**Annex A**

**Request**

*Your request is relation to CBD covering a timeframe of 1 April 2017 to 17 April 2019:*

> *1. Correspondence between: FSA and legal opinion given be its solicitors and / or European commission (In relation to solicitor opinions we are happy if needed to have solicitors names redacted)*
> *2. FSA guidance issued to LA's specifically in relation to assured advice*
> *3. Working group meetings between Commission and related DGs and FSA*

**Response**

**Question 1**

This information has been withheld from disclosure under section 42 (legal professional privilege) of the Act. Further details about our use of this exemption has been provided in Annex B.

**Question 2**

Under Section 5 of the Food Safety Act 1990 Local Authorities in the UK are enforcement officers for food legislation. As far as Novel Food Regulations are concerned the Food Standard Agency (FSA) acts in an advisory capacity only and has no powers to carry out enforcement actions. To date the FSA has not provided assured advice to Local Authorities on novel foods. If the FSA was to provide assured advice this would be direct to a food business. The FSA provided generic advice to Local Authorities on CBD prior to 18 January which was the date the Novel Food Catalogue was changed. It amended this advice after 18 January. This generic advice is included in the information we are releasing. Please see Annex C.

Please note that some of the information has been withheld under 40 (personal information) of the Act. The information has been redacted and marked with the number of the relevant section of the Act in square brackets. Please see Annex B for further details.

**Question 3**

The information requested has been provided in Annex C.

Please note that some of the information has been withheld under 27 (international relations) of the Act. The information has been redacted and marked with the number of the relevant section of the Act in square brackets. Please see Annex B for further details.

**Annex C – FOI 2412 Information for disclosure**

**Generic Advice to Local Authorities prior to the Novel Food Catalogue amendments on 18 January 2019.**

**From:** Novelfoods
**Sent:** 21 November 2018 16:02
**To:** @preston.gov.uk> **S40 (2) and (3)**
**Subject:** RE: manufacturer of Jelly sweets and drinks containing CBD

Dear [Preston City Council] **S40 (2) and (3**)

Thank you for your email regarding CBD.

Novel Foods are foods which have not been consumed to a significant degree within the EU before 15 May 1997. All novel foods are required to undergo a mandatory pre-market safety assessment and authorisation under the Novel Foods Regulation (Regulation (EU) No 2015/2283) before they can be legally marketed in the EU.

When considering Hemp products account must be taken as to whether the product may be subject to other legal frameworks depending on the composition and nature of the product. If a product is considered a controlled substance or a medicine it would be outside the definition of food and regulated by those regulatory frameworks.

In the UK, the use of hemp in food is considered on a case-by-case basis dependant on factors such as the amount of hemp present in the final product, extent of use and the anticipated intake, claims being made and the potential physiological effect. Any food product sold containing hemp would be subject to the relevant requirements of food law.

From a novel foods perspective, while a significant history of consumption exists for industrial hemp strains of *Cannabis sativa* (plants, beans and oils with no content - or low- of cannabinol and cannabinin), there is no established history of use for selective extracts of CBD where the level of CBD is concentrated compared to the source. In the case of hemp extracts including CBD extracts where there is not a history of consumption, these are considered to be novel foods and a risk assessment and authorisation is required under the Novel Foods Regulation before they can be sold. If you have information to support a history of consumption for these products, please let us know and we can provide further details on the process for assessing information to demonstrate a history of consumption. To date no authorisations for CBD extracts of hemp have been granted but an application is at an early stage of assessment in the novel foods authorisation process at EU level.

You should be aware that the cannabis plant as a whole is strictly controlled under the Misuse of Drugs Act 1971, although certain parts, when separated from the rest of the plant are not; these are:

a) Mature stalk or any such plant,

b) Fibre produced from mature stalk of any such plant and
c) Seed of any such plant.

The Home Office is responsible for governing the misuse of drugs and more information can be found at their web-site at http://www.homeoffice.gov.uk.

Kind Regards,

[Food Standards Agency] **S40 (2) and (3)**

[ **S40 (2) and (3)** ] Food Policy Division, Food Standards Agency
6th Floor, Clive House, 70 Petty France, London, SW1H 9EX
https://www.food.gov.uk/business-guidance/novel-foods

**Generic Advice to Local Authorities after Novel Food Catalogue was amended on 18 January 2019.**

**From:** Novelfoods
**Sent:** 16 April 2019 12:52
**To:** @nottscc.gov.uk> **S40 (2) and (3**)
**Subject:** RE: Cannabidiol

Dear [Nottinghamshire County Council] **S40 (2) and (3)**

Thank you for your email enquiring about CBD products.

There has been a recent change to the Novel Food Catalogue which affects some Cannabidiol (CBD) products. It's been clarified that CBD extracts are 'novel' and must be authorised before they are permitted to be placed on the market. New foods have to be evaluated and authorised before they can be sold unless there is evidence they have a history of consumption before May 1997. Food businesses have not shown evidence of this for CBD products and CBD is therefore considered a novel food in the European Union.

The FSA agrees with the rest of the EU that CBD extracts are novel foods and we are working with local authorities, businesses and consumers to clarify how to achieve compliance in the marketplace in a proportionate manner.

We are progressing these discussions at pace and at a very senior level, but is important that due consideration is given to assessing the many issues in play. We will provide further clarification as soon as soon as possible.

For now, it is the responsibility of a business to determine if any CBD product they want to sell is novel. However, where they are not sure, they can ask for a formal opinion of their specific product under Article 4 of the EU Regulations. This isn't a full authorisation application and is the best way to get a definitive answer on if a product is novel. Further details on how you may do this are detailed in EC Regulation

2018/456 which is at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0456&from=EN.

Warm regards

**S40 (2) and (3)**
[Food Standards Agency]
E: Novelfoods@food.gov.uk

## EU Working Group discussions on Cannabis

### Meeting of 12 March 2018

### 6. SUMMARY OF MEETING

Finally work to develop revised text on CBD and its novel food status continued. With consensus reached that the focus of the definition should be on concentrating intrinsically present CBD. This may need some further refinement before this is published for use by enforcement authorities.

### Agenda item 4: CBD

Prior to the meeting **Cion** had circulated the background document by email highlighting the suggestions for updating the novel food catalogue provided by member states in light of the previous discussions. **Cion** introduced the document that summarised the challenges and provided a revised suggestion that sought to address the different positions that had been outlined. They explained that for technical reasons the entry cannot be updated to the proposed new format for the catalogue.

**Cion** explained that it was clear that hemp oil is not novel but there is some confusion over the use of terminology such as hemp oil and CBD oil. While generally **Member States (MS)** agreed that with the previous [**MS [S27(1)]** proposal there were some concerns that this did not fully represent the situation and that products with a history of consumption could be unintentionally captured. This is complicated by the different parts of the plants with different natural levels of CBD being used in some products.

The discussion proceeded to explore drafting suggestions for the text which covered the questions raised by **Cion** in their document. The first point was around the use of term selective extraction as included in the **UK** suggestion provided. A **MS [S27(1)]** suggested that what is meant by selective extraction should be included in the text. This was supported by **MS [S27(1)] and the UK** with the addition of retaining the term selective extraction. A **MS [S27(1)]** felt once the explanation was included the term could be removed and this was done.

A **MS [S27(1)]** suggested that in explaining what is meant by selective extraction it should not refer to the intention as this was difficult to enforce. This resulted in a lot of discussion around terms such as an increase of CBD relative to another parameter. At the suggestion of a **MS [S27(1)]** supported by A **MS [S27(1)]** the reference became around an increased concentration of CBD relative to the starting material. This was generally accepted. It was also clarified that the text refers to foods including food supplements following a point from three **MS[S27(1)]** .

There was discussion on the text in the draft on the parts of the plant covered. A **MS [S27(1)]** had previously suggested that flowers could not be used in food. The text on hemp seed oils not being novel was removed following an intervention by a **MS [S27(1)]. MS[S27(1)]** highlighting that to be more precise a threshold level would be needed. A **MS [S27(1)]** suggested that EFSA be approached for a risk assessment but **Cion** countered that this would not provide assistance in the short term.

There was a short discussion on how to manage the potential for strains of industrial hemp with higher natural levels of CBD. A **MS[S27(1)]** indicated that they wanted to be clear on the strains that could be used. **UK** suggested that of course strains produced by traditional breeding practices would not be novel but that the wider factor of which strains were permitted in food would apply. **Cion** noted the potential for non-traditional breeding techniques to be used. **Cion** supported by a **MS [S27(1)]** and **UK** agreed to copy the text from the *Cannabis sativa* entry on industrial hemp strains to also be included in the CBD entry.

**MS [S27(1)]** favoured referencing examples of the methods of extraction in the text so long as this was not an exhaustive list.

On the draft that was reached there remained a concern highlighted by a **MS [S27(1)]** supported by a **MS [S27(1)]** and **UK** that even in traditional hemp seed extractions the level of CBD could be concentrated. **Cion** did not fully accept this point but would consider this again. **Cion** concluded that the entry was developing but did not outline the next steps.

**Meeting on 15 May 2018**

**6. SUMMARY OF MEETING**

A presentation from a member state on the way forward for CBD and the products from hemp resulted in a lively discussion. While the focus was mainly consideration of the novel food status of parts of the plant, hemp seed extracts and selective extracts, wider issues were also explored. In particular whether there are wider safety issues and the ongoing work in the area of contaminants was considered. Calls were made for an Article 8 request under 178/2002 to consider the safety of this type of product. It was noted that CBD is leading this market but other cannabinoids are beginning to come through. This is of course a complex issue with links to medicines and national drugs policy and these will need to be considered as the food issues develop.

**Agenda Item 10: Status of *Cannabis sativa*, CBD and Cannabinoids**

**[ S27(1)**

]

A lively discussion followed in which a **MS [S27(1)]** requested clarity on which parts of the plant are novel as the catalogue currently says “most parts of the plant are not novel”. A **MS [S27(1)]** particularly wanted agreement on leaves to feedback to industry. **Cion** commented that the key issue is improving the catalogue.

A **MS[S27(1)]** make the point that leaves and flowers have a history of consumption primarily in beer and lemonade for their flavouring properties. They raised concerns that when flowers are used in food (not just as a flavouring) the product is not safe as they contain high levels of THC. **Cion** commented that one of these issues might be a novel food issue in terms of whether there is a history of consumption but any safety issue where foods are not novel is for General Food Law. A **MS [S27(1)]** suggested that this may be an issue to discuss with the contaminants group. The work of this group in collecting data on the presence of THC in products was noted.

A **MS[S27(1)]** supported by A **MS[S27(1)]** raised the issue of using oil to dilute extract so the final product has levels of CBD consistent with those naturally. Operators were considering only the end product and it needed to be clear that the extract is a novel ingredient and can’t be used without authorisation. Suggested wording included use of “selective extraction” or “enriched” in the definition.

A **MS[S27(1)]** suggested a maximum amount of CBD or THC but **Cion** rejected this and noted that this is for individual MS to decide. They suggested that there is insufficient data to explore a maximum levels approach and this is more linked to safety than novel food status. **Cion** emphasised that the key things to have a basic approach of deciding what is novel or not.

A **MS [S27(1)]** welcomed this and noted that there needs to be consensus of which products were on the market prior to 1997. They preferred a simple definition. A **MS [S27(1)]** flagged that a simple solution might not be possible but greater clarity was needed and perhaps previous versions of the catalogue would provide a good basis for considering this. welcomed this approach. A **MS[S27(1)]** suggest that this could be wider than CBD and other cannabinoids are coming through, so the approach once developed, should apply more widely to other selective extracts.

A **MS [S27(1)]** raised the issue of medicinal uses and **Cion** noted that the issue of whether products are medicines is at the discretion of MS. A **MS[S27(1)]**

questioned what had been agreed at SCOPAFF in the past as this should the starting point. The UK provided clarity that it was plant parts that were considered not novel and therefore maybe separate entries for plant parts and hemp seed oils were needed from the other types of extracts that appeared to be novel. **MS [S27(1)]** suggested combining entries in the catalogue as was done for Stevia to make clear which uses have a history of consumption although a member state emphasised that hemp seed oil was not novel and subject to a codex standard.

A **MS** questioned whether from an EU legislative perspective cultivators of *Cannabis sativa* need to comply with 0.2% THC in hemp for cultivation if not seeking state aid and therefore whether this was best descriptor for the permitted chemovars. A **MS** explained in accordance with their national legislation this acted as a requirement but that this may be different in other MS. A **MS** noted that they are facing issues with plant breeding and hemp. **Cion** proposed that by 31st May all MS to send proposals of how the catalogue could be improved. **Cion** will put together a draft proposal once suggestions are received and circulate this back to MS. **Cion** suggested one way to do this could be to have 3 entries:

1. Hemp products / parts of the plant that aren't novel
2. Novel extracts
3. Other parts of the plant

**Meeting on 5 July 2018**

**SUMMARY OF MEETING**

There was a lively discussion on the status of *Cannabis sativa*, CBD and cannabinoids. While the development of the novel foods catalogue entry is ongoing, consensus is beginning to emerge on the novel food status of parts of *C. sativa* plants. Further discussion is need on the status of extracts. This is of course a complex issue with links to medicines and national drugs policy and the development of the entry is being considered in this context.

**Agenda Item 15: Status of *Cannabis sativa*, CBD and Cannabinoids.**
**Cion** commented that the route to achieving legal clarity on the novel food status of the different forms of *Cannabis sativa* and related products would be the use of Article 5. However, given the nature of discussions to date it seemed preferred to improve the wording for the entries in the novel food catalogue. It was noted that this isn't legally binding and can be challenged. **Cion** have drawn up 2 proposal options for discussion on which comments received in May. There is a need to further refine these entries.

Cion summarised the background to this issue:

- Standing Committee in 1997 agreed that hemp flowers used in beer have a history of consumption

- Standing Committee in 2012 had a change of views on foods containing cannabis extracts. Member States can use foods when cannabidiols can't be detected. **[ S27(1)**

**]**

Consensus was reached that anything from *Cannabis sativa* L. seeds are not novel. There continues to be confusion over the status of leaves, extracts other than those from the seed due to the potential cross contamination with THC. It was noted that tea and beverages produced by infusion or brewing methods which appear to have a history of consumption are a type of extract. The question posed was the approach that should be taken.

Cion highlighted that they had met with the UK Cannabis Trade Association (CTA) who had flagged that $CO_2$ and ethanol extraction techniques were in use in the industry. Their view was that using simple extraction 40% CBD could be extracted from the plant material using two passes of extraction the first to extract from the plant and the second to remove waxes and some terpenes. Cion asked Member states for insight into their positions.

**[ S27(1)**

**]**

A **MS[S27(1)]** have asked industry for evidence of HoC but they haven't received any evidence. A member state was only aware of HoC of seeds. A Member state only legally allow seeds, seed oil and protein from hemp seeds - anything else is considered illegal or unclear with regard to novel foods. Supplements need to be registered and any that contain Cannabis are assessed to determine if they are a medicine. So far, the 2 assessed were regarded as medicines.

The UK were invited by **Cion** to explain the work of the CTA. **UK** commented that the CTA are new and growing in the UK and the EU and they are actively working with producers and through the food chain. The association recognises that highly refined extracts are novel but they view whole plant extracts that retain the balance of cannabinoids as not novel. They claim these have been used for a long time but have not provided evidence to support this. The FSA have been flagging the legal requirements and refer to the novel food catalogue as a basis for the position in the UK that refined extracts are novel, some products have a history of consumption but for others the status is not yet clear. It was highlighted that there was ongoing work with the medicines and drugs authorities in the UK. However, the lack of clarity meant enforcement of the novel food regulations could be challenged.

A **MS [S27(1)]** sought clarification of the basis of the current text and Cion flagged it reflected the response from the member states.  sought clarification on whether hemp products containing oil from the stalks are novel and asked for these to be considered not novel. A member state was of the view that it was parts of the plant used as ingredients that were not novel rather than extracts.

**UK** noted that the General Food Law has come in since the standing committee position in 1997 and called for consideration of the interaction of the UN Convention on Narcotics which defines cannabis as the fruiting bodies and upper leaves. Clarification was sought on whether these would be considered as food. **Cion** suggested that if using registered varieties these are likely to be food. A **MS [S27(1)]** commented that as the convention is implemented in each Member State individually it is hard to comment on this across Member States. The implementation of the convention in a member state had formed the basis for the saying that THC should be undetected in hemp products.

A **MS [S27(1)]**  suggested that all Member States collect history of consumption of all products other than seeds in order to form a better basis for the discussion. **Cion** agreed with the principle but felt this could not be systematic as there is limited information available. The situation seemed to be complicated when products were on national markets and it would be for authorities to manage.

There was discussion around the use of parts of *Cannabis sativa* particularly leaves and flowers for flavouring purposes. There was agreement on wording that flowers have a history of use in beer in the same way as hops. A **MS [S27(1)]**  to check history of use and see if this is specifically for lemonade or is more general than that. This was felt to be important by **MS [S27(1)]**  as reflecting the information Member States hold and to maintain the previous Standing Committee decisions. The potential for some to be flavouring preparations was raised by A Member state. **Cion** agreed to check with flavourings colleagues. A **MS [S27(1)]** preferred to reflect the wording from previous decisions.

A **MS [S27(1)]**  sought clarification on whether this type of use also reflected hemp juices. They considered that this was too broad as it could cover several parts of the plant. It was also explored if the reference for the use should be restricted to lemonade or if other non-alcoholic beverages should be included. A **MS [S27(1)]** preferred that this reflected the documented use.

There was discussion around the terms used. A **MS [S27(1)]** suggested that *C. sativa* is either always followed by (fibre hemp) or never. A **MS [S27(1)]** suggested industry don’t like the terms fibre hemp.

In response to **Cion** question on whether the wording on the need to check with Member States on any specific requirements in the respective countries should be

retained, **UK** asked to keep wording due to the medicines and drug legislation interactions that could be different between Member States. A **MS [S27(1)]** commented that the use of seeds should be 'as such' in the first bullet point of the current draft. This was noted.

The issue of developing the extracts entry was raised and it was felt that further development was needed. **Cion** commented that this was the aspect that was likely to have a larger impact on industry. The discussion ended with the progress that had been achieved noted but with recognition that further discussion was needed.

**Meeting on 10 September - Detail**
Agenda Item 11 on Status of Cannabis sativa, CBD and Cannabinoids – This item was not discussed

**Meeting on 16 October 2018**

**SUMMARY OF MEETING**

The European Industrial Hemp Association (EIHA) and the British Association of Cannabis gave a joint presentation on CBD and cannabinoids which resulted in a lively discussion. No concrete evidence of a history of consumption in the EU before 1997 was provided. MS were in agreement that evidence would be needed to confirm CBD extracts are not novel. This is of course a complex issue with links to medicines and national drugs policy.

**Agenda Item 10: Status of Cannabis sativa, CBD and cannabinoids**

The EIHA and the British Association of Cannabis gave a joint presentation. This covered health claims safety and the limited information they have on history of consumption before 1997.

A lively discussion followed in which **Cion** clarified that we are focusing on whether products are novel rather than the safety to begin with.

A **MS [S27(1)]** questioned some of the information provided on history of consumption. The organisations noted that they do not have concrete information on history of consumption besides old cookbooks and some historical suggestions. **Cion** reiterated that clear evidence would be needed to back up HoC.

The presentation included a suggestion to cap the maximum amount of CBD/cannabidiol extracts at 5% as CBD content in raw biomass for EU registered varieties is between 1-5%. A **MS [S27(1)]** explained that as there hasn't been evidence of use of enriched CBD extract, it doesn't matter if this is then diluted to 5% or lower, it would be novel. If the extraction method has been used before, but the end product hasn't been consumed before, it would also be novel.

A **MS** suggested that if the organisations have safety data, they should submit a novel food authorisation. The BIHA responded that it is a long process and they already have 20 million users. A **MS [S27(1)]** also suggested an Article 4 application to determine the novel status.

**[ S27(1)**

**]**

**Meeting of 14 and 15 January 2019**

**SUMMARY OF MEETING**

A lively discussion on amendments proposed to the entries for *Cannabis sativa* and CBD and Cannabinoids took place with the aim of achieving a consensus on the novel status of products already on the market and also those proposed to be marketed. A second aim was to amend the Novel Food Catalogue wording to produce greater clarity which would enable FBOs to make decisions on marketing their products. MS agreed FBOs and relevant trade associations had not provided evidence of a history of consumption in the EU before 1997 for either food supplements containing CBD, or extracts of CBD, and as a consequence they were novel foods.

**Agenda Item 14**: **Cannabidiol**

Cion introduced this item. It noted that the information in the catalogue was not clear and the aim of the meeting was to get a consensus and to find the right wording for both *Cannabis sativa* and Cannabididol in the Novel Food Catalogue.

Industry had not been able to provide a history of consumption data for CBD since putting it on the market. The key point was that the history of consumption had to be for the products on the market.

Cion asked MS if CBD in food supplements were novel. All MS present agreed that it was.

A **MS [S27(1)]** commented that aqueous extracts of CBD could be enriched. As CBD doesn't dissolve easily in water then terpenes could be added. Another **MS [S27(1)]** agreed with this priniciple. A **MS [S27(1)]** questioned which aqueous extracts were being referred to and which plant parts were to be used. A **MS[S27(1)]** commented that tea was usually sold as hemp tea not as CBD. The **MS [S27(1)]** agreed that hemp tea was not novel. If the extract was produced using benzene, CO2 or alcohol

or extracts all these extracts are novel as the processes hadn't been used in the production of CBD prior to May1997. It was accepted that hemp and hemp derived products were not novel and cold pressed seed oil was also not novel.

A **MS [S27(1)]** considered that all CBD was novel and only seed derivatives were not novel. Another **MS [S27(1)]** commented flowers and leaves were not allowed in products because of narcotics legislation. It also considered only oils derived from seeds were not novel. Other MS had the same position. It was agreed the Novel Food Catalogue entry should be very clear. The Catalogue entry should confirm which extracts were novel and which weren't.

Cion informed the meeting a disclaimer should be put in the catalogue on the basis of the Member states information. An explanation was needed if a change was to be made. A **MS [S27(1)]** commented that cannabidiol could come from contamination.

A Member state informed the meeting that it had issued statements that CBD extracts were novel. It noted that there was a distinction between contaminants and intentional constituents. The member state viewed intentional constituents of foodstuffs as novel.

Member States reaffirmed industry had not provided documentation which confirmed a history of consumption of CBD extracts. **[S27(1)**

**]**

Producers making an application for authorisation of CBD as a novel food are not making applications under Article 4 of the Novel Food Regulations (EU)2015/2283.

A Common definition as to whether of not CBD is novel is required in the Novel Food Catalogue. It was not necessary to have a separate entry for cannabidiol.

A **MS [S27(1)]** noted that some Hemp products should be regulated under the Misuse of Drugs Act. It further noted there was nothing in food law about the 0.2% THC levels. This figure related to farm payments.

The meeting agreed the novel status of CBD extracts and supplements. The discussion was to be continued at the next meeting.

**Meeting of 12 March 2019**

**SUMMARY OF MEETING**

The morning was dominated by CBD considerations, with both the European Industrial Hemp Association (EIHA) and the Cannabis Trades Association (CTA) providing consecutive presentations. No additional history of consumption for CBD extracts was provided and despite industry contestations to the contrary, **MSs** were in agreement that CBD extracts are novel. **MSs** agreed that whilst the Novel Food Catalogue entry wasn't entirely satisfactory, a further change at this time wouldn't be appropriate. **[S27(1)**

**]**

**Agenda Item 6: Status of *Cannabis sativa*, CBD and Cannabinoids**

Overall: Industry representatives gave 2 consecutive presentations, following by questions from the **MSs**. After presentations (once industry had left), **MSs** discussed CBD further and agreed the EU Novel Food Catalogue remains unaltered, and that in general the enforcement approach should be consistent across **MSs** where practical; although it was acknowledged a firm and uniform timeframe for compliance was unlikely.

Points of note:

**Whilst Industry Present**

- Presentations by **EIHA** (European Industrial Hemp Association) and **CTA** (Cannabis Trades Association). Their contention remains that CBD extracts are not novel as they derive from hemp and are similar to 'making a cup of tea'. They want hemp leaves/flowers added to the Catalogue as not novel, use of traditional extraction methods to make CBD not novel, naturally occurring Cannabinoids not novel, a max dose of 160mg per day for adults, and support to devise private standards. **EIHA** confirmed money was available for toxicology but not certain what to do. **MSs** advised they should request an Article 4 consideration, or could apply for authoristion under Article 10; noting that MSs could also raise an Article 5, and several Article 10 applications had already been received from others.

**After Industry Left the Meeting**

- Limited new history of consumption evidence provided, and it exclusively related to hemp derived products (not CBD extracts).
- CBD issue is complex with several legislation regimes: novel food, medical, drugs, animal feed, environmental.
- **[S27(1)**
- 
- **]**. It's for individual **MSs** to determine if treated as a drug or medicine.
- EU Novel Foods Catalogue remains unchanged, with no current firm proposals to review this further; although acknowledgement that the Catalogue entry isn't optimal. **EC** will consider this issue further.
- No disagreement amongst **MSs** on novel food status of CBD extracts; they're novel.
- Consideration of future enforcement should be consistent amongst **MSs** where possible; noting that there is variation between legislative regimes due to drug and medicinal legislation variation. **[S27(1)**
- **]**
- In relation to CBD safety **EFSA** confirmed that not aware of anything to suggest safety concerns but can't state with certainty as applications don't have adequate information at this time.

Contrasting MS positions:

**Whilst Industry Present**

- **[S27(1)**

]

A **MS[S27(1)]** advised that medical and drug legislation not harmonised so a consistent approach across all **MSs** is not possible.

A **MS [S27(1)]** confirmed that other novel products were made by concentrating certain aspects (comparable to the cup of tea analogy) e.g. lycopene from tomatoes; the focus being on if the product itself is novel.

**After Industry Left the Meeting**

- A **MS [S27(1)]** raised that they felt the Catalogue needed further clarification. **EC** confirmed that the Catalogue has an impact (even though not legally binding). **[S27(1)**
- **[S27(1)**

**]**