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Proposal for discussion

As a result of the last WG meeting, it was concluded that MS would provide some inputs in order to improve the entries of *Cannabis sativa* L. and CBD in the NFC.

The proposal for discussion is as follows:

#### ***Cannabis sativa* L.**

##### Common Names

Kanepe (sējas) (LV), Hampa (SE), Hemp (FN), manjuna (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), hanlik kanep (ET), konopi saté (CZ), ~~Marichuana~~ *Cáñamo* (ES), indiat kender (HU), ινδική κόμβοβίς (EL), navadna ali industrijska konoplja (SI), hamppu (FI)

In the European Union, the cultivation of *Cannabis sativa* L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0,2 % (w/w) of the plant.

Opt on 1: The following products from *Cannabis sativa* plant have a history of consumption in the EU and therefore are not novel:

- ~~foods based on the seeds such as hemp seeds~~ Seeds, seed oil, hemp seed flour, hemp seed protein, hemp seed milk, hemp seed butter,
- tea, herbal and fruit infusions consisting of or prepared with leaves or flower buds (of *Cannabis sativa* L. only),
- beer and beer like beverage (when used in the same manner as hop flowers), lemonade prepared with flowers (when used in the same manner as hop flowers)
- lemonade prepared with flowers
- ~~the products obtained from the upper part of the hemp plant leaves~~
- ~~the oil of leaves or flowers~~

##### Opt on 2 (BE, AT, DE)

Without prejudice to other legal requirements concerning the consumption of hemp (*Cannabis sativa*) and hemp products, following parts of this plant are considered as not novel: seeds, seed oil, defatted seeds, leaves (only in tea or infusions), flowers (only if resin has been extracted before and only for flavouring purposes).

Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.

##### Status



Other products from *Cannabis sativa* L. (e.g. fiber hemp) used in foods should be considered novel, unless a history of consumption in the EU is demonstrated. Where they are unsure whether or not such a product falls within the scope of Regulation 2015/2283, food business operators shall submit a consultation request under the requirements of Regulation (EU) 2018/456.

##### Status

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**Commented** : Based on the 1997 SCOPFAH statement, should be considered the use of leaves and flowers in some beverages as HoC?

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**Commented** : "Seed oil, defatted seeds": We do not agree to the idea of XXX. Seed oil and defatted seeds should both remain listed. Because the products' composition may significantly differ from the seeds. In contrast, seed products like hemp milk with equivalent composition do not need to be mentioned.

**Commented** : "Leaves": Same legal problem as for stevia:  
Regulation (EU) 2015/2283 does not distinguish between the use of a food in tea/infusion or other uses as food. We support such approach because of different contents of ingredients after infusion compared with contents when consuming the whole plant part. In the later case safe use is not guaranteed. But we see the risk of legal trouble.

**Commented** : According article 1 Nr. 1 h) of "Single Convention on Narcotic Drugs, 1954", it should be mentioned that only the flowering or fruiting tops from which the resin has been extracted may be marketable as food.

**Commented** : AT comments: For flavouring purposes normally leaves and flowers are used from the upper parts of the plant.

**Commented** : AT comments: Bear in mind that also new products raise markets where in the end the cannabinoid content (CBD) is relatively high.  
<https://www.leeeradocate.com/articles/16508/cannabis-infused-beers-on-the-rise/>  
Vermont saw its first CBD beer withilling Trail Brewing's Labor Day draft only release of an IPA combining freshly grated ginger with hemp honey from nearby growers Luce Farm. With about 20 milligrams of CBD per serving...

I think we should therefore insert something in relation to the content of cannabinoids of hemp flavours. The flavour results from the terpenes and not from the cannabinoids.

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**Cannabinoids**

The hemp plant contains a number of cannabinoids and the most relevant ones are as follows: delta-9-tetrahydrocannabinol (A<sup>9</sup>-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A (A<sup>9</sup>-THCA-A), delta-9-tetrahydrocannabinolic acid B (A<sup>9</sup>-THCA-B), delta-8-tetrahydrocannabinol (A<sup>8</sup>-THC), cannabidiol (CBD), cannabidiol (CBD), and delta-9-tetrahydrocannabinol (A<sup>9</sup>-THC).

The request concerns the presence of Cannabidiol (CBD) in foods; food supplements as it is one of the most predominant cannabinoids in Cannabis sativa plant.

Extracts of Cannabis sativa L. in which the cannabinoid level is higher than the level in the parts of the plant used as source material, are considered as novel. This applies to both the extracts whether used as such themselves and [any] products to which they are added as an ingredient in other products (such as hemp seed oil).

Synthetically obtained cannabinoids are considered as novel.

Status



**Commented** : It seems to be that many CBD in ES are allegedly "legally" marketed in a number of MS with a level up to 53%. If this is the case what approach should be taken? This level comes from a first extraction. Usually, ethanol as an extraction solvent, is able to extract higher amount of CBD than CO2. Some CBD are subject to a second extraction.

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Comments from MS

#### Belgian proposal and comments from AT

#### Remarks:

-> Providing one novel food status for a plant is not always possible as the status depends on the parts used or the type of extract used. It is easier if the not novel parts and novel parts are mentioned in one entry for cannabis sativa L. The extract can also be added to the same entry (cfr. Stevia rebaudiana) for a full understanding of the situation.

-> hemp seed protein and so called "hemp milk" are processed hemp seeds. Hemp seed protein are defatted and milled hemp seeds until powder. "Hemp milk" are milled hemp seeds with added water. As the seeds are considered as not novel, the "hemp milk" does not need to be mentioned. Moreover, "milk" is a protected denomination.

#### Proposal:

##### ***Cannabis sativa L.***

##### Common Names

Kaņepe (sējas) (LV), Hampa (SE), Hemp (FN), marijuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), hanlik kanep (ET), konopi seté (CZ), Marihuana (ES), indiai kender (HU), ινδική κάνναβις (FI), navadna ali industrijska konoplja (SI), hampu (FI)

In the European Union, the cultivation of Cannabis sativa L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0,2 % of the plant.

Without prejudice to other legal requirements concerning the consumption of hemp (Cannabis sativa) and hemp products, following parts of this plant are considered as not novel: seeds, seed oil, defatted seeds, leaves (for infusions or flavouring purposes), flowers (only for flavouring purposes).

Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities

##### Status



The leaves, stems and flowers to be consumed as such are considered as novel.

##### status



**Commented** : For flavouring purposes normally leaves and flowers are used from the upper parts of the plant.

**Commented** : Bear in mind that also new products raise markets where in the end, the cannabinoid content (CBD) is relatively high.

<https://www.beeradvocate.com/articles/16508/cannabis-infused-beers-on-the-rise/>

Vermont saw its first CBD beer with Long Trail Brewing's Labor Day draft only release of an IPA combining freshly grated ginger with hemp honey from nearby growers Lure Farm. With about 20 milligrams of CBD per serving...

think we should therefore insert something in relation to the content of cannabinoids of hemp flavours. The flavour results from the terpenes and not from the cannabinoids

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Remark: the conclusion on CBD will depend on which parts of the plant are considered as **Not Novel** (status for the flower or the leaves?).

-> If the leaves and flowers as such are regarded as novel (except in infusions or flavouring purposes), any extract containing cannabinoids should be considered as novel (unless there is a HOC for those extracts which does not seem to be the case).

#### **Cannabidiol / ~~cannabinoids~~**

Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant.

Extracts of cannabis sativa containing cannabinoids are considered as novel, whether used as such or added as an ingredient in other products (such as hemp seed oil).

Synthetically obtained cannabinoids are considered as novel.

Status



-> If the leaves and flowers are considered as not novel, then it should be specified that the extracts in which the cannabinoid level is higher than the level in the source material are considered as novel

#### **Cannabidiol / ~~cannabinoids~~**

Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant.

Extracts of cannabis sativa in which the cannabinoid level is higher than the level in the parts of the plant used as source material, are considered as novel, whether used as such or added as an ingredient in other products (such as hemp seed oil).

Synthetically obtained cannabinoids are considered as novel.

Status



**Commented** [redacted]: Should we mention some of the other cannabinoids like CBG or CBN...?

**Commented** [redacted]: Not possible when we think on nearly 5% of CBD in hemp flowers...



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#### Belgian proposal with DE comments

##### Remarks:

-> Providing one novel food status for a plant is not always possible as the status depends on the parts used or the type of extract used. It is easier if the not novel parts and novel parts are mentioned in one entry for *Cannabis sativa* L. The extract can also be added to the same entry (cf. *Stevia rebaudiana*) for a full understanding of the situation.

-> hemp seed protein and so called "hemp milk" are processed hemp seeds. Hemp seed protein are defatted and milled hemp seeds until powder. "Hemp milk" are milled hemp seeds with added water. As the seeds are considered as not novel, the "hemp milk" does not need to be mentioned. Moreover, "milk" is a protected denomination.

##### Proposal:

###### *Cannabis sativa* L.

###### Common Names

Kaņepe (sējas) (LV), Hampa (SE), Hemp (EN), marijuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), hanlík kanep (ET), konopi seté (CZ), Marihuana (ES), indiar kender (HU), ινδική κάνναβις (EL), navadina ali industrijska konoplja (SI), hampuu (FI)

In the European Union, the cultivation of *Cannabis sativa* L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0,2 % of the plant. The food business operator is responsible to guarantee and prove these requirements.

Without prejudice to other legal requirements concerning the consumption of hemp (*Cannabis sativa*) and hemp products, following parts of this plant are considered as not novel: seeds, seed oil, defatted seeds, leaves (only in tea or infusions), flowers (only if resin has been extracted before and only for flavouring purposes).

Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.

###### Status



The leaves, stems and flowers to be consumed as such are considered as novel.

###### status



##### Commented

Germany fully agrees to the remarks of Belgian

##### Commented

"Seed oil, defatted seeds": We do not agree to the idea of ~~XXX~~. Seed oil and defatted seeds should both remain listed. Because the products composition may significantly differ from the seeds. In contrast, seed products like hemp milk with equivalent composition do not need to be mentioned.

##### Commented

"leaves": Same legal problem as for stevia. Regulation (EU) 2015/2283 does not distinguish between the use of a food as tea/infusion or other uses as food. We support such approach because of different contents of ingredients after infusion compared with contents when consuming the whole plant part. In the later case safe use is not guaranteed. But we see the risk of legal trouble.

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According article 1 Nr. 1 b) of "Single Convention on Narcotic Drugs, 1961", it should be mentioned, that only the flowering or fruiting tops from which the resin has been extracted may be marketable as food.

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Extracts of *Cannabis sativa* containing non-addictive cannabidiol or other non-addictive cannabinoids are novel. This applies to both the extracts themselves and [any] products to which they are added as an ingredient (such as hemp seed oil).

Synthetically obtained non-addictive cannabinoids are considered as novel.

Status



#### Czech comments

##### Introduction

CR does not consider the plant of *Cannabis sativa* as "novel" but the use in food is restricted as follows:

Conditions for handling with dependency producing substance „hemp“ in form of extract and tincture thus also for the processing of the extract from „technical hemp“ in the purpose of gaining the substance CBD is regulated by the Act No. 167/1998 Coll., on dependency producing substance

This Act defines „cannabis – hemp“ as „flowering or fruiting tops of plant of the genus Cannabis or aboveground part of plant of the genus Cannabis“ – should contain THC.

THC is considered as psychoactive substance (Annex 4 of the Act No. 167/1998 Coll.)

Decree No. 225/2008 Coll., laying down requirements on food supplements and enrichment of foodstuffs - prohibits enrichment of foodstuff with addictive or psychoactive substances.

In fact only seeds and leaves (stem) can be used in food (in this case hemp has been traditionally used in the CR and we do not consider it as novel), products MUST be with non-detected THC.

##### Extracts

- extracts are listed in Order of the Government No. 463/2013 Coll., regarding lists of dependency producing substances, and their use in food is not permitted (the whole plant of *Cannabis sativa* including flower is used)
- for handling of extracts the permission is required. The handling permits shall be issued by the Ministry of Health

Cannabidiol/other cannabinoids

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CR differentiates between the oil produced from seeds of hemp (*Cannabis*) with natural occurrence (amount) of CBD and oils enriched by CBD (which might be very difficult because we know that some varieties might be very rich in CBD)

The history of consumption in significant degree of the products with the CBD produced by the supercritical CO<sub>2</sub> extraction has not been proved that's why we consider it as novel and the application has been submitted.

### **Proposal**

#### *Cannabis sativa L.*

##### **Common Names**

Kaņepe (sējas) (LV), Hampa (SF), Hemp (FN), marijuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), harilik kanep (ET), konopi seté (CZ), Marihuana (ES), indiai kender (HU), ινδική κάνναβις (EL), navadna ali industrijska konoplja (SI), hamppu (FI)

##### **Common Names**

In the European Union, the cultivation of *Cannabis sativa* L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant. Without prejudice to other legal requirements concerning the consumption of hemp (*Cannabis sativa*) and hemp products, Regulation (EU) 2015/2283 on novel foods is not applicable to most foods and food ingredients from this plant". **Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities**

#### **1. NOT NOVEL:**

seeds and leaves (stem) – plant without „flowering or fruiting tops of plant of the genus *Cannabis* or aboveground part of plant" and its products

examples: seeds, oil, ground seeds (flour, powder, so called "milk" etc.), leaves, dried leaves (for herbal infusions) etc.

#### **2. NOVEL:**

Cannabidiol / other cannabinoids – synthetically produced

Products of *cannabis sativa* in which the cannabinoid level is higher than the level in the parts of the plant used as source material, are considered as novel, used as such or added as an ingredient in other products (such as hemp seed oil).

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### 3. Extracts: case by case

Extracts defined as: "obtained by physical or chemical methods from the plant of Cannabis". Extracts obtained using alcohol (spirits) from the plant of Cannabis (in the Czech Republic without „flowering or fruiting tops of plant of the genus Cannabis or aboveground part of plant“) should not be considered as novel (because this practice does not give rises to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable changes) → the amount of cannabinoids and other substances should be the same as in the source material (the plant of Cannabis).

But enrichment of foods by this extract or extracts obtained by using different methods should be assessed case by case, in most cases will be probably "novel".

Generally extracts should not be produced for the food production in the CR (because the whole plant is used including „flowering or fruiting tops of plant of the genus Cannabis or aboveground part of plant“)

## ES comments

As regard of the modification of the public novel food catalogue about the status of the plant *cannabis sativa* and its components, we propose as follows:

- **Entry 1: Cannabis sativa**

In the European Union, the cultivation of *Cannabis sativa L* varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant.

Without prejudice to other legal requirements concerning the consumption of hemp (*Cannabis sativa*) and hemp products, only seeds (whose content in THC is lower than 0.2%) and food products derived from these seeds do not falling under the scope of the Regulation on Novel Foods.

Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.

Status: 

- **Entry 1: Cannabidiol/Cannabinoids**

Name of the food: Cannabidiol (CBD), other cannabinoids: CBG, CBN,...



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Additional information: Tetrahydrocannabinol (THC) and cannabidiol (CBD) are one of the major cannabinoids in *Cannabis sativa* plant. Other cannabinoids are cannabigerol (CBG), cannabivarin (CBV),...



Status:

We would like to add that *Cannabis Sativa L* has not been evaluated for obtaining natural aromatic substances or flavoring preparations.

On the other hand *Cannabis Sativa L* is in the compendium of EFSA of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern and it refers to serial parts: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.281>

#### NL comments

#### *Cannabis sativa L.*

##### Common Names

Kaņepe (sējas) (LV), Hampa (SE), Hemp (FN), marihuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), hanlik kanep (ET), konopi seté (CZ), Marihuana (ES), indiai kender (HU), ινδική κόμβα (EL), navadni ali industrijska konoplja (SI), hampuu (FI)

In the European Union, the cultivation of *Cannabis sativa L.* varieties (fiber hemp) is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant.

In some Member States, other specific national legislation may restrict the placing on the market of products from fiber hemp as a food or food ingredient.

The following products from *Cannabis sativa* (fiber hemp) have a history of consumption in the EU and are therefore not novel:

- specifically named foods based on hemp seed: hemp seed oil; hemp seed flour (do other examples of products from hemp seed need to be included? - input MS)
- tea, [herbal and fruit infusions] containing or prepared with leaves of *Cannabis sativa* only,
- beer and lemonade prepared with flowers
- other products? - input MS

##### Status



Extracts of *Cannabis sativa* (fiber hemp) containing cannabidiol or other cannabinoids are novel. This applies to both the extracts themselves and [any] products to which they are added as an ingredient (such as hemp seed oil).

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(Even though we don't think that it would be necessary, this text could also be used as a separate entry for CBD in the NEC, if that would be considered helpful for food business operators)

Status



Other products from *Cannabis sativa* (fiber hemp) should be considered novel, unless a history of consumption in the EU is demonstrated. Where they are unsure whether or not such a product falls within the scope of Regulation 2015/2283, food business operators may present evidence of this through the procedure for determination of novel food status described in Article 4 of this Regulation.

Status



If I correctly understood the talk given by Klaus, it seems *C. sativa* is the only species used for the production of hemp and hemp products used as food so is there a need to differentiate hemp from *C. sativa* or could we define what exactly is hemp as it is used for food and fibre

#### IE comments

I refer to the proposed NEC entries as they relate to *Cannabis sativa* and CBD oil. The meeting record shows the following:

The statement made at the Standing Committee for Foodstuffs on 18 Dec on hemp plant and hemp flowers was read out by UK (The Standing Committee agreed that hemp flower used for the production of beer-like beverages are considered to be food ingredients and not additives since they are used in the same manner as hop flower. Secondly it was decided that foods containing parts of the hemp plant do not fall under the scope of Regulation (EC) No 258/97).

It was proposed to establish in the NEC 3 entries, namely one entry for what is not considered novel such as hemp seed products (e.g. hemp seed milk, hemp seed protein, hemp seed oil). Following the Standing Committee it could also be added hemp flower used for the production of beer-like beverages as long as it is used in the same manner as hop flower.

Second entry should refer to what is novel: CBD or any extract.

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Third entry should refer to the plant Cannabis sativa

I think the suggested entry "one" may contradict the Standing Committee agreement "foods containing parts of the hemp plant do not fall under the scope of Regulation (EC) No 258/97" as it would list examples (e.g. hemp seed milk, hemp seed protein, hemp seed oil) as not novel which in turn could suggest that all other parts may be novel. In this case, hemp oil from plant parts other than seed (if that is possible?) could be deemed novel and I haven't seen any evidence for or against this. The possible problem for regulators is that the current and previous NFC entries are not specific about which parts of the hemp plant are not novel and these entries have been the basis of advice to industry for many years up to now. If we now limit the plant parts that we consider are not novel we risk direct contradiction of earlier advice over many years which in turn could risk legal action similar to that already ongoing in the Czech Republic.

We should clarify that products derived by any non-aqueous extraction procedure do not have a HOC in the EU and therefore such derived products are novel unless evidence to the contrary can be provided.

#### UK comments

Thank you for this further opportunity to input on the development of the novel food catalogue entries for both Cannabis sativa and cannabinoid extracts. We would agree with many of the points raised by colleagues and feel the Belgian proposal provides a useful basis for discussion covering many of the key issues. We wanted to raise some specific points to ensure any resulting entries are clear both for businesses but also for enforcers as we are receiving many questions on this issue and currently enforcement can be problematic due to the lack of clarity.

We agree with the point raised by IE that previous advice on the plant has been used by industry as a basis for developing products. But we feel that it is important to be clear which parts of the Cannabis sativa plant there is evidence of a history of consumption for and there is evidence that the blanket approach has led to confusion. References to the use of flowers and leaves in infusions and beer production are useful as this reflects the evidence available.

On the extracts entry we would prefer that this is called cannabinoids to reflect that other cannabinoids are likely to become of interest if restrictions are placed on CBD. We would also like to make clear that the hemp seed extracts are covered in the other entry to avoid confusion on which entry applies. We prefer the companion approach suggested by Belgium. While we see the attraction of a simple approach we can see no way of avoiding problems from contamination of non-novel extract products if this approach is not taken.

We strongly support inclusion of text that makes clear it is not just extracts that are covered here but also the addition of novel ingredients which will more accurately reflect our current knowledge. It may be clearer if changed to:

*Extracts of cannabis sativa in which the cannabinoid level is higher than the level in the parts of the plant used as source material, are considered as novel. This applies to both the extracts whether used as such themselves and (any) products to which they are added as an ingredient in other products (such as hemp seed oil).*

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We would like to flag the issue of whole plant extracts, as this is often how these products are presented to competent authorities and this can be used to describe a wide range of products some not specific extracts of any one cannabinoid. We have no particular information to support a history of consumption for these extracts which have varying compositions and degrees of purification. We believe there may have been some use of alcohol extracts in particular pre the 1930's when the prohibitive approach to drugs was introduced creating potential, if evidence can be produced, that some of these products may not be novel. Part of assessing any information produced by industry will be whether these products were consumed as foods rather than traditional herbal medicines or even flavouring preparations. In any case it would be for companies to show evidence of this through an Article 4 request. We wanted to flag this issue as something that industry are likely to want to lobby on and may need to be included in the catalogue entries in future, if more information is supplied by industry which demonstrates a history of consumption

#### Greene comments

Taken into consideration the various views of the M-S, we would like to point out the following:

1. The current (and previous) entry for Cannabis sativa is general and it includes plant and plant parts, as well as plant products. It is quite risky, for both the authorities and FPOs, to decide after several years this entry into two parts, one for plant and plant parts and one for products. So we propose to amend the two existing entries. If I well understand, Belgium, Austria and Spain propose two entries.

2. As it concerns the entry for Cannabis sativa, if we reach an agreement about which part is novel or not novel, we can modify this entry excluding some parts (flowers?) and their products (extracts etc).

3. As it concerns the entry for cannabinoid, we agree to include other cannabinoids but not cannabinoids with additive properties, because any additive substance cannot be a food ingredient which has been intentionally used. These substances could be found in foodstuffs only as contaminants in low concentrations. We also agree with Belgium that a reference to synthetic (non additive) cannabinoids should be made.

So we could support the "structure" of the Belgian proposal with some modifications, if we accept that hemp flower extracts in beer-like beverages have been used only for flavouring purposes. We attach our modifications to the Belgian proposal.

#### Proposal:

##### Cannabis sativa L.

##### Common Names

Kanepje (sâias) (LV), Hampa (SE), Hemp (EN), marijuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), hanlík kaner (ET), konopi sete (CZ), Marijuana (ES), indiai kender (HU), indiki kenderőc (FI), navacna ali indijska konoplja (SI), hamppu (FI)

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In the European Union, the cultivation of Cannabis sativa L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant.

Without prejudice to other legal requirements concerning the consumption of hemp (Cannabis sativa) and hemp products, following parts of this plant are considered as not novel: seeds, ~~seed oil~~ oil-related seeds, leaves (only in tea or infusions), flowers (only for flavouring purposes).

The leaves, stems and flowers and their products are considered as novel.

Flowers have been used only for flavouring purposes

Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities

Status



Remark: the conclusion on CBD will depend on which parts of the plant are considered as Not Novel (status for the flower or the leaves?).

→ If the leaves and flowers as such are regarded as novel (except in infusions or flavouring purposes), any extract containing cannabinoids should be considered as novel (unless there is a HOC for these extracts which does not seem to be the case).

Cannabidiol / non-addictive cannabinoids

Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant.

Extracts of cannabis sativa in which the cannabidiol/cannabinoid level is higher than the level in the parts of the plant used as source material (seeds or leaves) are considered as novel, ~~whether used as such or added as an ingredient in other products (such as hemp seed oil)~~, regardless the production process (selective extraction, extraction followed by concentration steps, addition of pure cannabinoids etc).



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#### Italy comments

Let me do a short summary:

- 1) According to Art 2 of reg. 178/2002 "narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961" are not included in food definition;
- 2) According to the United Nations Single Convention on Narcotic Drugs, 1961
  - art. 1: "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated;
  - art. 28: "This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes;
  - cannabis (defined as art. 1) and cannabis resin are included in the list of drugs in schedule I.

So if reg. 178/2002 excludes from the food definition substances included in the convention on narcotics, and Cannabis flowers are in the list of the Convention, whereas the exclusion from the Convention applies to seed and fibre obtained by plants under 0.2% of THC, are flowers, also if derived from industrial purposes plants, excluded from the food definition or not?

We agree with the Belgium proposal for the NEC entry, but regarding flowers we would like first to discuss if they are or not included in food definition, because if they are not reg. 2015/2283 is not applicable, they are not novel they CANNOT be used in food and CANNOT obtain an authorization...

Thanks to the Commission for the clarification.

Best Regards

#### **Standing Committee for Foodstuffs (Summary record 18 December 1997)**

The Standing Committee agreed on 18 December 1997 that hemp flowers used for the production of beer-like beverages are considered to be food ingredients and not additives since they are used in the same manner as hop flowers.

It was also decided that foods containing parts of the hemp plant do not fall under the scope of Regulation (EC) No 258/97.

STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH, SECTION ON GENERAL FOOD LAW (Summary Record of Meeting of 30 April 2012)

#### **2. Exchange of views of the Committee on the legal situation in Member States concerning the marketing of foods containing cannabis extract (MH)**

Following a written question from the European Parliament on the matter, the Commission asked for an exchange on views on the legal situation in Member States concerning the marketing of foods containing cannabis extracts.

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The vast majority of the delegations declared that, at national level, such foods are regulated by the (EU) General Food Law, health legislation and drug law. On the basis on these provisions, these Member States allow the use of cannabis extracts in foods provided that their active substances cannot be detected or their Tetrahydrocannabinol (THC) level is insignificant. Some delegations specified that specific pre-authorisation procedure is required before placing on the market of such foods in their territory. Only few delegations affirmed that, in their countries, hemp as whole is not allowed to be used in foods.

In addition, all Member States agreed that the labelling of foods containing cannabis in a way that it promotes their alleged drug effects is to be considered as misleading and contrary to the EU legislation. In order to avoid the consumer being misled by such practices, few Member States have foreseen specific labelling requirements in the matter. The Commission took note of all information provided by the Member States.

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#### DK comments

We have asked Danish producers to send us any documentation they might have on use of *Cannabis sativa* L. (other plant parts than seeds) as a food in Denmark before 15 May 1992. We have not received any information from our industry. Therefore, with regard to use of other parts of the plant to a significant degree we will have to rely on information from other Member States.

As there is a change of the general situation in Denmark regarding hemp products, I would like to inform you about it.

The Danish Ministry of Health did until July 1th 2018 not allow hemp products with detectable content of THC on the Danish market in order to prevent psychotropic substances being on the market. As this national legislation also covered food products, we did so far not need to have specific restrictions or advice on THC levels in food.

However, from July 1th the Ministry of Health changed their 0 limit to a limit of 0,2% (2.000 mg/kg) THC, and we have therefore now established guidance levels for content of THC in food. If the content of THC is below the guidance levels we do not consider the food unsafe according to the EU Food Law (Reg. 178/2002, Article 14). If the content is higher we will ask the food operator to document the safety of the product.

You can find the guidance on our [webpage](#) (so far unfortunately only in Danish). You find it under "Brug af hamp i fødevarer" if you press the "+" bottom.

The guidance levels are as follows:

	Seed	Flour*	Oil	Beer	Tea**	Bread and other food***
(mg/kg)						
THC <sup>(1)</sup>	2,0	2,0	4,0	0,25	0,25	0,25
Total THC <sup>(2)</sup>	5,0	5,0	10,0	0,50	0,50	0,50

\* Including protein powder

\*\* Content in brewed tea.

\*\*\* Other food products containing hemp provided that they are not in conflict with the Novel Food Regulation.

<sup>1</sup> THC = total content of A9-THC and A8-THC.

<sup>2</sup> Total THC = total content of A9-THC, A8-THC and THC-acid.