Australian Government
Department of Health
Therapeutic Goods Administration

Notice of interim decisions to amend (or not amend) the current Poisons Standard

12 October 2021

TGA Health Safety Regulation

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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 decision in relation to eugenol

During the pre-meeting public consultation, stakeholders advised that certain medical uses of eugenol may be impacted by the proposed amendments. As such, the substance was referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session. An update on the interim decision for eugenol was included in the Joint ACMS-ACCS #28 public notice of interim decisions.

3. Interim decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #31, June 2021)

3.1 Interim decision in relation to 2-amino-5-methylphenol

Proposal

A Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposed to create a new Schedule 10 entry for 2-amino-5-methyl phenol to prohibit its sale, supply and use. The substance is currently not specifically scheduled in the Poisons Standard.

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 2-amino-5-methylphenol in the current Poisons Standard as follows:

Schedule 10 – New Entry

2-AMINO-5-METHYLPHENOL in preparations for cosmetic use.

Schedule 7 – New Entry

2-AMINO-5-METHYLPHENOL **except** when included in Schedule 10.

Index – New Entry

2-AMINO-5-METHYLPHENOL

Schedule 10
Schedule 7

Materials considered

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

- A human health tier II assessment for 2-amino-5-methylphenol, published by AICIS (26 October 2018);
- The two public submissions, both 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 Chemicals Scheduling (ACCS #31);
- 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; and (c) the toxicity of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and

- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of ACCS advice to the delegate

The Committee advised that new entries for 2-amino-5-methylphenol be created in Schedule 10 and Schedule 7 of the Poisons Standard as follows:

Schedule 10 – New Entry

2-AMINO-5-METHYLPHENOL in preparations for cosmetic use.

Schedule 7 – New Entry

2-AMINO-5-METHYLPHENOL **except** when included in Schedule 10.

Index – New Entry

2-AMINO-5-METHYLPHENOL

Schedule 10
Schedule 7

The Committee also recommended an implementation date of **1 February 2022**.

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 purpose for which a substance is to be used and the extent of use of a substance; and (c) the toxicity of a substance.

The reasons for the advice included:

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

- Clear evidence of interaction with DNA and its exposure at 1.5% to the public that uses permanent hair dyes.
- Non-cosmetic uses meet the scheduling factors for Schedule 7.
- May be used as a raw material or in laboratory consumables.

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

- Substance is considered to be in use as a component in permanent hair dye solutions.
- May be in use in hair dyes in Australia.
- Industry bodies that responded to the public consultation indicated that their members do not use the substance.
- The substance is highly likely to be supplied to and used in research laboratories, noting the fairly simple chemical structure.

c) *the toxicity of a substance*

- The substance is acutely toxic by the oral route.
- The substance has the potential for interactions with DNA.
- The substance is a moderate skin sensitiser

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

- Nil

e) *the potential for abuse of a substance*

- Nil

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

- Nil

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

I have made an interim decision to create new Schedule 10 and Schedule 7 entries for 2-amino-5-methylphenol, as recommended by the Committee. The proposed Schedule 10 entry would capture cosmetic use of the substance, while all other uses would fall under Schedule 7. The detailed reasons for my decision follow.

2-amino-5-methylphenol is an ingredient in hair dye products. There are currently no restrictions on the use of this substance in Australia.

I note the comparison of this substance with the structurally similar 2-amino-5-ethylphenol. 2-amino-5-ethylphenol is listed in Schedule 6 of the Poisons Standard and is of considerably lower toxicity than 2-amino-5-methylphenol. The European Union Scientific Committee on Consumer Safety (EU SCCS) opinion on 2-amino-5-ethylphenol states that it does not pose a risk to the health of the consumer at a maximum on-head concentration of 1.0%, apart from its sensitisation potential which is the primary basis for the Schedule 6 entry.

I acknowledge that 2-amino-5-methylphenol's acute oral toxicity data (1225 – 1375 mg/kg bw in rats) aligns with the scheduling factors for Schedule 6, and it is regarded as a moderate skin sensitiser based on results from a local lymph node assay. However, I note that the data on eye and skin irritation properties of the substance are limited, and there is a distinct lack of data on acute or repeated dermal and inhalation toxicity.

I agree with the Committee that the primary concern related to the toxicity of this substance is its potential for genotoxicity. I have noted the EU SCCS opinion on the substance, which indicates that it has potential for interaction with DNA and concluded that the substance was not safe for consumers when used in oxidative hair dye formulations with a concentration of 1.5%. This conclusion is supported by a number of *in vitro* assay results, including:

- Bacterial reverse mutation assay in *Salmonella typhimurium*;
- Thymidine kinase gene mutation test in mouse lymphoma cells with metabolic activation, indicating a clastogenic effect;
- Micronucleus test in human lymphocytes without metabolic activation, indicating genotoxicity; and
- Alkaline comet assay with Chinese hamster lung cells.

The irreversible systemic toxicity associated with the substance, especially when considering that safer alternatives are readily available for substitution, would align 2-amino-5-methylphenol with the Schedule 10 factors. The public health risk substantially outweighs the benefits, to the extent that restricting public access to this level is warranted. This serious public health risk is restricted to cosmetic use.

In addition, I have noted that a metabolite of the substance, namely N-acetyl-2-amino-5-methylphenol, was declared genotoxic by the EU SCCS based on the results of an *in vitro* micronucleus assay.

I have considered the public submissions regarding the scheduling application. In particular, I note the written submission which opposed the proposed comprehensive Schedule 10 entry on the grounds of the reduced exposure pathways associated with non-cosmetic uses of the substance, such as laboratory and industrial use. I agree with the Committee's advice that the relatively simple chemical structure of the substance lends it to use as a synthetic building block for laboratory reagents, and that a Schedule 10 entry without exemptions may be unnecessarily restrictive.

Noting the substantial barriers to state and territories in authorising the use of Schedule 10 substances, I have decided to restrict the new Schedule 10 entry for the substance to preparations for cosmetic use only at this time. By creating a Schedule 7 entry to capture all other uses of the substance, suitable safeguards can be implemented for a substance with such associated toxicity, while not unduly preventing access for use in applications with a lower level of exposure. A Schedule 7 entry enables access only to authorised users, who have been adequately trained and informed of the potential harm the substance may cause at low levels of exposure.

Given the potential harms associated with the substance, I see no reason to delay implementation of the new entries into the Poisons Standard.

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 purpose for which a substance is to be used and the extent of use of a substance; and (c) the toxicity of a substance.

Proposed implementation date

1 February 2022

3.2 Interim decision in relation to 6-methoxy-N2-methyl-2,3-pyridinediamine

Proposal

A Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposed to create a new Schedule 7 entry for 6-methoxy-N2-methyl-2,3-pyridinediamine, with exceptions for low concentrations in cosmetic products with compliant labelling. The substance is currently unscheduled.

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 6-methoxy-N2-methyl-2,3-pyridinediamine in the current Poisons Standard as follows:

Schedule 6 – New Entry

6-METHOXY-N2-METHYL-2,3-PYRIDINEDIAMINE **except** when used in oxidative or non-oxidative hair dyes at a concentration of 1.0% or less when the immediate container and primary pack are labelled:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients that may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5mm in height.

Index – New Entry

6-METHOXY-N2-METHYL-2,3-PYRIDINEDIAMINE

Schedule 6

Materials considered

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

- A human health tier II assessment for 6-methoxy-N2-methyl-2,3-pyridinediamine, published by AICIS (8 March 2019);
- The European Chemicals Agency (ECHA) substance infocard for 6-methoxy-N2-methylpyridine-2,3-diamine dihydrochloride;
- The two public submissions, both 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 Chemicals Scheduling (ACCS #31);
- 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 ACCS advice to the delegate

The Committee advised that a new entry for 6-methoxy-N2-methyl-2,3-pyridinediamine be created in Schedule 6 of the Poisons Standard as follows:

Schedule 6 – New Entry

6-METHOXY-N2-METHYL-2,3-PYRIDINEDIAMINE **except** when used in oxidative or non-oxidative hair dyes at a concentration of 1.0% or less when the immediate container and primary pack are labelled:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients that may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5mm in height.

Index – New Entry

6-METHOXY-N2-METHYL-2,3-PYRIDINEDIAMINE

Schedule 6

The Committee also recommended an implementation date of **1 June 2022**.

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; 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*

- The substance is used in hair dye products, however, there has been one reported case of skin sensitisation as a result of using a hair dye product containing the substance.
- It is acutely toxic orally and is a moderate skin sensitiser.

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

- The substance has been reported as an ingredient in hair dyes, but the extent of its use in this regard is not clear. There appear to be no other materials or products available in Australia containing the substance outside hair dye products.

c) *the toxicity of a substance*

- The substance is acutely toxic by the oral route, and is a moderate skin sensitiser.

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

- Use of the substance is restricted in hair dyes in both the EU and the Association of South East Asian Nations (ASEAN) as follows:
  - § After mixing under oxidative conditions, the maximum concentration applied must not exceed 1.0% as the dihydrochloride salt;
  - § Maximum concentration in finished non-oxidative products is 1.0% as the dihydrochloride salt.
- The 1.0% concentration restriction is acceptable and aligns with cosmetic regulations in the EU.
- Because it is used in hair dyes, products containing the substance will often already contain some labelled warnings of the potential hazards of the product.

e) *the potential for abuse of a substance*

- Nil

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

- The substance is currently unscheduled, so it was recommended that an extended transition period is given for manufacturers to implement the changes.

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

I have made an interim decision to create a new Schedule 6 entry for 6-methoxy-N2-methyl-2,3-pyridinediamine, as recommended by the Committee. The proposed entry incudes exceptions for hair dyes with low concentrations of the substance, if labelled with appropriate warning statements to prevent skin sensitisation. The detailed reasons for my decision follow.

I have considered the initial proposal to create a new Schedule 7 entry for 6-methoxy-N2-methyl-2,3-pyridinediamine. The substance is currently unscheduled with no limitations on use or with labelling. The substance is reported to be used in hair dyes in Australia, however exposure is considered hazardous by a number of pathways. In particular, I note that the European Chemicals Agency[1] deems the substance to be harmful if swallowed and has the potential to cause serious eye damage and allergic skin reactions.

I have noted a documented case of a severe adverse reaction to the substance. A 65 year old Australian woman required hospitalisation for severe oedema and exudation stemming from contact dermatitis, following repeated and prolonged exposure to the substance as an ingredient of oxidative hair dyes. This report is indicative of the potential hazards presented by exposure to the substance in typical use.

I agree with the Committee's advice that the toxicity data associated with the substance may align better with the Schedule 6 scheduling factors, rather than the proposed Schedule 7 scheduling factors. The toxicity data included in the human health tier II assessment and considered in the decision include:

- The substance is moderately acutely toxic by the oral route (LD50 of 650-813 mg/kg bw in rats);
- A moderate skin sensitiser, based on a local lymph node assay on mice;
- Considered to be a slight skin irritant, based on slight erythema in one test subject on the acute dermal irritation study in rabbits;
- Not considered irritating to the eyes at 5% dilution;
- Not considered to be genotoxic or to cause specific developmental toxicity.

I also agree with the Committee that the new Schedule 6 entry should include the 1.0% cut-off as is considered safe by several international standards, including those of the Association of Southeast Asian Nations and the EU Cosmetic Regulations.

I have considered the wording for labelling of products containing the substance, including the possibility of alignment with labelling requirements in the EU. While the proposal suggested the phrase, "contains ingredients which may cause skin sensitisation to certain individuals", the EU labelling regulations for the substance include "can cause allergic reaction". I have noted the Committee's recommendation that the warning labels maintain consistency with labelling requirements for substances which can cause serious eye damage. I have decided to model the wording for warning labels from similar substances that have previously been considered and included in the Poisons Standard.

I have considered the two written submissions which were received regarding this substance, noting that both submissions were largely supportive of scheduling. I have considered the concerns raised in one of the submissions regarding the proposed labelling requirements, which

[1] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.073.272

encouraged alignment with the EU regulations, however for the reasons given above I have decided not to take this approach.

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 have considered the public submissions calling for a longer transition period to allow for any re-formulation and labelling changes and agree with the committee advice that an implementation date of 1 June 2022 is appropriate.

Proposed implementation date

1 June 2022

3.3 Interim decision in relation to lead acetates

Proposal

A Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposed to create a new Schedule 10 entry for lead acetates in preparations for use as hair cosmetics. The proposed entry would prohibit the sale, supply and use of preparations that are currently captured by the Schedule 5 entry for lead compounds.

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 lead compounds in the current Poisons Standard as follows:

Schedule 10

LEAD COMPOUNDS in paints, tinters, inks or ink additives **except** in preparations containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive.

Schedule 6 – Amend Entry

LEAD COMPOUNDS **except**:

g) when included in Schedule 4 ~~or 5~~;

h) in paints, tinters, inks or ink additives;

i) in preparations for cosmetic use containing 100 mg/kg or less of lead;

j) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

k) in ceramic glazes when labelled with the warning statement:

CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.

written in letters not less than 1.5 mm in height.

Schedule 5 – Delete Entry

~~LEAD COMPOUNDS in preparations for use as hair cosmetics.~~

Appendix E, Part 2

POISON	STANDARD STATEMENTS
LEAD COMPOUNDS	
• in hair cosmetics	A
• in other preparations	A, S1
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). **S1** – If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.	

Appendix F, Part 3

POISON	WARNING STATEMENTS	SAFETY DIRECTION
Glazing preparations containing LEAD COMPOUNDS.	**50** - Unless adequately fired, utensils glazed with this preparation must not be used as containers for food or beverages; to do so may cause lead poisoning.	
LEAD COMPOUNDS		
a) in hair cosmetics.	**25** - Do not use on broken skin. Wash hands thoroughly after use.	
b) when in Schedule 6.		**1** - Avoid contact with eyes. **4** - Avoid contact with skin. **8** - Avoid breathing dust (or) vapour (or) spray mist.

Index – Amend Entry

LEAD COMPOUNDS
cross reference: GLAZING PREPARATIONS, PRINTING INKS or INK ADDITIVES, SELENIUM

Schedule 10
Schedule 6
~~Schedule 5~~
Appendix E, Part 2
Appendix F, Part 3
Appendix F, Part 3 (glazing preparations)

Materials considered

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

- A human health tier III assessment for lead acetates, published by AICIS (28 June 2020);
- The three public submissions, two 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 Chemicals Scheduling (ACCS #31);
- 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 ACCS advice to the delegate

The Committee did not recommend a Schedule 10 entry for lead acetates in hair cosmetics and advised that the scheduling of lead compounds in hair cosmetics be amended in the Poisons Standard as follows:

Schedule 6 – Amend Entry

LEAD COMPOUNDS **except**:

a) when included in Schedule 4 ~~or 5~~;

b) in paints, tinters, inks or ink additives;

c) in preparations for cosmetic use containing 100 mg/kg or less of lead;

d) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

e) in ceramic glazes when labelled with the warning statement:

CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.

written in letters not less than 1.5 mm in height.

Schedule 5 – Delete Entry

~~LEAD COMPOUNDS in preparations for use as hair cosmetics.~~

Index – Amend Entry

LEAD COMPOUNDS
cross reference: GLAZING PREPARATIONS, PRINTING INKS or INK ADDITIVES, SELENIUM

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

The Committee also recommended an implementation date of **1 June 2022**.

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; 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*

- Risk of accidental ingestion/absorption through use of hair products.

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

- Used in hair dyes.

c) *the toxicity of a substance*

- Lead is a cumulative toxicant.
- Can cause irreversible neurotoxicity.

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

- Lead acetate concentration of 0.5% in the product available on the Australian market.

e) *the potential for abuse of a substance*

- Nil

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

- The intent of the Committee is to reduce general lead exposure in the community.
- The suggested June implementation date may help industry transition into supplying lead-free hair dye products.

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

I have made an interim decision to delete the Schedule 5 entry for lead compounds in hair cosmetics. As a result, the amended scheduling would capture hair cosmetics that contain lead acetates under the Schedule 6 entry for lead compounds, with a cut-off concentration of 100 parts per million (equivalent to 100 mg/kg). 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 lead is a cumulative toxicant that affects multiple body systems and can cause neurotoxicity. Even at relatively low levels of exposure, the substance can seriously and irreversibly affect a child's brain development, leading to a variety of behavioural and learning disorders. As such, there are significant national and international efforts to limit lead exposure, particularly in children and pregnant women. The current proposal relates to lead acetates that are used in progressive hair dye products at a concentration of 0.6% (extrapolated from FDA concentration cut-offs[2]). Under current scheduling, these would be captured in Schedule 5 of the Poisons Standard. However, given the potential for neurotoxicity in children, I am of the view that further controls are warranted.

The public health risk of lead acetate hair dye products depends on the use patterns and exposure pathways, particularly to children and pregnant women. I note that the proposal specifically focusses on 'progressive' hair dye formulations. These formulations refer to the application of the hair products on several instances, often daily for several weeks, and are used predominantly by men to gradually darken greying hair. They are also clear in colour and are not washed out of hair after application. Progressive hair dyes therefore differ from traditional products, which tend to be conspicuously coloured and are rinsed out of hair after a set amount of time. I note that a recent human health tier III assessment modelled these differing patterns of hair dye use – reporting that incidental ingestion could increase blood lead levels by up to 28 µg/dL in users and 10 µg/dL in children living in the same household[3]. This would result in blood lead levels known to cause brain and organ damage (10 µg/dL), and that far exceed levels considered 'at risk' (5 µg/dL)[4]. The potential for such high levels of lead exposure is of significant concern.

Nonetheless, in considering new restrictions on lead acetate hair dyes, I note that the Committee advised caution in interpreting modelling data presented in the tier III risk assessment. Members noted that there were minimal pathways for lead exposure in adults, including pregnant women; even when exposed to highly contaminated environments, blood lead levels are only likely to increase by about 3 µg/dL[5]. Moreover, adults do not tend to leave hair dye products on exposed surfaces that could lead to oral exposure by children. As such, I acknowledge that there is some uncertainty regarding the potential for toxic lead exposure from progressive hair dyes, though I am of the view that it is necessary to phase lead out of products used by the general public wherever possible.

I note that the initial proposal sought to remove lead-containing hair dyes from the market by creating a Schedule 10 entry for lead acetates. While I agree with the intent to limit lead exposure, I consider that the risk/benefit profile of lead acetates, when used in low concentrations in progressive hair dye products, is not consistent with inclusion in Schedule 10. I agree with the Committee's assessment of lead acetates against the Schedule 10 scheduling factors:

- The substance does not pose such a high public health risk that prohibition is warranted.
- The public health risks do not substantially outweigh the benefits to the extent that no other schedule is appropriate.

[2] https://www.regulations.gov/document/FDA-2017-C-1951-0223
[3] https://www.industrialchemicals.gov.au/sites/default/files/Lead%20acetates_%20Human%20health%20tier%20III%20assessment.pdf
[4] https://www.nhmrc.gov.au/sites/default/files/documents/reports/statement-lead-human-health-eh58.pdf
[5] https://doi.org/10.1136/jech.40.1.18

On balance, I consider that creating a new Schedule 10 entry for lead acetates is not appropriate. However, it is also clear that the current scheduling is insufficient, i.e. the current labelling requirements for hair cosmetics containing lead acetates may not adequately warn consumers of the dangers of exposure. The need for tighter restrictions is supported by the Committee's view that lead acetates meet the Schedule 6 scheduling factors:

- The substance has a moderate toxicity which may cause severe injury if taken internally.
- The substance presents a moderate hazard from repeated use in hair dyes, and a moderate risk of producing irreversible (neuro-) toxicity.
- Harm to users can be reduced to some extent through strong label warnings.
- The substance has a moderate potential for causing harm, especially to children or pregnant women.

Based on these findings, I have assessed that it is appropriate to capture hair dye products containing lead acetates in Schedule 6 of the Poisons Standard. In considering a cut-off concentration, I note that lead is limited to 100 parts per million (ppm) in other cosmetics such as lipsticks, and also in art supplies. Given that hair dyes have similar (if not fewer) oral exposure pathways when compared to these products, I believe that a Schedule 6 cut-off concentration of 100 ppm (100 mg/kg) is adequately stringent.

In making my decision, I have considered the two written public submissions that were received during the pre-meeting consultation, which were both opposed to the proposed scheduling. Accord Australasia noted that lead acetate was reinstated in the United States in 2019, in apparent contradiction with the initial scheduling proposal. However, I note that the final decision in the United States is on hold as a result of the FDA's consultation and decision process rather than an endorsement of product safety. I also note that Combe Asia-Pacific expressed several concerns regarding the data modelling used in the human health tier III assessment for lead acetates. They also discussed the need for a non-zero cut-off for lead concentrations and noted that the proposed scheduling would lead to a mismatch between the regulation of hair dyes and other cosmetics containing lead. As such, stakeholders advised that the proposed Schedule 10 entry may be excessive.

In my view, concerns regarding data modelling are proportionally addressed by listing lead acetates in Schedule 6 rather than Schedule 10. Introducing a 100 ppm cut-off concentration would also bring the regulation of progressive hair dyes in line with other cosmetics, and is consistent with the Committee's analysis of the public health risks. Though relatively modest, these changes may encourage industry to formulate lead-free progressive hair dye products without creating excessive barriers.

In considering the wording of a Schedule 6 entry, I note that salts of lead are difficult to regulate. Lead is the readily measurable (and toxic) component of the substance, while the salt component (i.e. acetate) is more difficult to verify through chemical testing. As such, the enforcement of concentration limits may prove unnecessarily difficult if lead acetates are defined as a salt. To assist with the implementation of the proposed scheduling amendments, I have decided to capture lead acetates in the Poisons Standard based on their elemental lead content.

I note that other lead-containing cosmetics are already captured in Schedule 6, with a cut-off concentration of 100 ppm, and are defined in terms of elemental lead. As such, the desired regulation of lead acetates can be achieved by deleting the Schedule 5 entry for lead-containing hair cosmetics – and capturing relevant hair dye products under the existing Schedule 6 entry for lead-containing cosmetic products.

I have therefore made an interim decision to delete the Schedule 5 entry for lead compounds. This amendment will result in the requirement for lead-containing progressive hair dye products to be Schedule 6 compliant, unless present at concentrations below 100 ppm (100 mg/kg). I am of the view that these changes will meaningfully contribute to ongoing efforts to phase out lead from Australian products.

To allow the industry time to reformulate their products, I have decided on a later implementation date of 1 June 2022.

Proposed implementation date

1 June 2022