laiką suvartojamas maisto produkto kiekis, pavyzdžiui:

Vartotojui, kurio kūno svoris sudaro 60 kg, THC ŪPED sudaro 0,06 mg. Todėl tokiam vartotojui vartojant maisto papildą, pagamintą iš kanapių sėklų, vartotojams pateikiamą 1 g sveriančiose kapsulėse, kurias rekomenduojama vartoti po 1 vienetą per dieną, vienoje kapsulėje esantis THC kiekis galėtų sudaryti būtent 0,06 mg; vadinasi, 1 kg nurodyto maisto papildo galėtų būti net iki 60 mg THC.

Šis pavyzdys aiškiai demonstruoja, jog žemesnių leidžiamų THC kiekių nustatymas maisto produktų kategorijoms, kurių vartotojai suvartoja itin mažai, yra neproporcingas ir prieštaraujantis pačiai ŪPED – per trumpą laiko tarpą suvartojamos dozės - koncepcijai.

II.2. Europos Sąjungos THC reguliacinės politikos kryptys

Bendrovė pažymi, jog leistino THC kiekio pluoštinių kanapių sėklose bei augaluose nustatymo srityje Europos parlamentas seka Jungtinių Amerikos Valstijų pavyzdžiu ir 2020 m. spalio 23 d. patvirtino[10] strateginį sprendimą, kuriuo buvo nustatyta 0,3 procento leidžiama THC norma kanapių augaluose ir sėklose. Šis sprendimas buvo galutinai

[9] https://www.15min.lt/maistas/naujiena/virtuve/verta-zinoti-produktu-svorio-lentele-1044-246197

įtvirtintas 2021 m. gruodžio 2 d. Europos Parlamento ir Tarybos reglamente (ES) 2021/2115, kuriuo nustatomos valstybių narių pagal bendrą žemės ūkio politiką rengtinų strateginių planų (BŽŪP strateginių planų), finansuotinų iš Europos žemės ūkio garantijų fondo (EŽŪGF) ir iš Europos žemės ūkio fondo kaimo plėtrai (EŽŪFKP), rėmimo taisyklės ir panaikinami reglamentai (ES) Nr. 1305/2013 ir (ES) Nr. 1307/2013[11] (toliau – **BŽŪP reglamentas**), kurio 4 straipsnio 4 punkte buvo nustatyta, jog „*Kanapėms auginti naudojami plotai laikomi reikalavimus atitinkančiais hektarais tik tuo atveju, jei auginamų veislių kanapėse tetrahidrokanabinolio kiekis sudaro ne daugiau kaip 0,3 %*“. Nurodytas BŽŪP reglamentas bus taikomas nuo 2023 m. sausio 1 d. (BŽŪP reglamento 1 straipsnio 2 dalis).

Pažymėtina, jog ši 0,3 % THC norma kanapių augaluose buvo pasirinkta ne atsitiktinai – ši leistina THC riba taip pat yra įtvirtinta Jungtinių Amerikos Valstijų federaliniame 2018 m. žemės ūkio įstatymo[12] 297A straipsnio 1 punkte: „*Sąvoka „kanapės“ reiškia augalą Cannabis sativa L. ir bet kurią to augalo dalį, įskaitant jo sėklas ir visus darinius, ekstraktus, kanabinoidus, izomerus, rūgštis, druskas ir izomerų druskas, augančias ar ne, kurių delta -9 tetrahidrokanabinolio koncentracija yra ne didesnė kaip 0,3 % sausos masės*“.

Tai rodo, jog Europos Sąjungos teisinis reguliavimas THC kiekio nustatymo srityje ne griežtėja, o atvirkščiai – atsižvelgiant į kitų pasaulio valstybių praktiką be naujausius mokslinių tyrimų duomenis yra liberalizuojamas.

Planuojama, jog nuo 2023 m. sausio 1 d. Europos Sąjungoje turėtų įsigalioti ir pakeista 2006 m. gruodžio 19 d. Komisijos reglamento (EB) Nr. 1881/2006, nustatantis didžiausias leistinas tam tikrų teršalų maisto produktuose koncentracijas redakcija[13] (toliau – **Koncentracijų reglamentas**), pagal kurią **didžiausias leidžiamas THC kiekis pluoštinių kanapių sėklų aliejuje yra 7,5 mg/kg, o kanapių sėklose, maltose kanapių sėklose, kanapių sėklose, iš kurių (iš dalies) pašalinti riebalai, ir kituose iš kanapių sėklų pagamintuose ar perdirbtuose produktuose didžiausias leidžiamas THC kiekis yra 3 mg/kg**. Tačiau pažymėtina, jog Tarybos Reglamento (EEB) Nr. 315/93 1993 m. vasario 8 d. nustatantis Bendrijos procedūras dėl maisto teršalų (toliau – **Teršalų reglamentas**), kurio 2 straipsnio 3 dalies nuostatomis („*Visuomenės sveikatai apsaugoti ir atsižvelgiant į 1 dalį, prireikus Komisija gali nustatyti didžiausias leidžiamas ribas konkretiems teršalams*“) vadovaujantis ir buvo patvirtintas Koncentracijų reglamentas, 5 straipsnio 1 dalyje nustatyta, jog „*Valstybės narės negali drausti, riboti arba trukdyti pateikti į rinką maisto produktus, kurie atitinka šio reglamento ar konkrečių nuostatų, priimtų pagal šį reglamentą, reikalavimus dėl teršalų kiekio tuose maisto produktuose*“, tai yra, valstybės narės be rimto pagrindo neturi teisės nustatyti

[10] Amendments adopted by the European Parliament on 23 October 2020 on the proposal for a regulation of the European Parliament and of the Council establishing rules on support for strategic plans to be drawn up by Member States under the Common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulation (EU) No 1305/2013 of the European Parliament and of the Council and Regulation (EU) No 1307/2013 of the European Parliament and of the Council (COM(2018)0392 – C8-0248/2018 –2018/0216(COD)). Prieiga internetu:

[11] Prieiga internetu: https://eur-lex.europa.eu/legal-content/LT/TXT/?uri=CELEX%3A02021R2115-20220422

[12] Prieiga internetu: https://www.congress.gov/bill/115th-congress/house-bill/2/text

[13] Prieiga internetu: https://ec.europa.eu/transparency/comitology-register/screen/documents/079361/1/consult?lang=en

apribojimų leidžiamiems teršalų kiekiams, kurie galėtų apriboti laisvą prekių judėjimą Bendrojoje rinkoje.

Šie nauji teisės aktai įrodo du svarbius faktus:

i. Europos Sąjungoje tarptautiniu mastu įtvirtinamas teisinis reguliavimas juda ne nuostatų griežtinimo, o atvirkščiai – jų atlaisvinimo kryptimi;

ii. Nacionaliniai teisės aktai, nustatantys objektyviu pavojumi nepagrįstus apribojimus laisvam prekių judėjimui Bendrojoje rinkoje, įskaitant žemesnių leidžiamų konkrečių teršalų normų nustatymą, prieštarauja Teršalų reglamento nuostatoms.

III. APIBENDRINIMAS

Šiame Rašte pateikti mokslinių tyrimų bei mokslinių tyrimų analizių duomenys, kuriuose pateikiama informacija apie nustatytą THC poveikį žmonių organizmui bei rekomendacijos dėl leistinų THC kiekių maisto produktuose nustatymo, įrodo, jog Projekte pateikiami didžiausi leistini THC kiekiai galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose yra nustatyti daug mažesni, nei kiekiai, kurių suvartojimas žmogaus organizmui neturi neigiamo poveikio.

Pažymėtina, jog mokslinių tyrimų duomenys veda prie konsensuso, jog EMST nustatyta ŪPED – 1 µg (0,001 mg) Δ9-THC kilogramui kūno masės – yra mažesnė, nei reikalinga siekiant apsaugoti vartotojus nuo galimo neigiamo THC poveikio, nes jos apskaičiavimo metodas turi du esminius trūkumus:

i. nustatomas NK, kuris yra itin daug ir nepateisinamai aukštesnis už kitoms (net stipresnį neigiamą poveikį turinčioms) psichoaktyviosioms medžiagoms nustatytą NK;

ii. LOEL 2,5 mg Δ9-THC dozė, atitinkanti 0,036 mg Δ9-THC/kg kūno svorio per parą asmeniui, sveriančiam 70 kg, yra nustatyta neatsižvelgiant į THC poveikio žmogaus organizmui trukmę po THC dozės suvartojimo.

Tai reiškia, jog EMST nustatytos ŪPED – 1 µg (0,001 mg) Δ9-THC kilogramui kūno masės ir LOEL - 2,5 mg Δ9-THC yra nustatytos daug kartų mažesnės, nei realiai minimalų poveikį žmogaus organizmui galinčios turėti dozės, tai yra, nebūtų pagrįsta papildomai mažinti šias ribas.

Atsižvelgiant į šią informaciją, pažymėtina, jog, vadovaujantis Teršalų reglamento nuostatomis, valstybės narės negali nustatyti objektyviu pavojumi nepagrįstų apribojimų laisvam prekių judėjimui Bendrojoje rinkoje, įskaitant žemesnių leidžiamų konkrečių teršalų normų nustatymą, todėl žemesnių, nei planuojamose patvirtinti Koncentracijų reglamento pataisose nustatytų didžiausių leidžiamų tetrahidrokanabinolio kiekių nustatymas prieštarautų Teršalų reglamento nuostatoms. Kadangi Koncentracijų reglamente planuojamos įtvirtinti THC normos jau yra daug kartų mažesnės, nei moksliniais duomenimis pagrįstos LOEL, tokie apribojimai negalėtų būti pateisinti objektyviu pavojumi vartotojų sveikatai.

Nustatant didžiausius leidžiamus tetrahidrokanabinolio kiekius galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose taip pat ne mažiau svarbu identifikuoti, kokį kiekį tam tikros maisto produktų kategorijos produktų vartotojai gali suvartoti per dieną. Todėl, nustatant didžiausią leidžiamą tetrahidrokanabinolio kiekį maisto papilduose turėtų būti atsižvelgiama į šios kategorijos maisto produktų suvartojimą per dieną – įprastai maisto papildai vartojami nedidelėmis dozėmis, dažniausiai sudarančiomis 1-2 g, todėl, nustatant didžiausią leidžiamą tetrahidrokanabinolio kiekį viename kilograme šios kategorijos

maisto produkto, šis kiekis turėtų būti didesnis ar lygus didžiausiam leidžiamam THC kiekiui pluoštinių kanapių sėklų aliejuje, kurio per dieną (matuojant svoriu) vartotojai gali suvartoti daug daugiau.

Svarbu atkreipti dėmesį ir tai, jog nepagrįstai žemų didžiausių leidžiamų tetrahidrokanabinolio kiekių galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose nustatymas neproporcingai riboja pluoštinių kanapių perdirbėjų veiklą bei galimybes vystyti savo veiklą, nes itin mažų didžiausių leidžiamų THC kiekių tam tikrose produktų kategorijose nustatymas riboja gamintojų galimybes verstis šių gaminių gamyba dėl technologinių apribojimų

Todėl darytina išvada, jog Projekte nustatyti didžiausi leidžiami tetrahidrokanabinolio kiekiai – ypač 2 mg/kg maisto papilduose, 0,02 ng/kg nealkoholiniuose gėrimuose – yra nepagrįsti objektyviais duomenimis bei, jei įsigalios planuojami Koncentracijų reglamento pakeitimai, prieštaraus Teršalų reglamento nuostatoms. Projekte įtvirtinami kiekiai nesuteikia apsaugos vartotojams, tačiau nepagrįstai riboja gamintojus, gaminančius produktus iš pluoštinių kanapių.

IV. PRAŠYMAI

Atsižvelgdama į aukščiau pateiktą informaciją, Bendrovė prašo Lietuvos Respublikos sveikatos apsaugos ministerijos ir Lietuvos Respublikos žemės ūkio ministerijos iš naujo peržiūrėti Projekte nustatytus didžiausius leidžiamus tetrahidrokanabinolio kiekius galutiniam vartojimui skirtuose pluoštinių kanapių gaminiuose ir nustatyti naują jo vertę maisto papildų (išskyrus maisto papildus, skirtus vartoti kūdikiams, vaikams iki 18 m., nėščioms ir žindančioms moterims) kategorijai, nustatant didžiausią leidžiamą tetrahidrokanabinolio kiekį 7,5 mg/kg.

Bendrovė tikisi, kad šiame rašte pateiktos pastabos ir pasiūlymai Jums bus naudingi. Esame pasiruošę plačiau aptarti bei pristatyti juos.

Tikimės dalykiško ir geranoriško bendradarbiavimo.

Pagarbiai,

Biosyyd, UAB vardu
Generalinė direktorė
Vida Audra Budrienė

Biosyyd, UAB
Company code 304741925, VAT payer code LT100011778216
Address A. Juozapavičiaus ave. 7, LT-45251 Kaunas

Submitted by email.
The original will not be sent.
Signed with a secure e-signature.

To: Ministry of Health of the Republic of Lithuania
ministerija@sam.lt

Ministry of Agriculture of the Republic of Lithuania
zum@zum.lt

APPEAL
Regarding the draft Order of the Minister of Health of the Republic of Lithuania and the Minister of Agriculture of the Republic of Lithuania "On the Approval of the List of Maximum Permissible Levels of Tetrahydrocannabinol in Hemp Products for Final Consumption or Their Categories"

23 June 2022
Kaunas

Dear Sir or Madam,

Biosyyd, UAB (hereinafter referred to as the **Company**) is active in the production of end-use products from hemp for consumption and in the production of intermediate products, as well as in research on hemp products. The Company, having familiarised itself with the draft Order of the Minister of Health of the Republic of Lithuania and the Minister of Agriculture of the Republic of Lithuania "On the Approval of the List of Maximum Permissible Levels of Tetrahydrocannabinol in Fibrous Cannabis Products for Final Consumption of Their Categories" published on 6 June 2022 in the Legal Acts Project Database (project registration No. 22-8495, interactive access: https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/fa7dbd70e55811ec896de0b71e988500?positionInSearchResults=0&searchModelUUID=45ad0dd0-1002-440f-8f52-7dce0adf9ca7) (hereinafter referred to as the **Draft**) and the cover letter for the coordination of the Draft prepared by the Ministry of Health of the Republic of Lithuania (No (1.1.9E-413)10-, hereinafter referred to as the **Cover Letter**), submit the following comments and suggestions on the content of the Draft.

The Company kindly notes that the maximum levels of tetrahydrocannabinol (hereinafter referred to as **THC**) in end-use hemp products or categories of hemp products set out in the Project are extremely low. The low levels in the draft are so low that they limit the ability of producers of hemp products to produce these products, as the processes and equipment used in production cannot reliably and consistently achieve the required levels. On the other hand, the limits set are not based on objective scientific evidence, nor do they take into account the recommended and expected intake levels of specific products, which have an impact on the final THC intake of consumers.

Therefore, the following is the scientific research data and information on THC maximum limits in other countries on the basis of which the Company is requesting an increase in the Draft's THC maximum limits for end-use hemp products.

DEFINITIONS

BgVV	German Federal Institute for Consumer Health Protection and Veterinary Medicine;
EFSA	European Union Food Safety Authority;
Commission	Commission of the European Union;
LOEL	lowest observed adverse effect *level* - the lowest dose at which the observed effect in the treatment group indicates an adverse influence on the subject;
ADI	Acceptable daily intake;
UC	an uncertainty coefficient used to compensate for the lack of knowledge of the precision of the test results and the difficulty of assessing effects in different individuals and/or under different exposure conditions;
NOAEL	*no observed adverse effect level* means an experimentally determined level of exposure of an organism at which there is no biologically or statistically significant increase in the frequency or severity of any adverse effect under the test protocol;
THC	tetrahydrocannabinol;
ARD	*acute reference dose* - the approximate amount of a substance in food or drinking water, expressed as a proportion of body weight, that can be consumed in a short period of time, usually over a single meal or a single day, without appreciable risk to the health of the consumer, based on all the facts known at the time of the assessment. It is usually expressed in milligrams per kilogram of body weight;

I. RECOMMENDATIONS FROM SCIENTIFIC ORGANISATIONS

Nova-Institute is an independent institute, founded in 1994, which carries out scientific research and provides consultancy. Nova-Institute carries out research and consultancy activities in the following areas: bio-based materials and chemicals, biotechnology, natural fibres, composites. Nova-Institute is a member of the Knowledge4Policy platform of the European Commission , an initiative for evidence-based policymaking[1].

Nova-Institute specialists, biomedical PhDs M.D. Gerhard Nahler, PhD (Clinical Investigation Support GmbH, Austria), M.D. Eberhard Pirich, Prof. Dr. Rudolf Brenneisen (University of Bern, Switzerland) and Prof. Giampaolo Grassi (CRA-CIN, Italy) published a guideline in July 2015 on "Scientifically sound guidelines for THC in food in Europe"[2] (hereinafter referred to as the **Guideline**), which provides information relevant for the establishment of the permitted THC levels in products intended for final consumption.

The guidance provided in the Guidelines was based on scientifically validated LOELs for THC: after synthesising data from a large number of scientific studies, a THC LOEL of 2.5 mg per person twice daily was identified (after finding that a dose of 5-15 mg THC produces mild psychotropic effects, while a dose of 2.5 mg THC is equivalent to a placebo effect and may in rare cases produce mild psychotropic or psychomotor effects in

1 https://knowledge4policy.ec.europa.eu/organisation/nova-institute_en
2 Internet access: https://silo.tips/download/scientifically-sound-guidelines-for-thc-in-food-in-europe

humans, e.g. The effects of a single dose of THC typically last for about 4-6 hours, in exceptional cases up to 8 hours, and on average people spend 16 hours a day without sleeping).

The Guidelines, after a thorough review of the literature on THC use and effects, set a LOEL of 2.5 mg THC intake per person twice a day (finding that a dose of 5-15 mg of THC produces mild psychotropic effects, while a dose of 2.5 mg of THC is equivalent to a placebo effect and may, in rare cases, produce minor psychotropic or psychomotor effects in humans, such as a feeling of intoxication). Given that the effects of THC wear off within 8 hours when taken orally, twice-daily use has been identified, with people spending an average of 16 hours a day without sleep. Using a 20 UC derived from inter-individual differences (5), greater foetal and neonatal vulnerability (2), and potential interactions with other substances (2), an ADI of 0.120 mg THC per person was derived at twice daily doses. Although human studies have shown that values using NOAELs may be lower, this document proposes a UC of 20 because the NOAEL is not yet known. Currently, only LOELs can be established on the basis of research data. Table 1 below shows the evolution of the LOEL and the uncertainty factors associated with THC in cannabis edibles.

Table 1 - Comparison of THC LOELs and UCs in cannabis edibles based on the values proposed by BgVV 1998, EFSA 2011 and 2015 and Nova-Institute 2015

	BgVV 1998	EMST 2011	EMST 2015	Nova-Institute 2015
LOEL (mg/kg)	2.5	2.5	2.5	5*
UC	20-40	100	30	20**

** 2.5 mg twice a day*
*** Suggested value derived from data from clinical trials with cannabis extracts and THC in humans. Additional uncertainty factors are not justified. A lower UC may be used; however, methodological uncertainties in determining a reasonable UC may lead to future assessments of the proposed value.*

Once the safely tolerable oral THC intake and the UC have been established, the corresponding maximum dietary THC concentrations have been determined using the consumption patterns of the respective cannabis food products. Although typical consumption patterns (determined According to the 2012 data from German Federal Ministry of Food, Agriculture and Consumer Protection) was the starting point, consumption above average quantities was also taken into account. As cannabis-based foods can be consumed in widely varying quantities, several categories and their respective limits have been established. The limit for each category is a function of the average consumption per category and the sum of all THC intakes per food item. The sum of all categories should not exceed the ADI of 0.120 mg THC twice a day. Table 2 summarises the guideline values proposed by the Nova-Institute, based on scientifically valid assessments of THC exposure. As a means of comparison, the results are also presented for the regulation of the permitted THC content worldwide.

Table 2 - Nova-Institute proposal for the regulation of THC in intermediate and final foodstuffs by category and equivalent values in the listed countries (mg/kg)

Products for final consumption	Values offered by Nova-Institute	Guidance	Permissible THC levels			Industry agreements	
		BgVV	Switzerland	Belgium	Canada	Australia and New Zealand	United States of

							America
Oils: hemp oil	10	5	20	10	10	10	5
"High volume" products (proteins): hemp tofu	0.15	0.15	1	0.2	-	-	-
hemp milk analogue	0.15	0.005	0.2	0.2	-	0.2	-
"High-volume" products (carbohydrates): breads, pastries, pasta, breakfast cereals	0.1	0.15	2	0.2	-	-	-
"Low volume" products: sweets, snacks	0.35	0.15	-	0.2	-	-	-
Alcoholic beverages Strong	0.1	0.005	5	0.2	-	0.2	-
Beer	0.1	0.005	0.2	0.2	-	0.2	-
Non-heated non-alcoholic beverages: soft drinks	0.1	0.005	0.2	0.2	-	0.2	-
Heated non-alcoholic beverages: herbal and fruit teas	0.1	0.005	0.2	0.2	-	0.2	-

Based on the above recommended maximum THC levels for finished products, maximum THC levels for cannabis raw materials and intermediates were derived (Table 3).

Table 3 - Nova-Institute's proposed maximum THC levels in cannabis raw materials and intermediates, derived from Nova-Institute's proposed THC levels in end-use (final consumption) products based on selected recipes and consumption patterns, and indicative values and thresholds for selected countries (mg/kg)

Raw materials and intermediate products	Values offered by Nova-Institute	Guidance	Permissible THC levels			Industry agreements	
		BgVV	Switzerland	Belgium	Canada	Australia and New Zealand	United States of America
Hemp seeds, unhulled	5.0	-	10	5	10	5	-
Hulled hemp seeds	2.5	-	10	5	-	5	1.5
Cannabis oil	10	5	20	10	10	10	5
Cannabis flour/cannabis flour	3.5	-	-	5	-	5	-

Nova-Institute has also commented on the EFSA's use of UC - 30 - which is used to set the LOEL for certain cannabis products intended for final consumption. In a paper published in May 2018 on "THC (tetrahydrocannabinol) limits and reference values in cannabis food"[3], Nova-Institute noted that EFSA and the BgVV have chosen a disproportionately and unjustifiably higher UC for the calculation of the maximum THC levels than for the

[3] Internet access: https://eiha.org/media/2019/06/19-06-18_Limit-and-guideline-values-for-THC-in-hemp-foods.pdf

calculation of the UC's for other psychoactive substances, such as for the opium alkaloids (EFSA UC 3), nicotine (EFSA and BgVV UC 4.4), alcohol (neither EFSA nor BgVV have carried out a risk assessment or set an ADI for food) or caffeine (EFSA has set an ADI only for energy drinks and two new foods).

Therefore, a very high THC UC determination results in a very low THC ADI (as the ADI is calculated as LOEL divided by UC).

The main findings of the Nova-Institute are:

i. **The maximum permitted levels of THC in products intended for final consumption must be set taking into account the average and maximum consumption of the products in the specific category of products intended for final consumption, as well as the average and maximum duration of the effects of THC on the human body after consumption;**

ii. **The EFSA's THC UC (30) is disproportionately high, out of line with the UCs for other psychoactive substances, and therefore the THC has a proportionally much lower ADI than the ADIs for other psychoactive substances.**

II. EUROPEAN UNION LEGAL FRAMEWORK

The Commission and the EFSA have made scientifically based recommendations on the maximum THC levels in hemp products intended for final consumption. It should be noted that the guidelines set maximum THC levels on the basis of data on the average intake of cannabis products and the average body weight of the consumers of those products.

II.1. EFSA Recommendations

EFSA has established an **ARD of 1 µg (0.001 mg) Δ^9-THC per kilogram of body weight** in its Scientific Opinion of 26 June 2015 on the risks to human health from the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin.[4]

This recommendation was made on the basis of data on the levels of THC whose consumption can have adverse effects on the human body:

i. The 2002 Food Standards Agency of Australia and New Zealand, FSANZ, has assessed the safety of THC in food. FSANZ considered that it was appropriate to define the parameter, i.e., people's ability to perform tasks. FSANZ has determined the ADI based on the interpretation of the results of the human study. The study investigated the effects of oral THC on ability, cognitive function and mood at doses of 0, 5, 10, 15 and 20 mg per person[5]. The **LOEL** was set at **5 mg per person** (corresponding to a dose level of 60 µg/kg body weight). FSANZ concluded that the effects of this dose were minimal and reversible and that no psychotropic effects were observed. FSANZ has established an **ADI of 6 µg/kg** of body weight, taking into account the potential difference in response in the human population.

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[4] EFSA CONTAM Group (EFSA Contaminants in the Food Chain group), Scientific opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin of year 2015. EFSA Journal 2015;13(6):4141, 125 p. doi:10.2903/j. EFSA .2015.4141. Internet access: https://EMST.onlinelibrary.wiley.com/doi/epdf/10.2903/j.EMST.2015.4141

[5] Chesher GB, Bird KD, Jackson DM, Perrignon A and Starmer GA, 1990. The effects of orally administered Δ9-tetrahydrocannabinol in man on mood and performance measures: A dose response study. Pharmacology Biochemistry and Behavior,35, 861–864.

ii. The 2011 Croatian Food Agency has issued a scientific opinion on the health effects of consuming cannabis products (cannabis oil and cannabis seeds). The opinion specifies a **500 µg (0.5 mg) ADI**. This was set at the **NOAEL** for psychotropic effects of **10** (2 × 5) **mg THC per person** (70 kg body weight);

iii. The 2011 EFSA Panel on Additives and Products or Substrates used in Animal Feed (FEEDAP Panel) has published a scientific opinion on the safety of the use of hemp (Cannabis genus) in animal feed (EFSA FEEDAP Panel, 2011). A **dose of 2,5 mg THC, corresponding to 0,04 mg THC/kg body weight** (60 kg body weight), has been established in human studies[6] [7] [8] as the **LOEL** for psychotropic effects (including euphoria, dizziness, disturbances in thinking and drowsiness, and impairment of performance, including reaction time and memory function) after single or repeated exposure.

The EFSA, summarising the results of the scientific studies, concluded that a dose of **2,5 mg Δ^9-THC**, corresponding to 0,036 mg Δ^9-**THC/kg body weight per day for a person weighing 70 kg, can be considered as a LOEL** which, in addition to inducing appetite, may also have adverse effects on the central nervous system. It is also the lowest dose with moderate adverse effects in single-dose studies in healthy volunteers.

From a LOEL of 0.036 mg/kg of body weight/day, an ARD of 1 µg Δ^9- THC/kg of body weight was derived using UC 30. This dose was derived taking into account the possible variation in exposure in the population and the likelihood of unobserved effects. The setting of an ADI was not considered necessary because ensuring that exposure is below the ARD would also protect against possible re-exposure.

This means that the limit of 1 µg Δ9-THC/kg body weight has been set with caution, i.e., not only on the basis of the research data on the lowest dose causing measurable effects on the human body, but also with an additional 36-fold reduction of this LOEL (1 µg = 0.001 mg) in order to protect the consumers.

It should be noted that this level (1 µg Δ9-THC/kg body weight) is also mentioned on 1 December 2016 Commission Recommendation 2016/2115 on the monitoring of Δ9-tetrahydrocannabinol, its precursors and other cannabinoids in food: "*Tetrahydrocannabinol, more specifically delta-9-tetrahydrocannabinol (Δ9-THC), is the most significant constituent of the cannabis plant Cannabis sativa. EFSA has set an acute reference dose (ARD) of 1 µg Δ9-THC/kg body weight*.

In line with these EFSA recommendations, the setting of maximum THC levels in products intended for final consumption must take into account the recommended and actual consumption of these products (e.g. the

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[6] Beal JE, Olson R, Lefkowitz L, Larenstein L, Bellman P, Yangco B, Morales JO, Murphy R, Powderly W, Plasse TF, Mosdell KW and Shepard KV, 1997. Long-term efficacy and safety of dronabinol for acquired immunodeficiency syndrome-associated anorexia. Journal of Pain and Symptom Management,14, 7–14.

[7] BgVV (German Federal Institute for Consumer Health Protection and Veterinary Medicine), 1997. Einsatz von hanf in lebensmitteln kann gesundheitlich problematisch sein. BgVV Pressedienst (Press Release) 026/97, 22.10.1997.
BgVV (German Federal Institute for Consumer Health Protection and Veterinary Medicine), 2000. BgVV empfiehlt richtewerte für THC (tetrahydrocannabinol) in hanfhaltigen lebensmitteln. BgVV Pressedienst (Press Release) 07/2000, 16.03.2000.

[8] Ramaekers JG, Berghaus G, van Laar M and Drummer OH, 2004. Dose related risk of motor vehicle crashes after cannabis use. Drug and Alcohol Dependence,73, 109–119.

implementation of the proposed changes to the Concentration Regulation would result in a maximum THC level being set for oil from hemp seeds, which is more than twice the limit for hemp seeds and other products produced or processed from hemp seeds - this difference is based on the fact that the consumption of hemp seed oil by consumers is lower than that of other forms of products).

For example, an adult consumer with a body weight of 60 kg would have an ARD of 60 µg or 0,06 mg, which means that such a consumer would need to consume 8 grams of hemp seed oil or 20 grams of hemp seed to reach the ARD set by EFSA.

These quantities correspond to the quantities of food that a consumer can consume in one meal - for example, one tablespoon of vegetable oil weighs approximately 20 g[9], so half a tablespoon of hemp seed oil used to flavour one meal would constitute the EFSA ARD.

This further demonstrates that the EFSA's ARD focuses on the amount of end-use products that can be consumed in one meal.

Therefore, in view of the fact that the ARD for THC is set with a focus on the amount of food that can be consumed in a short period of time, and the fact that the ARD is much lower than the LOEL norm, it is evident that the setting of maximum permitted THC levels for specific categories of products intended for final consumption requires an assessment of how much of the product category is likely to be consumed by consumers in a short period of time.

Based on the above information, the calculation of the maximum THC content allowed in the food supplement category should also take into account the amount of THC consumed in a short period of time, for example:

For a user with a body weight of 60 kg, the THC ARD is 0,06 mg. Therefore, if such a consumer were to consume a food supplement made from cannabis seeds, which is provided to the consumer in capsules weighing 1 g and which are recommended to be consumed one per day, the amount of THC contained in one capsule could be exactly 0,06 mg, which means that up to 60 mg of THC could be present in 1 kg of the said food supplement.

This example clearly demonstrates that setting lower THC limits for food categories that are consumed at very low levels by consumers is disproportionate and contrary to the very concept of the ARD - a dose consumed in a short period of time.

II.2. Regulatory policies on THC in the European Union

The Company notes that the European Parliament has followed the example of the United States of America in setting the THC content of hemp seeds and plants, and on 23 October 2020 adopted[10] a policy decision setting the THC content of hemp plants and

[9] https://www.15min.lt/maistas/naujiena/virtuve/verta-zinoti-produktu-svorio-lentele-1044-246197

[10] Amendments adopted by the European Parliament on 23 October 2020 on the proposal for a regulation of the European Parliament and of the Council establishing rules on support for strategic plans to be drawn up by Member States under the Common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulation (EU) No 1305/2013 of the European Parliament and of the Council and Regulation (EU) No 1307/2013 of the European Parliament and of the Council (COM(2018)0392 – C8-0248/2018 –2018/0216(COD)).

seeds at 0.3 %. This decision was finalised on 2 December 2021. Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013[11] (hereinafter referred to as the **CAP Regulation**), Article 4(4) of which provided that "*Areas used for the production of hemp shall only be considered as eligible hectares if the varieties of hemp cultivated have a tetrahydrocannabinol content of no more than 0.3%*. This CAP Regulation will apply from 1 January 2023 (Article 1(2) of the CAP Regulation).

It should be noted that this 0,3 % THC level in the cannabis plant was not chosen by chance, as this THC limit is also enshrined in Article 297A(1)of the United States Federal Agriculture Act 2018[12]: "*The term 'cannabis' means the plant Cannabis sativa L. and any part of that plant, including its seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts of isomers, whether or not in growth, with a concentration of delta-9 tetrahydrocannabinol of not more than 0.3 % by dry weight*".

This shows that the European Union's legal regulation of THC content is not tightening, but is instead being liberalised in line with the practices of other countries around the world, in addition to the latest scientific evidence.

Changes to take effect from 1 January 2023: It should enter into force in the European Union and be amended on 19 December 2006 by Commission Regulation (EC) No 1881/2006 laying down maximum levels for certain contaminants in foodstuffs[13] (hereinafter referred to as the **Concentration Regulation**), which sets a **maximum THC level of 7,5 mg/kg for hemp seed oil and a maximum THC level of 3 mg/kg for hemp seeds, ground hemp seeds, hemp seeds (partially) defatted, and other products produced or processed from hemp seeds**. However, it should be noted that Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (hereinafter referred to as the **Contamination Regulation**), Article 2(3) of which (*"In order to protect public health, and taking into account paragraph 1, the Commission may, where appropriate, set maximum levels for specific contaminants*"), which is the basis for the adoption of the Concentration Regulation, provides that *"Member States may not prohibit the presence of, restrict or impede the placing on the market of foodstuffs which comply with the requirements of this Regulation or of specific provisions adopted pursuant to this Regulation with regard to the levels of contaminants in those foodstuffs"*, i.e., Member States are not entitled to impose limits on the permitted levels of contaminants which could restrict the free movement of goods within the Single Market without reasonable grounds.

This new legislation proves two important facts:

i. In the EU, the international legal framework is moving in the direction of loosening, rather than tightening, regulations;

Internet access:

[11] Internet access: https://eur-lex.europa.eu/legal-content/LT/TXT/?uri=CELEX%3A02021R2115-20220422

[12] Internet access: https://www.congress.gov/bill/115th-congress/house-bill/2/text

[13] Internet access: https://ec.europa.eu/transparency/comitology-register/screen/documents/079161/1/consult?lang=en

ii. National legislation imposing restrictions on the free movement of goods within the Single Market which are not justified by objective risks, including the setting of lower permissible limits for specific contaminants, is contrary to the provisions of the Contamination Regulation.

III. SUMMARY

The scientific studies and research analyses presented in this Appeal, which provide information on the established effects of THC on the human body and the recommendations on the setting of THC tolerance levels in foodstuffs, demonstrate that the maximum THC levels in the Draft's end-use (final consumption) hemp products are set at levels significantly lower than the levels that would have no adverse effect on the human body.

It should be noted that the scientific evidence leads to a consensus that the EFSA's ARD of 1 µg (0,001 mg) of Δ9-THC per kilogram of body weight is lower than necessary to protect consumers from the potential adverse effects of THC, as the method used to calculate it has two fundamental flaws:

i. an UC that is extremely and unjustifiably higher than the UCs for other (even more potent) psychoactive substances;
ii. The LOEL of 2,5 mg of Δ9-THC, corresponding to 0,036 mg of Δ9-THC/kg body weight per day for a person weighing 70 kg, is established without taking into account the duration of exposure to THC in the human body following the consumption of the THC dose.

This means that the EFSA's ARD of 1 µg (0,001 mg) Δ9-THC per kilogram of body weight and the LOEL of 2,5 mg Δ9-THC are set at doses many times lower than the doses that would actually have a minimal effect on the human body, and that it would not be justified to lower the limits further.

In the light of this information, it should be noted that, in accordance with the provisions of the Contamination Regulation, Member States may not impose restrictions on the free movement of goods within the Single Market that are unjustified by an objective risk, including the imposition of lower permissible levels for specific contaminants, and that, therefore, it would be contrary to the provisions of the Contamination Regulation to set maximum levels for tetrahydrocannabinol lower than those laid down in the amendment to the Concentration Regulation that is planned to be accepted. As the THC levels planned to be introduced in the Concentration Regulation are already many times lower than the scientifically based LOEL, such restrictions could not be justified on the grounds of an objective risk to consumer health.

Equally important in setting maximum levels of tetrahydrocannabinol in hemp products intended for final consumption is the identification of the daily intake of consumers of a given food category. Therefore, the maximum level of tetrahydrocannabinol in food supplements should take into account the daily intake of this category of food, which is typically consumed in small doses, usually 1-2 g, and therefore, when setting the maximum level of tetrahydrocannabinol per kilogram of food in this category of food, should be greater than or equal to the maximum level of THC in hemp seed oil, which is likely to be consumed by consumers in much higher amounts per day, measured by weight.

It is also important to note that the setting of unreasonably low maximum permitted levels of tetrahydrocannabinol in hemp products for final consumption disproportionately

restricts the activities and development opportunities of hemp processors, as the setting of extremely low maximum permitted THC levels in certain product categories restricts the ability of producers to engage in the production of these products due to technological limitations

Therefore, it can be concluded that the maximum levels of tetrahydrocannabinol set out in the Draft - in particular 2 mg/kg in food supplements, 0.02 ng/kg in soft drinks - are not based on objective data and, if the planned amendments to the Concentration Regulation come into force, will be contrary to the provisions of the Contamination Regulation. The quantities in the draft do not protect consumers, but unduly restrict producers of products made from hemp.

IV. APPEAL

In the light of the above information, the Company requests the Ministry of Health of the Republic of Lithuania and the Ministry of Agriculture of the Republic of Lithuania to reconsider the maximum permitted levels of tetrahydrocannabinol in hemp products for final consumption set out in the Draft and to set a new value for the category of food supplements (except for the category of food supplements intended for use in the diet of infants, children under the age of 18 years and pregnant and lactating women), with a maximum level of 7,5 mg/kg.

The Company hopes that you will find the comments and suggestions in this appeal useful. We are ready to discuss and present them further.

We look forward to a constructive and good cooperation.

Sincerely,

On behalf of Biosyyd, UAB
General Director
Vida Audra Budrienė

Vertimų karaliai, PJSC
Company code:: 304255745
VAT: LT100010530314
Geležinio Vilko st. 18A, Vilnius
www.vertimukaraliai.lt
info@vertimukaralaiai.lt
Tel. +370 (630) 09 360

Certificate of Translation

CERTIFICATE NO. 3906

17-10-2022

We, Vertimų karaliai PJSC, company code 304255745, hereby certify that the translation provided is true and accurate and corresponds to the original submitted. The translation was completed by a qualified in-house translator working under employment contract No. 1, competent to translate according to the following language combination.

Translation from:	Lithuanian to English
Translator:	Silvija Kryževičiūtė
Phone number:	+370 (630) 09 360
Address:	Geležinio Vilko st. 18A, Vilnius

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Translator's signature

Authentication