Australian Government
Department of Health
Therapeutic Goods Administration

Notice of interim decisions to amend (or not amend) the current Poisons Standard
Joint ACMS-ACCS #28

12 October 2021

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

1. Notice of interim decisions made under Regulation 42ZCZN of the *Therapeutic Goods Regulations 1990*

This web publication constitutes a notice for the purposes of regulation 42ZCZP of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulation 42ZCZP, this notice sets out:

- the interim decisions made by a delegate of the Secretary under regulation 42ZCZN in relation to proposed amendments to the current Poisons Standard which were referred to an expert advisory committee under subdivision 3D.2 of the Regulations in June 2021;
- the proposed date of effect of the proposed amendments (in circumstances where the interim decision proposes an amendment to the current Poisons Standard).

In accordance with regulation 42ZCZP, interested persons (including the applicant requesting the amendment) are invited to make submissions to the Secretary in relation to these interim decisions on or before **11 November 2021**.

We have changed the way to make submissions.

Submissions should now be provided through our consultation hub. Submissions will be considered by the Delegate in making the final decision.

Please note that in accordance with subregulation 42ZCZQ(4) of the Regulations, the Secretary must publish all relevant submissions received, unless the Secretary considers the information to be confidential information.

2. Interim decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28, June 2021)

2.1 Interim decision in relation to ethanol and isopropanol in hand sanitisers

Proposal

The applicant(s) proposed to create new Schedule 6 entries for ethanol and isopropanol when present in hand sanitiser preparations at concentrations greater than 50%, with exceptions when meeting certain requirements for packaging, labelling, formulation and physical properties.

Neither substance is currently captured by any Schedule entry, although ethanol is listed in Appendix B (substances considered not to require control by scheduling) under the alternative name ethyl alcohol.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision not to amend the scheduling for ethanol and isopropanol in hand sanitisers in the current Poisons Standard.

Materials considered

In making this interim decision, the Delegate considered the following material:

- The applications to amend the current Poisons Standard with respect to ethanol and isopropanol;
- The six public submissions, all including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of ACMS-ACCS advice to the delegate

The Committee did not make a recommendation regarding the scheduling of ethanol and isopropanol in hand sanitisers. They advised that there were insufficient data provided to support changes to the current scheduling of either substance.

The Committee acknowledged that the increased use of high concentration, alcohol-based hand sanitisers (up to 90% concentration) in domestic settings has increased public health risks for accidental and deliberate ingestion. The Committee also acknowledged the increase in calls to Australian Poisons Information Centres (PICs) but noted there has been no information provided on the amounts ingested, the patient condition, the severity of the intoxication and the clinical outcomes – other than to indicate that some had presented to the hospital or general practitioner (GP). Members noted that no information was provided on whether the proposed scheduling changes would have prevented these incidents.

The Committee noted public submissions opposing the scheduling amendment for hand sanitisers and their long history of safe use. The Committee noted submissions calling for more time to monitor the impact of a number of regulatory changes and market stabilisation before assessing the need for scheduling intervention.

The Committee also considered public submissions that raised concerns regarding the proposed viscosity levels, mandatory inclusion of bittering agents, and questioning the practicality of including the label warnings to some products due to small packaging size and the lack of clarity around the proposed packaging requirements.

Reasons for the interim decision (including findings on material questions of fact)

I have made an interim decision not to amend the current Poisons Standard in relation to ethanol (ethyl alcohol) and isopropanol. The detailed reasons for my decision follow.

I find that the relevant provisions of Section 52E of the *Therapeutic Goods Act 1989* are: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

Concordant with the Scheduling Policy Framework (SPF 2018), I considered that ethanol and isopropanol do not meet the scheduling factors for inclusion in Schedule 6 (based on the toxicity of the substances).

- Ethyl alcohol (ethanol) has a low oral, dermal and inhalation toxicity. It is a moderate eye irritant and is neither a skin sensitiser nor skin irritant, although there is evidence of chronic irritation following repeat exposure in humans. The substance does not present a moderate hazard from repeated use in hand sanitisers.
- Isopropanol is a severe eye irritant in animal studies and is a skin irritant in humas following repeated exposure. However, the substance does not present a moderate hazard from repeated use in hand sanitisers.

On balance, ethyl alcohol and isopropanol do not fit the Schedule 6 scheduling factors when used in hand sanitisers. Furthermore, ethanol is currently exempt from scheduling via inclusion in Appendix B. As such, I am of the view that inclusion in Schedule 6 is not appropriate.

In considering the applications, I note that several problems associated with inadequate labelling, packaging and product presentation were recently addressed by amendments to the

Excluded Goods Order (EGD)[1] in April and May 2020. These updates allowed for the use of denaturants, and specified that products should not be presented in a way that could be mistaken for food or drink. The Trade Practices (Consumer Information Standards) (Cosmetics) Regulations 1991[2] was also amended in November 2020 to include additional requirements for cosmetic hand sanitisers containing alcohol. Published as the Consumer Goods (Cosmetics) Information Standard 2020[3] (CIS), it came into effect in May 2021 and includes requirements for the disclosure of the alcohol content, the inclusion of warning statements, and the substantiation of any claims on the label.

I also note several points raised in the written pre-meeting public submissions, of which four out of five opposed the amendments. Respondents noted that hand sanitisers have a long history of safe use, and that the increase in poisonings was due to the extraordinary demand at the start of the COVID-19 pandemic. Businesses with no previous experience pivoted to produce hand sanitisers, leading to well-intentioned but inappropriately packaged products entering the market. These submissions proposed that more time should be given to monitor whether the amendments to the EGD and the CIS, together with market stabilisation, will address the identified public health risks without the need for scheduling intervention.

In reaching my decision, I have considered data from the PICs that document up to a 2.5-fold increase in poisoning incidents reported to them from January to July 2020, compared to the same period in 2019. The increase in calls correlates with the first six months of the pandemic when there was a particularly significant demand for hand sanitisers in the community. However, the data do not distinguish whether these calls were related to factors such as poor packaging, poor presentation, low viscosity or lack of bittering agents; and the applicants have not addressed whether any of the proposed amendments would have prevented these incidents. I concur with the Committee's concern that there is no evidence that differently worded warning statements, changes to packaging or reformulation of products would have prevented these incidents.

I consider that effective hand sanitiser use is one of the key public health measures promoted by Australian health authorities for personal and population health, and safety during the ongoing pandemic. In this context, I note that an increased regulatory impost on industry may reduce the availability, or increase the cost, of hand sanitisers and therefore lead to negative public health outcomes. The proposed scheduling changes would have an impact across all regulated and compliant hand sanitiser products. I am also concerned that labelling these products as 'POISON' with an Appendix F warning of 'May be fatal to children' could be counter-productive and deter use. Furthermore the proposed labelling could cause confusion in light of government messaging encouraging consumers to use hand sanitisers when soap and water are unavailable.

I am not satisfied that the applicants have provided sufficient evidence to support the need for scheduling intervention at this time. I consider that the issues raised by the applicants are covered under the existing regulatory framework, and that the problems of inappropriate containers and labelling seen at the beginning of the pandemic appear to be self-correcting. Sales data provided in the submissions indicate that sales volumes are stabilising. I am of the view that more time should be given to monitor whether these developments, and the amendments to the EGD and the CIS, will address the identified public health risks without the need for scheduling amendments.

[1] https://www.legislation.gov.au/Series/F2020L00340

[2] Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (legislation.gov.au)

[3] https://www.legislation.gov.au/Series/F2020L01469

2.2 Interim decision in relation to methanol in hand sanitisers

Proposal

The applicant proposed to create a new Schedule 10 entry for methanol when used in hand sanitiser preparations at concentrations greater than 2%. The substance is currently captured in Schedule 6 at concentrations greater than 10%, Schedule 5 at concentrations between 2% and 10%, and is unscheduled at concentrations below 2%.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to amend the scheduling for methanol and create a new definition for hand sanitisers in the current Poisons Standard as follows:

Schedule 10 – New Entry

METHANOL in hand sanitisers containing more than 5 per cent methanol.

Schedule 6 – Amend Entry

METHANOL (excluding its derivatives) **except:**

a) when included in Schedule 5; or

b) when included in Schedule 10; or

c) in preparations containing 2 per cent or less of methanol.

Schedule 5 – Amend Entry

METHANOL (excluding its derivatives) in preparations containing 10 per cent or less of methanol **except**

a) when included in Schedule 10, or

b) in preparations containing 2 per cent or less of methanol.

Appendix E, Part 2

POISON	First Aid Instructions
METHANOL	
• above 10 per cent	**A, G3**
• 10 per cent or less	**A**
A – For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). **G3 -** If swallowed, do NOT induce vomiting.	

Appendix F, Part 3

Poison	Warning Statements	Safety Directions
METHANOL **except** in methylated spirit		**1** (Avoid contact with eyes), **4** (Avoid contact with skin), **8** (Avoid breathing dust (or) vapour (or) spray mist)

Index – Amend Entry

METHANOL

Schedule 10
Schedule 6
Schedule 5
Appendix E, Part 2
Appendix F, Part 3

PART 1 (INTERPRETATION) – New Entry

"**Hand sanitiser preparation**" means an antimicrobial skin care product:

a) that consists of, contains or generates one or more antimicrobial active substances; and

b) that is represented in any way to be, or is likely to be taken to be (whether because of the way in which it is presented or for any other reason):

i) for use on hands when soap and water are not available; and

ii) applied to the hands without rinsing off; and

iii) intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any microbes on the skin.

Materials considered

In making this interim decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to methanol;
- The five public submissions, all including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of ACMS-ACCS advice to the delegate

The Committee advised that the scheduling for methanol be amended in the Poisons Standard as follows:

Schedule 10 – New Entry

METHANOL in hand sanitisers containing more than 5 per cent methanol.

Schedule 6 – Amend Entry

METHANOL (excluding its derivatives) **except:**

a) when included in Schedule 5; or

b) when included in Schedule 10; or

c) in preparations containing 2 per cent or less of methanol.

Schedule 5 – Amend Entry

METHANOL (excluding its derivatives) in preparations containing 10 per cent or less of methanol **except**

a) when included in Schedule 10, or

b) in preparations containing 2 per cent or less of methanol.

The Committee also advised that Part 1 (Interpretation) of the Poisons Standard be amended to include a definition of 'hand sanitiser' based on the definition of hand sanitiser in the Consumer Goods (Cosmetics) Information Standard 2020[4], as follows:

"**Hand sanitiser preparation**" means an antimicrobial skin care product:

a) that consists of, contains or generates one or more antimicrobial active substances; and

b) that is represented in any way to be, or is likely to be taken to be (whether because of the way in which it is presented or for any other reason):

i) for use on hands when soap and water are not available; and

ii) applied to the hands without rinsing off; and

iii) intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any microbes on the skin.

The Committee also recommended an implementation date of **1 February 2022**, due to public health concerns associated with this substance.

Members agreed that the relevant matters under Section 52E(1) of the *Therapeutic Goods Act 1989* included: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the advice included:

[4] Consumer Goods (Cosmetics) Information Standard 2020 https://www.legislation.gov.au/Series/F2020L01469

a) the risks and benefits of the use of a substance

Risks:

- Methanol can be absorbed by all exposure pathways and can cause irreversible damage to humans at low doses particularly to the central nervous system including the optic nerve.
- Methanol can arise as a denaturing agent for ethanol or as a by–product from distillation processes.
- It may also be misused in hand sanitisers to a limited extent if ethanol or isopropyl alcohol is difficult to obtain due to supply chain issues, such as was experienced in the early days of the coronavirus pandemic.

Benefits:

- Methanol is an effective denaturing agent that can be added to consumer products containing ethanol to prevent intentional ingestion.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Denaturant in ethanol.

c) the toxicity of a substance

- Methanol is a central nervous system depressant and can cause irreversible damage including blindness.
- Methanol is toxic to humans at levels below those found in animal studies. This degree of toxicity is already accounted for in the current scheduling for methanol.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Used as a denaturant in ethanol, which is the active ingredient used in hand sanitiser preparations.
- The dosage is within the current parameters included in Schedules 5 and 6. However, the labelling requirements may need adjustment to account for its use in products that are meant to be in contact with the skin.

e) the potential for abuse of a substance

- Intentional and unintentional misuse from ingestion.

f) any other matters that the Secretary considers necessary to protect public health

- Consideration could be given to the current Schedule 5 and Schedule 6 entries with regards methanol as a denaturant with ethanol.
- Noting that the Australian Health Protection Principle Committee have undertaken some work around generic hand sanitiser use, a public guidance or education campaign regarding hand sanitiser use highlighting use in infants could be undertaken.

Reasons for the interim decision (including findings on material questions of fact)

I have made an interim decision to create a new Schedule 10 entry for methanol in hand sanitiser preparations containing more than 5 % methanol and include a new definition for hand sanitiser preparations in Part 1 of the Poisons Standard. The detailed reasons for my decision follow.

I agree with the Committee's findings that the relevant provisions of section 52E of the *Therapeutic Goods Act 1989* are: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

Having considered the scheduling factors for Schedules 5, 6 and 10, along with the available toxicological data, I consider that methanol does not broadly meet the Scheduling Factors for Schedule 10. Nevertheless, I acknowledge that the increased use of alcohol-based hand sanitisers (up to 90 % concentration) in domestic and community settings due to the COVID-19 pandemic has increased public health risks for accidental and deliberate ingestion, especially in young children.

Methanol is a central nervous system depressant and is toxic to humans in small quantities. The current entries in Schedule 5 (between 2 and 10 percent concentration) and Schedule 6 (greater than 10 percent concentration) are based on animal toxicological studies which indicate that methanol poses a low risk from all exposure routes. However, humans and non-human primates are more susceptible to toxic effects of methanol than other animals, due to their limited ability to oxidise formic acid, a metabolite of methanol. Given the irreversible toxic effects of methanol to humans even at low doses, I consider that methanol in hand sanitisers presents an unacceptable public health risk warranting a Schedule 10 entry for certain concentrations.

In reaching my decision to include methanol in hand sanitisers in Schedule 10, I have taken into account data from the Victorian and Queensland Poisons Information Centres (PICs) demonstrating the up to 250% increase in calls for advice about hand sanitisers during the first half of 2020 compared to the same period in 2019. While this increase in calls to the PICs correlates with the spike in demand for hand sanitisers by the public due to the onset of the COVID-19 pandemic, I am concerned that the data shows that the majority of calls involved accidental poisoning in children under 5 years of age and deliberate misuse in adolescents (15 to 19 years of age). While no information was provided on the amounts of hand sanitiser ingested, patient condition, the severity of the intoxication and the clinical outcomes, the data indicate that the increased availability and use of alcohol-based sanitisers in the community due to the pandemic has led to an increased risk of accidental poisoning.

I have considered the international reports of toxicity cited by the applicants, however these reports have not been material to my decision. The reports of toxicity in the United States (US), the European Union (EU) and Mexico, were the result of adulteration and deliberate falsification. In the United States, deaths were reported as being due to ingestion of hand sanitisers containing methanol at up to 81 % (V/V).[5] In the EU, multiple hand sanitisers were recalled for high (up to 48%) methanol.[6] Issues regarding unacceptably high levels of methanol have not been detected in Australia from imported products and there is no evidence that currently registered hand sanitisers that use pharmacopoeial or food grade ingredients (as required under the OTC monograph, or the Therapeutic Goods (Excluded Goods – Hand Sanitisers) Determination 2020 *(EGD)*)[7] present the same risk.

I have considered the five public submissions, of which three were in opposition, one partially in support and one fully supportive of the proposal. In particular, I note that two of the submissions opposed to the proposed 2% limit on methanol, considered that this limit to be too restrictive, given that the use of the substance as a denaturant in ethanol may cause some

[5] https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem

[6] https://mccaa.org.mt/media/5782/safety-gate-notifications-hand-disinfectants.pdf

[7] https://www.legislation.gov.au/Series/F2020L00340

currently marketed hand sanitiser products to exceed the 2% limit. I acknowledge that the 5% limit proposed in one of the submissions is achievable for manufacturers, while also addressing the health issues associated with this substance.

In deciding on a concentration cut-off to Schedule 10, I have taken into consideration the advice from the Committee and public submissions from industry that had raised concerns that a cut-off of greater than 2% is excessive given that TGA-approved hand sanitisers, containing nominal amounts of methanol as a denaturant, have been marketed for several years without any reported incidents[8] related to the methanol content. Moreover, the adverse events associated with unacceptably high levels of methanol, as seen in international jurisdictions, have not been detected in Australia with imported hand sanitisers. I have also noted that the Australian Taxation Office Excise (Denatured Spirits) Determination 2016 (N0.3)[9] mandates that when denaturing 100 % ethanol with methanol, the minimum concentration of methanol must be 5% volume/volume (V/V). The applicant's proposed scheduling amendment would prohibit ethanol denatured with methanol from being used in ethanol-based hand sanitiser products despite the lack of clear evidence of harms.

I agree with the Committee's advice that a cut-off 5% is preferrable to a 2% cut-off , as a methanol concentration of greater than 5 % is not required for hand sanitiser use and would not adversely impact currently supplied compliant products. On this basis, I have decided that a concentration cut-off to Schedule 10, of greater than 5 % methanol is appropriate to address identified public health risks from unintentional or intentional ingestion, while not impacting compliant hand sanitiser products currently marketed in Australia.

I concur with the Committee that a definition for 'hand sanitiser' in Part 1, Interpretation, of the Poisons Standard is also required for clarity to prevent other legitimate products being unintentionally captured by the new Schedule 10 entry. I have decided to adopt the hand sanitiser definition from the Consumer Goods (Cosmetics) Information Standard 2020.[10].This will provide consistency and certainty for manufacturers and sponsors of both therapeutic and cosmetic hand sanitisers.

Proposed implementation date

1 February 2022

2.3 Interim decision in relation to eugenol

Proposal

A Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposed to amend the Schedule 6 entry for eugenol to reduce concentration cut-offs for cosmetic preparations intended for skin contact.

Erratum

The original proposal contained errors regarding the European Union regulation of eugenol, where limits were incorrectly indicated as prohibitive. References to these limits were corrected prior to consideration by the Committee, and the proposed scheduling was amended to align with the EU requirements as follows:

[8] https://www.tga.gov.au/database-adverse-event-notifications-daen

[9] https://www.legislation.gov.au/Details/F2016L01523

[10] https://www.legislation.gov.au/Series/F2020L01469

The updated proposal considered by the Committee sought to require eugenol to be disclosed on the label of unscheduled products intended for skin contact. Leave on preparations with concentrations of greater than 0.001% eugenol, and rinse off preparations with concentrations of greater than 0.01% eugenol, would be captured in Schedule 6 unless the substance is listed on the label.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision not to amend the scheduling for eugenol in the current Poisons Standard.

Materials considered

In making this interim decision, the Delegate considered the following material:

- A human health tier II assessment for eugenol, published by AICIS (30 June 2020);
- The 11 public submissions, all including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #28);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of ACMS-ACCS advice to the delegate

The Committee advised that the current scheduling for eugenol remains appropriate.

Members agreed that the relevant matters under Section 52E(1) of the *Therapeutic Goods Act 1989* included: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the advice included:

a) the risks and benefits of the use of a substance

– Potential risk for skin sensitisation and eye irritation.

b) the purposes for which a substance is to be used and the extent of use of a substance

– Widely used in cosmetic and household products as a fragrance compound, including as a component of essential oils.

c) the toxicity of a substance

- Critical adverse health effects are eye irritation and skin sensitisation. Overall acute toxicity is consistent with a primary entry in Schedule 6.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Inclusion of the presence of eugenol on labels of cosmetic products is recommended as a risk mitigation strategy in relation to skin sensitisation.

- Inclusion of cut-off concentrations equivalent to the maximum concentrations allowed by the IFRA Standard for eugenol could minimise the risk of eye irritation.

e) the potential for abuse of a substance

Nil

f) any other matter that the Secretary considers necessary to protect public health

- No signals indicate an increasing or changing risk profile for eugenol. Therefore, alignment with international standards and regulatory controls over cosmetics is recommended.

Reasons for the interim decision (including findings on material questions of fact)

I have made an interim decision not to amend the current Poisons Standard in relation to eugenol. The detailed reasons for my decision follow.

I agree with the Committee's findings that the relevant provisions of section 52E of the *Therapeutic Goods Act 1989* are: (a) risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

I note that eugenol is an aromatic oil extracted from cloves, and is added to a variety of cosmetic, personal care and domestic products for its fragrance properties. Eugenol can also be produced synthetically. It has a wide range of uses in Australia, including in aftershaves, hair care products and bath products. However, the substance is also a well-known skin sensitiser, to the extent that it is used in fragrance mixes used for patch testing against common allergens. It is considered one of the most frequently reported allergens in consumer products. The current proposal seeks to reduce the elicitation of contact dermatitis by introducing a requirement for eugenol to be listed on the label of preparations intended for skin contact.

The critical health effects of eugenol were considered in a recent human health tier II assessment (AICIS, 2020). The report analysed data from a range of animal models and human reports, and concluded that the substance presents risk to the public due to eye irritation and skin sensitisation. Despite this potential, there is ample evidence that eugenol is included in products that are exposed to human skin during normal use. As such, I acknowledge that the proposed labelling requirements may help mitigate the potential for contact dermatitis in sensitised individuals.

In making my decision, I note that nine out of ten public submissions were opposed to the scheduling change, though this opposition may relate to errors in the initial proposal that have since been corrected. Respondents clarified the interpretation and intent of the EU labelling requirements – and suggested that the International Fragrance Association (IRFA) standards may provide more appropriate cut-offs. They also identified a wide range of products that contain eugenol and advised caution in capturing them as Schedule 6 poisons; as any changes to scheduling or labelling may impact the domestic and international sale of a wide range of

products. I consider that these concerns are pertinent and am of the view that the intended outcomes of the proposed scheduling changes have not been sufficiently established.

While there may be some benefit to rescheduling, I note that the scope of the initial consultation was limited. The original proposal focussed on eugenol in clove oil, with the intent of only amending the scheduling of cosmetic products. However, the proposed changes could capture a wide range of unintended domestic products such as detergents. Eugenol is also present as a major component of several essential oils that were not discussed in the proposal, including nutmeg, cinnamon, basil and bay leaf oil. It is a minor component of many other essential oils. New labelling requirements could affect the sale and supply of products containing these oils. As such, the scope, and public health outcomes for different classes of products, requires clarification and careful consideration before a decision can be made. Given the wide range of affected oils and products that were not captured in the initial consultation and the lack of information available to support these changes across all potentially impacted product types, I am in agreement with the Committee that a scheduling amendment is not appropriate at this time.

As such, I have made an interim decision not to amend the scheduling of eugenol at this time. While there may be some benefits to adding new labelling requirements, these require clarification and I agree with the Committee's advice that further consultation with affected stakeholders is necessary before further progressing such a proposal.