

Government response to the ACMD advice on consumer CBD Products

Dear CBD Sector Colleagues,

For clarity: The CTA is issuing this initial review to the CBD trade sector in parallel with any further future regulatory changes that might arise as an outcome from the Government response to the ACMD of the 24th October 2023 by Rt Hon Chris Philp Minister of State for Crime, Policing and Fire, and the FSA as the regulator involved in CBD as a Food.

The Full Letter to the ACMD from Rt Hon Chris Philps MP can be seen here:

<u>Government response to the ACMD's advice on consumer CBD products (accessible version) - GOV.UK</u> (www.gov.uk)

The CTA Key Points* for the CBD Industry as a result of the Government response to the ACMD Report:

- The Government is recognising consumer CBD products as a food and uncoupling this from the Home Office regulation in relation to narcotics and licencing.
- A `serving' has NOT been defined but may be defined in the future.
- Permitting 50micrograms for EACH phytocannabinoid per unit of consumption allows the consideration of a wider spectrum of CBD consumer products than currently thought. The Government hopes to bring forward secondary legislation in due course and recognises the `Unit of Consumption or Serving' will differ between different products.
- There will be an Exempt Product Definition (EPD) from the Home Office to the FSA in relation to consumer CBD products.
- A food is not a drug. This uncouples CBD as a foodstuff from the Misuse of Drugs Act and gives the freedom to the FSA to treat CBD as a Food under Food Law – hence phytocannabinoids are now `contaminants' in the food ingredient.
- Ensuring CBD is recognised as a food and setting THC and other phytocannabinoid levels in finished products should ease retail sales and speed up the Novel Food process.



www.cannabistrades.org 41 Wincolmlee, Hull, Yorkshire, UK, HU2 8AG

• Phytocannabinoid levels have the potential to increase over time under these recommendations as more toxicology and scientific data becomes available.

*This information is for guidance only and has not been checked legally or with government officials.

In support of these changes the CTA has provided the FSA with testing protocols, standardised COAs recommends only using accredited ISO17025/2017 laboratories.

This is the start of the changes for CBD as food ingredient within the FSA. The CTA will be part of a series of meetings being set up by the FSA (and others) in relation to CBD within these parameters being designated a food ingredient. The following is taken from the response:

Recommendation 1

- That the total dose of delta-9-THC (including delta-9-THCA) and all other controlled Phytocannabinoids in consumer CBD products be controlled.
- The dose of **EACH** controlled Phytocannabinoids should not exceed 50 micrograms per unit of consumption.
- A unit of consumption or 'single serving' being defined as the typical quantity of a CBD product consumed on one occasion.

Government response

The Government accepts this recommendation and intends to bring forward legislation to implement it, subject to Parliamentary approval. The specificity of the terms of legislative provisions setting the Unit of Consumption (or serving) for the permitted dose, which will differ between different products, will require further careful consideration.

Recommendation 2

 That regulatory authorities ensure that any consumer CBD product permitted to market has the limits on the content of controlled Phytocannabinoids such that the dose of delta-9-THC (including its precursor delta-9-THCA) and EACH of the other controlled Phytocannabinoids does not exceed 50 micrograms per unit of consumption.



www.cannabistrades.org 41 Wincolmlee, Hull, Yorkshire, UK, HU2 8AG
The Hemp Trades Association (trading as the Cannabis Trades Association UK) is a not for profit company limited by guarantee without share capital in England and Wales No. 10472540 incorporated in November 2016. • The ACMD advise another analysis of the controlled Phytocannabinoids content of consumer CBD products is performed by DSTL two years after the implementation of the regulations to check the level of compliance.

Defence Science and Technology Laboratory based in Salisbury https://www.gov.uk/government/organisations/defence-science-and-technology-laboratory

Government response

The Government accepts this recommendation in principle and, as outlined above, intends to bring forward legislation to prescribe the lawful amount of controlled phytocannabinoids in consumer CBD products.

We will work further with law enforcement, supported by regulatory authorities, on the mechanisms for the enforcement of legal requirements in respect of consumer CBD products.

Recommendation 3

• A further inter laboratory comparison trial (ring trial) should be commissioned specifically to support the capability of testing laboratories to detect controlled phytocannabinoids below the recommended maximum levels in a representative range of consumer CBD products.

Government response

The Government accepts this recommendation in principle, <u>subject to funding</u> being found.

Recommendation 4

• That development of more accurate testing for controlled phytocannabinoids is supported (as outlined in Notes 1 – 3 below) to allow testing capabilities to develop and be fully regulated.

<u>Note 1:</u>

Standardised protocols should be developed for the extraction, separation and quantification of controlled cannabinoids (and their precursor acids) from consumer CBD products.

These must be of sufficient reproducibility and sensitivity to be appropriate for the measurement of the level of controlled phytocannabinoids as recommended in this report.



www.cannabistrades.org 41 Wincolmlee, Hull, Yorkshire, UK, HU2 8AG
The Hemp Trades Association (trading as the Cannabis Trades Association UK) is a not for profit company limited by

guarantee without share capital in England and Wales No. 10472540 incorporated in November 2016.

Note 2:

As chemical reference standards are not currently commercially available for all controlled phytocannabinoids, suppliers of chemical reference materials should be encouraged to produce certified standards for those controlled cannabinoids for which standards are not currently available.

Note 3:

ACMD supports the recommendation from the DSTL report (Defence Science and Technology Laboratory report, 2020b) that the analytical methods used should be accredited to ISO 17025:2017 to ensure appropriate method validation, quality control and independent assessment of the methods.

Government response

The Government accepts this recommendation in principle and will work with partners in industry to seek to meet these <u>ambitions</u>.

Recommendation to reform the Exempt Product Definition in relation to CBD products

- The ACMD recommends changing the first limb of exempt product definition to refer to the 'preparation or other product containing the controlled drug' rather than the 'controlled drug' except for 'research' purposes as defined in Schedule two of the Psychoactive Substances Act 2016.
- An example of such a wording could be: (a) the preparation or product containing the controlled drug is not intended for administration to a human being or animal other than for the purpose of approved scientific research, as defined in Schedule 2 of the Psychoactive Substances Act 2016.

Government response

The Government agrees in principle to amend the definition of the EPD and will consider the most effective ways in which to do so, recognising that ACMD may provide further advice on the exempt product definition in the context of its consideration of barriers to research with controlled drugs.



www.cannabistrades.org 41 Wincolmlee, Hull, Yorkshire, UK, HU2 8AG
The Hemp Trades Association (trading as the Cannabis Trades Association UK) is a not for profit company limited by guarantee without share capital in England and Wales No. 10472540 incorporated in November 2016.

To Conclude:

The Cannabis Trades Association (CTA) views the Ministers Response to the ACMD Report to be a positive step for consumer CBD products. We look forward to working with the FSA and Retailers in permitting the legal supply of Consumer CBD Foodstuffs within the UK and further afield.

Yours truly,

Mat Graham Woody

Mrs Marika Graham-Woods Executive Director Cannabis Trades Association and Hemp Trades Association

Legal Notes:

Psychoactive Substances Act 2016

https://www.legislation.gov.uk/ukpga/2016/2/crossheading/psychoactive-substances/enacted

2 Meaning of "psychoactive substance" etc

(1)In this Act "psychoactive substance" means any substance which—

(a)is capable of producing a psychoactive effect in a person who consumes it, and

(b) is not an exempted substance (see section 3).

(2)For the purposes of this Act a substance produces a psychoactive effect in a person if, by stimulating or depressing the person's central nervous system, it affects the person's mental functioning or emotional state; and references to a substance's psychoactive effects are to be read accordingly.

(3)For the purposes of this Act a person consumes a substance if the person causes or allows the substance, or fumes given off by the substance, to enter the person's body in any way.

3 Exempted substances

(1)In this Act "exempted substance" means a substance listed in Schedule 1.

(2) The Secretary of State may by regulations amend Schedule 1 in order to-

(a)add or vary any description of substance;

(b)remove any description of substance added under paragraph (a).

(3)Before making any regulations under this section the Secretary of State must consult—

(a) the Advisory Council on the Misuse of Drugs, and

(b) such other persons as the Secretary of State considers appropriate.



🕐 www.cannabistrades.org 👘 🖅 info@cannabistrades.org

41 Wincolmlee, Hull, Yorkshire, UK, HU2 8AG

(4)The power to make regulations under this section is exercisable by statutory instrument.(5)A statutory instrument containing regulations under this section may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.

Misuse of Drugs Regulations 2001

https://www.legislation.gov.uk/uksi/2001/3998/regulation/2/made

The Misuse of Drugs Regulations 2001

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

"the Act" means the Misuse of Drugs Act 1971;

"authorised as a member of a group" means authorised by virtue of being a member of a class as respects which the Secretary of State has granted an authority under and for the purposes of regulation 8(3), 9(3) or 10(3) which is in force, and "his group authority", in relation to a person who is a member of such a class, means the authority so granted to that class;

"document" has the same meaning as in Part I of the Civil Evidence Act $1968(\underline{1})$

"exempt product" means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where—

(a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal;

(b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and

(c) no one component part of the product or preparation contains more than one milligram of the

controlled drug or one microgram in the case of lysergide or any other *N*-alkyl derivative of lysergamide; "health prescription" means a prescription issued by a doctor or a dentist under the National Health Service Act 1977(<u>2</u>), the National Health Service (Scotland) Act 1978(<u>3</u>), the Health and Personal Social Services (Northern Ireland) Order 1972(<u>4</u>) or the National Health Service (Isle of Man) Acts 1948 to 1979 (Acts of Tynwald) or upon a form issued by a local authority for use in connection with the health service of that authority;

"installation manager" and "offshore installation" have the same meanings as in the Mineral Workings (Offshore Installations) Act 1971(<u>5</u>);

"master" and "seamen" have the same meanings as in the Merchant Shipping Act 1995(6);

"medicinal product" has the same meaning as in the Medicines Act 1968(7);

"officer of customs and excise" means an officer within the meaning of the Customs and Excise Management Act 1979(**8**);

"prescription" means a prescription issued by a doctor for the medical treatment of a single individual, by a dentist for the dental treatment of a single individual or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment;

"register" means a bound book and does not include any form of loose leaf register or card index;

"registered pharmacy" has the same meaning as in the Medicines Act 1968;

"retail dealer" means a person lawfully conducting a retail pharmacy business or a pharmacist engaged in supplying drugs to the public at a health centre within the meaning of the Medicines Act 1968;

"sister or acting sister" includes any male nurse occupying a similar position;

🕐 www.cannabistrades.org 👘 🖅 info@cannabistrades.org

41 Wincolmlee, Hull, Yorkshire, UK, HU2 8AG



"wholesale dealer" means a person who carries on the business of selling drugs to persons who buy to sell again.

(2) In these Regulations any reference to a regulation or schedule shall be construed as a reference to a regulation contained in these Regulations or, as the case may be, to a schedule to these Regulations, and any reference in a regulation or schedule to a paragraph shall be construed as a reference to a paragraph of that regulation or schedule.

(3) Nothing in these Regulations shall be construed as derogating from any power or immunity of the Crown, its servants or agents.



www.cannabistrades.org 41 Wincolmlee, Hull, Yorkshire, UK, HU2 8AG