Technical Alert

Codex / International update on Titanium dioxide

TGA Consultation: Proposed amendments to the Poisons Standard - Cannabis and tetrahydrocannabinols for veterinary use

Codex / International update on Titanium dioxide

The Codex Committee on Food Additives (CCFA) has confirmed the inclusion of Titanium Dioxide in the JECFA list of substances for evaluation, giving it the highest priority.

This decision received the full support of Australia (Department of Water, Agriculture and Environment), Canada, Colombia, EU, Peru, UK and USA who submitted written comments in favour of this review prior to the meeting. The EU notably clarified that the *'food additive will be banned in the EU and the EU will soon inform its trading partners on the measures to be taken"*. The EU ban is expected to be announced this month with a likely entry into force from January 2022.

Australia highlighted the significant potential for trade disruption due to EU action but recognised that in the absence of recent risk assessment by FAO/WHO bodies, there is uncertainty regarding the safety of the additive.

With regards to timing, JECFA clarified that its first action would be to establish criteria for the data which is necessary for the re-evaluation of the additive (most likely in 2022), issue a call for data in 2023, leading to an assessment in 2024. To the question raised by Australia whether this assessment could be accelerated given the potential global trade disruption, JECFA responded that they will do their very best to reduce this timeline.

TGA Consultation: Proposed amendments to the Poisons Standard - Cannabis and tetrahydrocannabinols for veterinary use

The TGA are consulting on Proposed amendments to the Poisons Standard – ACCS, ACMS and joint ACCS/ACMS meetings, November 2021, including a proposal to amend the existing Schedule 8 entries for cannabis and tetrahydrocannabinols to include veterinary use of these substances (except in animals for human consumption). The consultation closes on **7 October 2021**.The TGA website and consultation hub provide more information.

The reasons for the proposal include:

- Veterinarians currently only have access to S4 medicinal cannabis medicines via compounded formulations, "off-label" use in individual animals, or special consent to import an unregistered veterinary product. Vets have no access to cannabis or cannabis-related medicines under the existing S3, S8 and S9 entries for these substances. The applicant is seeking changes that would allow use of cannabis under the S8 entry for therapeutic use in animals.

- There has been a recent increase in animal research and real-world evidence. Rewording the S8 schedule of medicinal cannabis to include “therapeutic use in animals” will increase access and provide treatment option to veterinarians that are not presently available. This will benefit both humans and other animals.
- The same or similar therapeutic benefits experienced by humans are applicable for other animals, including those for products containing tetrahydrocannabinol (THC). Some of the possible indications for cannabinoid therapy in animals include pain relief, treatment of inflammation, treatment of cancers, treatment of anxiety and stress, treatment of epilepsy, appetite stimulant and as antioxidants and neuroprotectants.
- The endocannabinoid system (ECS) has been identified in nearly all animals (including humans), from complex mammals like primates to phylogenetically primitive animals such as the cnidarians. The near universal presence and early emergence of the ECS, evolutionarily, is a strong indicator of its biological importance. Cannabinoid receptors are expressed in most animals, including vertebrates (mammals, birds, reptiles, and fish) and invertebrates.
- The current wording impacts animal welfare in two ways. Firstly, animals do not have legal access to these new therapeutic tools that can provide improved outcomes and enhanced care for particular indications. Secondly, as public awareness of the benefits of medicinal cannabis grows, owners of animals are using illicit products without veterinary support, advice and control; potentially endangering the welfare of their animals.
- Accessing cannabis products through veterinarians offers benefits to veterinary healthcare professionals, their clients and their patients. In many countries such as Chile, Uruguay, Peru, Columbia and Mexico, veterinarians are allowed to prescribe cannabis to animals, and others like Canada and Brazil are currently considering applications to legislate the prescription of cannabis to animals.
- Due to the prolonged elimination time for many cannabinoids and the illicit nature of these substances in some settings, it is proposed to exclude “animals intended for human consumption” from the Schedule 8 entry; this treatment would be captured by the Schedule 9 entry.

Cannabis and tetrahydrocannabinols are currently in Schedule 8 and Schedule 9 of the Poisons Standard. The proposed scheduling seeks an amendment to the Schedule 8 entries only for cannabis or tetrahydrocannabinol:

Proposed scheduling

The applicant is not seeking amendment to the Schedule 9 entries for cannabis or tetrahydrocannabinols.

Schedule 8 – Amend Entry

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human or animal therapeutic use, when:

a) cultivated or produced, or in products manufactured[1], in accordance with the *Narcotic Drugs Act 1967*; and/or

b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or

c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

d) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or

ii) separately specified in the NABIXIMOLS entry in this Schedule; or

iii) captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or

iv) it is intended to be used on animals bred for human consumption.

TETRAHYDROCANNABINOLS when extracted from cannabis for human or animal therapeutic use, when:

a) included in products manufactured in accordance with the Narcotic Drugs Act 1967; and/or

b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or

c) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989,

except when:

i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or

ii) separately specified in the NABIXIMOLS entry in this Schedule; or

iii) captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or

iv) intended to be used on animals bred for human consumption.

Appendix D – Amend Entry

1. Poisons available only from or on the prescription or order of an authorised medical practitioner:

   ~~CANNABIS for human use.~~

   ~~TETRAHYDROCANNABINOLS for human use.~~

5. Poisons for which possession without authority is illegal (e.g. possession other than in accordance with a legal prescription).

   CANNABIS for human use.

   TETRAHYDROCANNABINOLS for human use.

Feedback to the TGA

Submissions to the consultation can be made to the TGA via the Department of Health Consultation Hub by the **7 October 2021**.

Resources

- TGA web page: Consultation: Proposed amendments to the Poisons Standard – ACCS, ACMS and joint ACCS/ACMS meetings, November 2021
- Department of Health Consultation Hub: Public consultation on proposed amendments to the Poisons Standard - ACMS, ACCS and Joint ACMS-ACCS, November 2021