To the Secretary,

Re: Poisons Standards - ACMS and Joint ACMS/ACCS meetings, June 2020. 2.2 Cannabidiol, Schedule 8 - Amend entry, Schedule 4- Amend Entry.

My name is Angus Murray, I am an Australian Cannabis professional and Horticulturist. I have just returned to Australia from Vancouver, Canada where I worked in the Cannabis industry in production facilities and biotech research.

I have read the proposed changes to CBD and would like to contribute to schedule 8 and 4. I support the amendment to the Poisons Standard on CBD. In safety of low dose cannabidiol (TGA, 2020) I feel the risks and safety of cannabidiol are addressed thoughtfully. However based on my professional experience schedule 8 and 4 pose difficult challenges to industry.

Schedule 8, d. iv) - Comments

iv) it is a whole plant cannabis product or distillate or isolate which contains at least 98 per cent cannabidiol and less than or equal to 0.2 per cent tetrahydrocannabinol (THC).

Based on my industry experience, the proposed 0.2% threshold for THC is unrealistically low. My suggestion before deciding on this schedule is to conduct a thorough literature review of testing lab certificates of analysis on CBD cultivars internationally. What ratios are currently being achieved in other markets by experienced Cannabis producers? I suggest a look at more realistic ratios of CBD:THC in more developed markets based on testing data.

THC and CBD share the same means of production via the Cannabigerolic acid (CBGA) synthase pathway (Sirikantaramas, et al., 2004). Rare low THC mutations are present but not ubiquitous. Other research notes THCAS and CBDAS mechanisms that underlie the genetic expression of the ratio in *Cannabis Sativa* remain unresolved (Laverty, et al., 2019).

Therefore, influencing *Cannabis Sativa* to produce minimal THC with high CBD is problematic. To summarise, a forced reduction of THC to 0.2% can also decrease potential CBD concentrations as potency of THC and CBD is intertwined.

I acknowledge and understand the desire to minimise THC. However, the cost to the consumer and producer outweigh the risk. Realistically, there is low risk to individuals if THC thresholds are increased under this amendment. A 1% total THC for plant material and 5% total THC for extracts is more sensible when preparations are delivered with CBD in low quantities.

Achieving trace/zero THC - Not impossible, but what's required?

- Long term plant breeding programs, substantial commitment to breeding work and substantial investment, Australia is 10+ years behind in genetic enhancement of Cannabis
- More expensive remediation practices Involving extract Isolation with laboratory solvents, smaller scale and expensive processes
- New research and development procedures genetic modification (GMO) and cultured Cannabinoids from yeast
- Synthetic Cannabinoid production effects of which are currently unknown
- Novel chemistry solutions and additives to pass or mask THC in testing

For reasons listed, the cost to producers and production process will involve artificially creating these ratios rather than using ratios that naturally occur in a given plant chemotype. It will make CBD expensive and less accessible to consumers. It will also create an industry less capable of exporting internationally due to cost of production.

THC's Psychoactivity when in CBD preparations. Should we be concerned if we have higher CBD:THC ratios?

Research exists around CBD's ability to Blunt $\Delta 9$ -THC-Induced Cognitive Impairment (Aso, et al, 2019). There is also research that CBD is shown to antagonise the effects of THC. Effectively giving CBD anxiolytic effects (Zuardi, 1982). That is to say, a 1% THC threshold for dry plant material and 5% THC threshold for extracts in CBD preparations will be well tolerated and even nullified by the overwhelming CBD content.

New & Existing Hemp licenses to cultivate CBD rich hemp

A great option to cultivate CBD cannabis would be to allow Hemp farmers to diversify their farming strategy into CBD cultivars. Australia in 2019 cultivated ~2500 hectares of licenced Cannabis space under hemp licences for food and fibre. The framework these farmers operate under would require little to no adaptation of government and producers provided the maximum **1% THC** legislation for hemp is retained. Hemp fields are superior candidates for broadacre CBD production and many adapted hemp varieties in Australia currently exist with total THC lower than 1%. Additionally, as we have seen in the United States the 0.3% THC threshold legislated in the farm bill (2018) is destroying many farmers' ambitions of contributing to the industry (Drotleff L, 2019).

At a time in Australia's history when economic productivity and ingenuity is required, utilizing and allowing this pre existing Australian hemp framework to pivot smoothly is optimal and principled thinking.

Schedule 4, a. - Comments

 a. cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation and any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation; or

Non psychoactive minor Cannabinoids

The potential of minor plant cannabinoids may well have therapeutic uses that overshadow the therapeutic potential of THC (Izzo, et al., 2009). It is my assertion that higher percentages of non psychoactive minor cannabinoids be addressed in these proposed amendments. The applications for diversity of medicine, research & development, product offerings and uses should be encouraged. An increase to **10%** for cannabinoids other than THC or CBD would be welcomed.

Schedule 4, b. - Comments

b. any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation. cannabidiol is a synthetic or semi-synthetic copy of the molecule and comprises 98 per cent or more of the total cannabinoid content of the preparation and any other synthetic or semi-synthetic cannabinoids, other than cannabidiol, must comprise 2 per per cent or less of the total cannabinoid content of the preparation.

I ask the TGA to reconcile statements made in the document: **Safety of low dose cannabidiol** On **Page 12** under **Other matters for consideration.**

The Author of this paragraph states of **Optical Isomers (Enantiomers)**

"Therefore, the use of synthetic CBD may have psychoactive potential that would not be found in plant-derived cannabidiol. This should be considered in any decision to down-schedule CBD." - (TGA, 2020)

Based on this information above and the author's later conclusions in the safety of low dose cannabidiol document I feel it is fair to request removal of synthetic cannabinoids from these proposed changes. For if the TGA is prepared to legalise synthetic CBD compounds noting concerns for psychoactivity this shows inconsistent messaging relating to THC and its prohibition.

Thanks for your time,

Angus Murray.

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