ECS Botanics Pty Ltd submission - Proposed Amendments to the Poisons Standard

Document information	
Purpose	The purpose of this document is to provide a summary of a review of the proposed changes to the TGA Poisons Standard regarding cannabis plant material and low dose cannabidiol.
Scope	This scope of this report focuses on • practicality of the proposed amendments from a business perspective • reduction of non-value-added activities (e.g. extra processing steps related to cannabis waste) • intersection and potential impact of other associated regulations from other government departments.

[redacted]

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1. Purpose

The purpose of this document is to provide a summary of a review of the proposed changes by the TGA to cannabis plant material and low dose cannabidiol:

Proposal	Major Changes	Reference
Proposed amendments referred for scheduling advice to ACMS **#2.2**	Down-scheduling of low-THC cannabis plant material to S4. Clarification of CBD.	https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-and-joint-acmsaccs-meetings-june-2020
Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS **#2.5**	Creation of a new category in the schedules for low dose CBD.	https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-joint-acmsaccs-meetings-june-2020#fn5

2. Scope

ECS Botanics Holding Limited and its subsidiary company, ECS Botanics Pty Ltd, is a diversified cannabis company with a background in industrial hemp seed farming, processing and sales. In 2019, the company was granted medicinal cannabis manufacturing and cultivation licences from the Office of Drug Control (ODC). The company has a commercial interest in being a large-scale cultivator and extractor of CBD-rich flower (and other extracts) for further processing.

The company has identified several challenges when determining the most practical cost-efficient and compliant way to operate, given the complications associated with the 'high' scheduling of medicinal cannabis materials regardless of their cannabinoid extraction capabilities.

Thus, the review undertaken has centred on:

- practicality of the proposed amendments from a business perspective
- reduction of non-value-added activities (e.g. extra processing steps related to cannabis waste)
  intersection and potential impact of other associated regulations from other government departments.

3. Comparison of the Proposed Changes and Commentary

3.1. Key

Key	Description
Orange italics	Changes pertaining to **#2.2**
Green italics	Changes pertaining to **#2.5**
Black text	Original
Blue text	Comments and discussion

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3.2. Table of Changes

The table below outlines the current vs the proposed situation:

Current	Proposed changes and comments
Schedule 9 CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), except: a) when separately specified in these Schedules; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre; or c) when in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, when labelled with either of the following warning statements: i)Not for internal use; or ii) Not to be taken.	**a) Clarification on waste cannabis material scheduling:** No changes are currently proposed, however clarification for waste cannabis material is required. Waste cannabis materials (stalks, stems, fan leaves, etc.) are considered medically uninteresting and unusable in extraction due to their low-to-no cannabinoid content (see *Table 1* in this paper) Waste cannabis materials are also not "prepared or packed for human therapeutic use" therefore are technically unable to be included in the S8 definition: "# CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use," This means that waste cannabis material should fall into the **S9** category. **b) Single Convention on Narcotic Drugs requirements:** The **UN Single Convention on Narcotic Drugs** only specifies interest in cannabis flowering heads (see **Article 1: Definitions** and **Article 28 Control of cannabis**): *(b)* "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated. *Article 28. Control of cannabis* 1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy. 2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

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Current	Proposed changes and comments
	As **Article 28, item 2** points out, industrial products (i.e. stalk, stem, etc. used for fibre) are excluded from the **UN Single Convention**, thus there appears to be no reason to control or track this type of waste, other than to verify that there is a method in place to grind up and compost waste (i.e. confirm the company renders waste materials as unusable for cuttings and further propagation), as is the case in the industrial hemp industry. **c) Office of Drug Control (ODC) requirements:** The ODC has specified that waste must be securely stored, which appears to be influenced by the TGA **Poisons Standard**. The ODC themselves don't specify waste in their **record keeping and reporting guidance**.* *Assuming here that: • "Crop" is only what is considered valuable (i.e. the cannabinoid-containing flower as specified in the **UN Single Convention**) • "Total" is the bulk harvest (and then dried) material • "Component" is trimmed bud (either rough trims for bulk packing or fine trims for finished product). Most have chosen to interpret cannabis waste material as S8 instead of S9 given that it has been generated under a **Narcotic Drugs Licence**, however the clarification and exclusion is sorely needed from a practical and operational perspective. **d) Additional clarification required for other cannabis extracts:** Other non-psychoactive and non-medicinal extracts of cannabis (either terpenes, flavonoids, or other minor cannabinoids) also technically fall under S9 as there is no provision for them in any other schedule. Arguably terpenes and flavonoids should not be scheduled at all even if they are extracted from cannabis as they can be found (and extracted) from other herbs and botanicals. Practically, other minor non-psychoactive cannabinoids could also be encapsulated under the S4 category (e.g. CBG, CBC, CBN, etc.). Given what little is known about their medical potential, a blanket statement of "other minor cannabinoids" could initially be acceptable until more is known about the compounds (and whether or not they require down-scheduling). A useful infographic is presented here. **e) Suggested modifications to the cannabis S9 entry:** "d) when it is in the form of waste cannabis plant material (i.e. stem, stalk and fan leaves) that contain negligible cannabinoid content." "e) when extracts are in the form of pure terpenes or flavonoid extracts that have been generated in the manufacturing process."

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Current	Proposed changes and comments
Schedule 8 # CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when: a) cultivated or produced, or in products manufactured [2], 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, e) 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	No major additional changes requested other than to potentially replace *"prepared or packed"* with "*produced or processed*" as those are the terms more commonly used (as in the **WHO guidance for Good Agricultural and Collection Practices** – "produced" is used throughout with specific mention made to "processing" in section **4.1 Post-harvest processing**). # CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when: a) cultivated or produced, or in products manufactured [2], 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 imported as therapeutic goods, c) 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, e) 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* (#2.5) *and* 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).* (#2.2)
Schedule 4 CANNABIDIOL in preparations for therapeutic use where:	No additional changes required to this entry. May like to consider creating a new entry in S4 to cover other minor non-psychoactive cannabinoids: "Other minor non-psychoactive cannabinoids that can be extracted from cannabis plant material (e.g. CBG, CBC, CBN, etc.), in preparations for therapeutic use."

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Current	Proposed changes and comments
a) cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and 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 in preparations for therapeutic use where: *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* *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 cent or less of the total cannabinoid content of the preparation.* *except when cannabidiol comprises 98 per cent or more of the total cannabinoid content and the tetrahydrocannabinol (THC) content is less than or equal to 0.2 per cent of the total cannabinoid content of the preparation.* (#2.2) c) *except when included in Schedule 3* (#2.5)
S3 – no entry for cannabis before	No additional changes required. *CANNABIDIOL in preparations for therapeutic use when:* *a. the cannabidiol is either plant derived, or when synthetic only contains the (-) CBD enantiomer; and* *b. the maximum recommended daily dose is 60 mg or less of cannabidiol; and* *c. in packs containing not more than 30 days' supply; and* *d. cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and* *e. 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; and* *f. for adults aged 18 years and over.* (#2.5)

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4. Discussion of Impact

4.1. Storage requirements - S8 to S4

Before, all cannabis material was classed as S8 Poisons and subject to Good Wholesaling storage requirements. This classification was made regardless of the actual THC content and was overkill when dealing with low-THC strains:

Specific Requirements for CD

10.4 CD, including CD waste, should be stored in a vault or safe and in accordance with applicable State or Territory legislation.

10.5 In the case of wholesalers with high or moderate risk, the vault or safe should be fitted with an alarm, seismic detectors and should be video monitored. In the case of wholesalers with high risk, the locking mechanism for the vault or safe should require two persons to gain access and be time-delayed.

10.6 The safe or vault should be located in a secure area of the building, out of public view, and kept locked except when in immediate use.

10.7 Access to the safe or vault should be limited to authorised staff, controlled and monitored via appropriate measures to be determined by the Security Risk Management Plan.

10.8 A Controlled Drugs register should be maintained at each site in accordance with State and Territory legislation. These records should be subject to regular audits and verification by a responsible supervisor or manager.

10.9 As waste containing CD has the same illicit value as saleable goods, waste, including expired products or manufacturing rejects, should be stored and handled under similar security to raw materials and commercial stock.

10.10 CD must be destroyed in accordance with State/Territory requirements.

10.11 Waste containing CD should be disposed of as soon as reasonably possible. Regular small runs to disposal facilities are likely to reduce the risk of diversion from storage.

10.12 Discarded raw material packaging that contained CD should be de-identified.

ODC security guidelines also recommend:

- a safe, vault or strong room depending on the volume of cannabis to be stored
- additional access controls into such spaces should also be considered.

Generally, the security requirements for S8 is also much higher (and more costly) than for S4 materials. This is influenced by the need for:

- a vault or a safe that can store large quantities of S8 drugs - impractical when trying to generate large quantities of biomass (not finished product) for extraction
- a minimum of two layers of security which can result in two layers of climb-proof fencing for outdoor grows
- higher grades of security monitoring, detection systems, access control and alarms.

By down-scheduling low-THC plant material to S4, this alleviates a lot of the start-up and compliance costs involved for new businesses and is much more commensurate with the lower level of risk.

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This reclassification also aligns better with ODC security recommendations for low-THC crops, even if those recommendations are still too strict when compared to industrial hemp:

Requirements	High THC	Low THC
Intruder resistant cannabis site	Two layer perimeters such as building walls or climb-proof fencing	Sturdy high fencing, greenhouses, or other method which demonstrates the crop is intruder resistant
Physical security systems	Alarms, monitoring and CCTV	Back to base alarm system
Destruction and disposal processes	Monitored incineration or other tracked destruction	Local incineration or mulching

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4.2. Down-scheduling low Doses of CBD

A lot of the benefits have already been well summarised in the two TGA proposals, however there are some inconsistencies between the two. The table below seeks to highlight those differences as well as propose a middle ground:

Item	Proposal #2.2	Proposal #2.5	Middle ground
1	**Drug to drug interactions** Concerns about potential drug-CBD interactions can be handled effectively through limiting the amount of CBD able to be sold in a month's supply and the inclusion of appropriate warning labels.	**Drug to drug interactions** There is a high potential for drug-drug interactions when used concomitantly with many other commonly prescribed drugs that are metabolised via CYP pathways. Currently there is insufficient evidence as to whether these would not occur with the use of low dose CBD. **Side effects** Whilst there are some minor signals of adverse effects such as mild drowsiness and fatigue, this could be managed as for similar S3 medicines, such as requiring a label that indicates should not use if driving or operating machinery as for other medicines that can cause potential drowsiness. **Product information** Schedule 3 requires that both Product Information and Consumer Medicine Information is available. These documents could include information about drug-drug interactions. In addition, a S3 medicine requires interaction with a pharmacist that would further reduce any unintended drug-drug interactions. **Age restriction** The proposed Schedule 3 entry has been restricted to adults aged 18 and over as there is little evidence to establish the safe use of low dose CBD in children.	Information leaflets to be provided on/with CBD-containing products to include warnings on: • concomitant use with other drugs that are metabolised through the CYP pathway • side effects of mild drowsiness and fatigue • not to drive or operate heavy machinery while taking the product. • product recommended for those 18 years and above. Pharmacists can also be trained: • on the maximum permitted quantity of CBD to be sold in a month's supply • to check the customer's ID prior to authorising purchase.

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Item	Proposal #2.2	Proposal #2.5	Middle ground
2	**Rescheduling recommendation is unscheduled, or listed, or registered – depending on level of therapeutic claim.** The benefit/risk ratio is such that cannabidiol (CBD) formulations in which 98% or greater of the cannabinoid content is CBD and where the upper limit to THC content is 0.2% (by dry weight), should not be regulated as an unapproved medicine through its inclusion on Schedule 4 of the SUSMP, but instead, regulated as listed, assessed-listed or registered medicines (depending on the level of therapeutic claim) under the Australian Register of Therapeutic Goods (ARTG). Given its clear evidence of benefits, good safety profile and low risk, it should be regulated as a complementary medicine in the same way that other plant medicines (herbal medicines) are regulated in Australia.	**Rescheduling recommendation is S3 - Registered complementary medicines** It is proposed that down-scheduling to Schedule 3 is more appropriate than Schedule 2, as pharmacist advice is necessary to mitigate safety risks associated with CBD's high potential for drug-drug interactions when used concomitantly with many other commonly prescribed drugs that are metabolised via CYP pathways. The consumer can identify the ailments or symptoms that may be treated by the medicine but counselling and verification by a pharmacist is required before use to identify potential drug-drug interactions. Schedule 3 requires that both Product Information and Consumer Medicine Information is available to reinforce and/or expand on the safe use of CBD. Schedule 3 provides an appropriate level of health professional advice while increasing accessibility of CBD.	Both proposals agree on the complementary medicine category, however, regardless of what #2.2 suggests, it is not currently possible for CBD to be included in any lower schedule (listed medicines) due to its exclusion from the **Therapeutic Goods (Permissible Ingredients) Determination 2020** (as indicated by #2.5). It is also not possible for cannabidiol to be used in cosmetics manufacture; even after rescheduling to S3 or S2, it will still fall into a cosmetics-excluded category as defined by the **Therapeutic Goods (Excluded Goods Determination 2018)** (where cosmetics are not allowed to have S2, 3, 4 and 8 poisons as ingredients). However, given the conflict between the two proposals, the TGA could meet halfway for now and down-schedule low dose CBD to Schedule 2 Registered complementary medicines. GMP manufacture and quality standards still apply, as well as pharmacovigilance activities. Risks posed by concomitant medicine interactions can be mitigated as described in item 1.

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Item	Proposal #2.2	Proposal #2.5	Middle ground
3	**Benefit** Regulation of CBD as a complementary medicine will allow its prescription by other qualified healthcare practitioners such as western herbal medicine practitioners and registered Chinese herbal medicine practitioners, consistent with their scope of practice, and further increase access to patients. This amendment would allow the same level of access to CBD products as is enjoyed in many western countries including the US and countries within Europe where hemp-derived CBD products may be purchased over the counter or online.	**Benefit** In Australia, CBD is currently a Schedule 4 substance and therefore only available with a prescription. The access controls on CBD in Australia are notably more restrictive than comparable regulators. CBD is available as an over the counter product (for products without medicinal claims) in the UK and some US states.	Two proposals generally in agreement that down-scheduling will increase access by patients. It will also: • increase the available product range • create wider business opportunities • allow for more affordable compliance strategies for both TGA and ODC requirements • reduce the costs for customers • speed up the time for product-to-market.

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4.3. Request for the De-scheduling of Cannabis Waste

De-scheduling cannabis waste would specifically apply to only parts of the plant with low cannabinoid content, i.e. stem, stalk, fan leaves, etc.

As it currently stands, in many states S8 waste disposal often requires supervised destruction by an authorised person or medical healthcare professional which makes farming operations unnecessarily complicated. This additional intervention also contradicts with common practices in industrial hemp where cannabis flower is often generated as a by-product but does not require tracked or controlled disposal.

S8 and S4 classification can still be in place (and controlled destruction requirements) for parts of the plant that require the control (i.e. cannabinoid-rich flowering heads).

4.4. Request for the Exclusion of Terpenes and Flavonoids

The cannabis plant is full of many other valuable compounds that have no psychoactive or proven medicinal usage, which can be extracted and sold on to other markets.

If terpenes and flavonoids were specifically excluded from the "cannabis extracts" that require control this would greatly increase other product options for businesses who are able to extract.

4.5. Request for the Inclusion of "Other Minor Cannabinoids" in S4

While the Australian market is still relatively young, other markets internationally are significantly more advanced, and there is increasing demand for other minor cannabinoids.

Allowing the extraction of these other minor cannabinoids would again increase the product options for businesses, with the option for export to other markets.

It will also increase the ease of accessibility to these other compounds for research purposes.

4.6. Other Considerations

Proposal #2.2 recommended CBD to be rescheduled as: *"listed, assessed-listed or registered medicines (depending on the level of therapeutic claim) under the Australian Register of Therapeutic Goods (ARTG)."*

Thus, it would be worthwhile considering other categories and product forms for CBD – with its possible inclusion in:

- the Poisons Standard, e.g. in S5 or S6 and
- the Therapeutic Goods (Permissible Ingredients) Determination 2020.

If these new categories are created, CBD may be used in a much wider product range e.g. industrial uses, such as the incorporation of CBD into textiles for anti-microbial and anti-bacterial applications, and as cleaning agents. The delineation between CBD as an agricultural/industrial grade product vs a medicinal product could be controlled by the application of Good Agriculture and Collection Practices for the medicinal product as an additional (and auditable) standard.

While ideally these changes would all happen at once, this is understandably out of scope for this current Poisons rescheduling and will require more investigation (and collaboration between different government departments) prior to implementation.

As an aside, it is the hope that once cannabis waste is de-scheduled, that any waste plant material generated in medicinal cannabis production may be sold on to industrial hemp processors (for fibre) to minimise the amount of unnecessary waste and fully utilise the available raw materials.

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Later down the line, once the industry becomes more mature, (and industrial vs medicinal categories of CBD are better defined) it would be practical to revamp the controls in place for cannabis cultivation to a similar framework as seen in the Tasmanian Poppy industry. It would be beneficial for the cannabis industry at large if Industrial Hemp farmers were able to sell large scale biomass (i.e. low-THC flowering tops) to ODC-licenced manufacturers, as not only would it pave the way for the Australian CBD market to become globally competitive, but it would also increase consumer and patient affordability.

5. References

Title	Reference
Cannabis sativa: The Plant of the Thousand and One Molecules	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4740396/
Endocannabinoids and MRSA: Mechoulam Releases New Research	https://globalcannabinoidrc.com/f/endocannabinoids-and-mrsa-mechoulam-releases-new-research
Good Wholesaling Practice for Medicines in Schedules 2,3,4 and 8.	https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8
ODC Record keeping guidelines	https://www.odc.gov.au/publications/guideline-record-keeping-and-reporting
ODC Security Guidelines	https://www.odc.gov.au/node/136
Poisons Standard	https://www.tga.gov.au/publication/poisons-standard-susmp
Security requirements for different types of medicinal cannabis	https://www.odc.gov.au/news-media/news/security-requirements-different-types-medicinal-cannabis
The Potential of minor cannabinoids	https://www.visualcapitalist.com/the-potential-of-minor-cannabinoids/
Therapeutic Goods (Excluded Goods Determination 2018)	https://www.legislation.gov.au/Details/F2018L01350
Therapeutic Goods (Permissible Ingredients) Determination 2020	https://www.legislation.gov.au/Details/F2020L00150
UN Single Convention on Narcotic Drugs	https://www.unodc.org/documents/commissions/CND/Int_Drug_Control_Conventions/Ebook/The_International_Drug_Control_Conventions_E.pdf
WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants	https://apps.who.int/iris/bitstream/handle/10665/42783/9241546271.pdf;jsessionid=6657703AD4F4FD471D858351970ADFA9?sequence=1

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