

Novel Foods and Cannabidiol (CBD) Developments

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Your Trainer

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About this Presentation

- Reminder of the novel food regime
- Traditional foods
- Novel food trends
- Cannabidiol (CBD):
 - What it is
 - Legal considerations
- FSA Position
- Impact of Brexit



- Regulation (EU) 2015/2283 (Novel Food Regulation):
 - Novel food = any food that has not been consumed to a significant degree by humans in the EU before 15 May 1997:
 - Entirely new food
 - Traditional foods eaten elsewhere in the world, but not in the EU
 - Foods produced from new processes
 - Pre-market safety assessment and authorisation prior to marketing
 - Authorisations subject to conditions of use
- Novel Food (England) Regulations 2018
 - UK Regulations
 - Offence to breach
 - Fine (unlimited)
 - Enforcement by local authorities, including Trading Standards and Environmental Health Officers



Novel Food Decision Tree

Was the product on the EU market as a food or food ingredient and consumed to a significant degree before 15 May 1997?

Has there been any request of the European Commission as to whether the product requires authorisation under the Novel Food Regulation?

Has the product been authorised?

What are the conditions of the authorisation?



- Indicates status of foods
- Uses Latin names
- Status:



Actinidia arguta

Common Names

aktinidie význačná; mini kiwi (CZ), kiwiberries (UK)

Common Names

Actinidia arguta (hardy kiwi) is a perennial vine native to Japan, Korea, Northern China, and Russian Siberia. It produces a small fruit resembling the kiwifruit.

Status



What does it mean?

- Information on the ‘novel food’, including a description of its purpose and intended use, of the food itself, the processes involved in its production, its compositional data, specifications, history of uses, proposed uses/ use levels/ intakes, data on absorption/ distribution/ metabolism / excretion, nutritional information, toxicological information and allergenicity.
- Scientific studies relating to relevant information provided, for example studies on stability, or geno-toxicity (and information on the relevant study report(s)).
- Certificates of Analysis in relation to compositional data (and information on relevant analytical method(s)/ test centre(s)).
- Study reports for toxicity and summary of statistically significant differences between controls and the novel food (and details of the relevant study report(s)).
- Human studies relating to the novel food (and information on the relevant study report(s)).



Novel Foods- Examples and Trends

- Chia seeds
- Algae
- Insects
 - Whole and ground crickets
 - Migratory locust
 - Whole and ground grasshopper
 - Mealworm
- Allulose - sweetener



Traditional Foods (from outside EU)

- Regulation (EU) 2017/2468
- Traditional foods from third countries, derived from primary production and with a history of safe use for at least 25 years
- Simplified fast-track procedure of notification to be marketed in the EU
- Authorisation if no objections within 4 months



Examples:

- Fonio (*Digitaria Exilis*) – grains of a small seeded cereal – West African (gluten free)
- Haskap berries - whole berries – Japan
- Cacao fruit pulp – rich in sugars – Brazil
- Herbal infusion from coffee leaves – substitute for coffee/ tea - Ethiopia, South Sudan, Liberia, Indonesia and Jamaica
- Leaf powder of *Moringa stenopetala* – leaf powder – Ethiopia
- Sorghum Syrup – plant derived sweetener - USA

- List of authorisations under former regulation EC (No) 258/97
- Summary of applications and notifications under current Regulation
- Authorised foods:
 - Conditions of use
 - Labelling requirements
 - Specifications
 - Post-market monitoring requirements



Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Argan oil from <i>Argania spinosa</i>	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Argan oil' and if used as seasoning 'Vegetable oil only for seasoning' shall be mentioned on the label	
	As seasonings	Not specified		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of vegetable oils		

- Novel Food Catalogue:

- The hemp plant (*Cannabis sativa* L.) contains a number of cannabinoids and the most common ones are as follows: delta-9-tetrahydrocannabinol (Δ 9-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A (Δ 9-THCA-A), delta-9-tetrahydrocannabinolic acid B (Δ 9-THCA-B), delta-8-tetrahydrocannabinol (Δ 8-THC), **cannabidiol (CBD)**, its precursor in hemp cannabidiolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin (Δ 9-THCV).

- Product types:

- Food supplements
- Food and drink products
- Vapes (electronic cigarettes)
- Bath salts
- Creams/ balms/ cosmetic products
- Pet supplements



- Novel Food Catalogue:
 - Cannabis Sativa: In the EU, the **cultivation** of *Cannabis sativa* L. varieties is permitted 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)**. Some products derived from the *Cannabis sativa* plant or plant parts such as **seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel**. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States.
 - Without prejudice to the information provided in the novel food catalogue for the entry relating to *Cannabis sativa* L., extracts of *Cannabis sativa* L. and **derived products containing cannabinoids (including CBD) are considered novel foods** as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel.
- Misuse of Drugs Act 1971*
- Classification of product**
- Food Supplement laws
- Nutrition and Health Claims Regulation (NHCR)
- Food safety and hygiene laws



Further Guidance:

- *Home Office Drug Licensing Factsheet – Cannabis, CBD and Other Cannabinoids
- ** Guidance Note 8 on What is a Medicinal Product – Appendix 10

- Summary of Novel Food Applications submitted to European Commission (not yet approved):
 - Cannabidiol derived from chemical synthesis – Cibdol, Switzerland
 - Synthetic cannabidiol - Chanelle McCoy CBD LTD, Ireland
 - Trans-cannabidiol – Cannabis Pharma, S.R.O, Czech Republic
 - Synthetic trans-cannabidiol – CBDepot, Czech Republic
- EFSA Register of Questions :
 - Request from EC for scientific opinion on CBD as novel food 20.03.20 (ref Chanelle McCoy CBD Ltd application)
 - Request from EC scientific opinion on Cannabidiol derived from chemical synthesis as a novel food 15.01.20 (ref application by Cibdol and Arborlea)
 - Request for a scientific opinion on trans-Cannabidiol, synthesized as a novel food 26.11.19 (ref application by CBDepot) – nb EFSA suitability completed 23.03.20
 - Request for a scientific opinion on trans-Cannabidiol as a novel food 20.06.18 (ref Cannabis Pharma, S.R.O)
 - Request for an acute human exposure assessment to Δ^9 -tetrahydrocannabinol – as a contaminant in food – Report published 07.01.20 – Further research recommended, including consumption data of consumers of hemp



- Jan 2020:-
 - Take immediate action to gain authorisation as a novel food in relation to any CBD extract products you sell, or plan to sell in the future.
 - Otherwise, seek assurances from your suppliers/ manufacturers that they have done so.
 - Reports that CBD extracts and hemp products (such as cold-pressed oils) are the same are incorrect – CBD extracts and products they're added to are novel foods (hemp is not).
 - Where CBD extracts also contain THC (or other controlled cannabinoids) they will fall under the Misuse of Drugs Act 1971.



- Feb 2020:-
 - The FSA has set a **deadline of 31 March 2021** to submit, and have **validated**, your novel food authorisation applications.
 - After 31 March 2021, only products which have a fully validated application will be allowed to remain on the market.
 - All other novel CBD products will be removed from sale.
 - There are no protections from enforcement offered by any alternative route.
 - This deadline of 31 March **does not include products not yet on the market**. No new CBD extract or other novel products will be allowed on the market without having the appropriate authorisation.

- Those who are pregnant, breastfeeding or taking any medication should not consume CBD products.
- Healthy adults should think carefully before taking CBD.
- Recommendation of no more than 70mg a day (about 28 drops of 5% CBD) unless under medical direction.



CBD Approach – Other Jurisdictions

- Medicinal Product Approach
- Prohibition as Food Supplement
- Legal on prescription
- Use as food ingredient legal
- Country-by-country approach



- General:
 - Transition period
 - Article 4 Consultations on whether a food is novel
 - Current novel food authorisations
 - Applications after transition (1 January 2021):
 - UK regulated products service
 - FSA and FSS to conduct risk assessments
 - Required for changes to existing authorisations

- CBD
 - Timescales:
 - End of transition likely 1 Jan 2021
 - Novel food application to be validated by 31 March 2021
 - Position with ongoing applications unclear.
 - Consider advance consultation with FSA



Questions & Answers



Local Connections Global Influence