

Supplementary questions: University of Wollongong

1. Your submission raises some concerns in relation to proposed flavour restrictions (pages 4-5), including that there are already flavour concentrates on the market that could render these restrictions irrelevant and introduce a new 'pathway of harm'. Have you raised these concerns with the Therapeutic Goods Administration and what was its response?

These concerns have not been directly raised with the Therapeutic Goods Administration (TGA) as our most recent formal submission to the TGA was in January 2023, well before the announcement of the ban on disposable devices. Flavour concentrates are unlikely to be used with closed-system devices (disposables and pods) and are instead most likely to be utilised by individuals using refillable (open-style) devices. The presence of these flavour concentrates has only become relevant to the conversation around vaping since the ban on disposables and the recent announcements regarding the limitations to tobacco and mint flavours. These flavour concentrates have been available on the Australian market for a number of years from both Australian and overseas retailers (for example: <https://www.flavourworld.com.au/> and <https://getsuckered.com/>). We have not received a response back from the TGA following our latest formal submission in January 2023 (our full submission can be found at [ANON-BVEN-CDKZ-Q - response.pdf](#)).

We have included the sections of our January 2023 submission to the TGA which pertain to a discussion of flavours below:

Section 3. Strengthening the product standard regarding minimum quality and safety standards for NVPs

Flavours

Whilst the number of different flavour names appear to be constantly increasing, chemical analysis has not seen a significant change in the number or type of different flavouring molecules appearing in these products, with the exception of the recent increase in the use of cooling agents. Cooling agents (particularly WS-23) are highly prevalent in disposable e-cigarettes, likely as a mechanism for covering the burning sensation from the high concentration nicotine salts present in these products. WS-23 is present in virtually all disposable vaping devices we have analysed recently, usually at high concentrations, including in flavours without 'ice' / 'iced' or a similar indicator in the name. Limiting flavours to tobacco only or similar has been proposed in several jurisdictions. The issue with limiting to tobacco only flavours is this: What would constitute a tobacco flavour? All tobacco-flavoured e-liquids we have analysed in our laboratory contain not only a range of flavouring molecules to compose the tobacco flavour but also the same sweet flavours as the dessert and fruit-based e-liquids. Would it only have to have tobacco in the name, or would there be specific flavouring molecules required? How many flavouring molecules would it be allowed to contain? Which ones? Once again, only the legally obtained NVPs would be affected by this change. A useful limitation on flavouring would be ensuring that all names relate to an actual flavour rather than abstract names. Recent examples of these abstract names include: 'Fury' 'Assault' and 'Blitz'. If possible, this should be applied across all vaping products not just NVPs.

Q1. Do you support restricting or prohibiting the inclusion of flavours in NVPs? If so, which flavours would you like to see restricted? Should all flavours be prohibited or should tobacco flavour still be permitted?

We would like to see flavour names be limited to those which relate directly to an actual flavour (tobacco, desserts, fruits etc...) with the removal of abstract names such as 'Fury'. Limiting flavours to 'Tobacco' only does not indicate what flavour molecules are actually permitted as current tobacco flavoured vapes are not significantly different in content from other flavours such as dessert. We do not support the banning of all flavours. We would support, however, the inclusion of the currently banned flavours in non-nicotine containing products. Despite several ingredients being currently prohibited due to known toxicities in NVPs under TGO110, this only applies to nicotine-containing products. Until both nicotine-containing and nicotine-free products are regulated together, these prohibited substances are currently permitted in nicotine-free products which is a cause for potential increased health concerns for users of these products.

Q2. Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients? Why?

Pulegone, a mint flavouring which is found in some e-liquids is a known carcinogen. We recommend it is added to the list of banned flavours in NVPs in Australia. [*Jabba SV and Jordt S. JAMA Intern Med. 2019; 179(12): 1721–1723. doi:10.1001/jamainternmed.2019.3649]*