Australian Government
Department of Health
Therapeutic Goods Administration

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

TGA Health Safety Regulation

Contents

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

This web publication constitutes a notice for the purposes of regulation 42ZCZS and regulation 42ZCZX of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS and 42ZCZX, this notice publishes the:

- decisions made by a delegate of the Secretary pursuant to regulations 42ZCZR and 42ZCZU;
- reasons for those final decisions; and
- date of effect of those decisions.

2 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #33, March 2021)

2.1 Final decision in relation to metoclopramide

Proposal

The applicant proposed an amendment to include metoclopramide in Appendix H of the Poisons Standard to allow direct-to-consumer advertising of pharmacist-only medicines containing the substance.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision not to amend the current Poisons Standard in relation to metoclopramide.

Materials considered

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

- The application to amend the current Poisons Standard with respect to metoclopramide;
- The 31 public submissions, including five written submissions, 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 Scheduling (ACMS #33);
- The two public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (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 (e) the potential for abuse of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- Appendix 1 - Guidelines for advertisements for medicines containing Schedule 3 substances (tga.gov.au).

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

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to metoclopramide. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that the written public submissions received during the second round of consultation were not opposed to the interim decision.

2.2 Final decision in relation to chloramphenicol

Proposal

The applicant proposed an amendment to include chloramphenicol in Appendix H of the Poisons Standard to allow direct-to-consumer advertising of pharmacist-only medicines containing the substance.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision not to amend the current Poisons Standard in relation to chloramphenicol.

Materials considered

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

- The application to amend the current Poisons Standard with respect to chloramphenicol;
- The 62 public submissions 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 Scheduling (ACMS #33);
- The two public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (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; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- Appendix 1 - Guidelines for advertisements for medicines containing Schedule 3 substances (tga.gov.au)

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

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to chloramphenicol. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that the written public submissions received during the second round of consultation were fully supportive of the interim decision.

2.3 Final decision in relation to prochlorperazine

Proposal

The applicant proposed an amendment to include prochlorperazine in Appendix H of the Poisons Standard to allow direct-to-consumer advertising of pharmacist-only medicines containing the substance.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision not to amend the current Poisons Standard in relation to prochlorperazine.

Materials considered

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

- The application to amend the current Poisons Standard with respect to prochlorperazine;
- The 60 public submissions 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 Scheduling (ACMS #33);
- The two public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (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; and (e) the potential for abuse of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- Appendix 1 - Guidelines for advertisements for medicines containing Schedule 3 substances (tga.gov.au).

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

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to prochlorperazine. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that the written public submissions received during the second round of consultation were fully supportive of the interim decision.

2.4 Final decision in relation to processed *Aconitum carmichaelii*

Proposal

The applicant proposed an amendment to the scheduling of processed *Aconitum carmichaelii* (*A. carmichaelii)* with the intent that it is down-scheduled to general sales level in certain

preparations used in Traditional Chinese Medicine (TCM). *A. carmichaelii* is currently listed in Schedules 2 and 4 of the Poisons Standard, with exceptions at low levels of alkaloids.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision not to amend the current Poisons Standard in relation to processed *A. carmichaelii*.

Materials considered

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

- The application to amend the current Poisons Standard with respect to processed *A. carmichaelii*;
- The 331 public submissions, including 52 written submissions, 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 Scheduling (ACMS #33);
- The six public submissions, including four written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (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.

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

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to *A. carmichaelii*. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations.

I note that all four written public submissions were opposed to the interim decision, including an extensive response from the Federation of Chinese Medicine and Acupuncture Societies of Australia (FCMA). The FCMA argued that accredited TCM practitioners are better far better trained to supply the herb than legal prescribers/dispensers under Schedules 2 and 4. They also contended that the exemption for these medicines would only allow its use by accredited TCM practitioners rather than the general public. I have carefully considered these concerns and acknowledge that TCM practitioners and dispensers are well-trained health professionals with knowledge and understanding of substances such as *A carmichaelii*. However, there is currently no pathway to enforce the guidelines proposed by the applicant or limit access to substances that are exempt from scheduling to only TCM practitioners. As such, rescheduling is not appropriate at this time.

3 Final decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #27, March 2021)

3.1 Final decision in relation to kambo

Proposal

A Delegate of the Secretary of the Commonwealth Department of Health (the Delegate) proposed an amendment to include kambo in Schedule 9 of the Poisons Standard in response to concerns regarding its impact on public health.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the scheduling of kambo in the current Poisons Standard as follows:

Schedule 10 – New Entry

KAMBO

Index – New Entry

KAMBO
cross reference: Secretion of the South American Giant Leaf Frog or Giant Monkey Frog (*Phyllomedusa bicolor*)

Schedule 10

Materials considered

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

- An external expert evaluation on the properties of kambo;
- The 83 public submissions, including 23 written submissions, 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 #27);
- The written public submission received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (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);
- The Scheduling handbook: Guidance for amending the Poisons Standard;

- A review by J Hesselink, Kambo and its Multitude of Biological Effects: Adverse Events or Pharmacological Effects? (2018);
- A case report by Pogorzelska and Łapiński, Toxic hepatitis caused by the excretions of the Phyllomedusa bicolor frog – a case report (2017);
- A case report by Gonzaga et al., Kambo Frog Poison as a Cause of Esophageal Rupture (2020);
- A case report by Roy et al., Can Overuse of Kambô Cause Psychosis? (2018);
- A case report by Aquila et al., The Biological Effects of Kambo: Is There a Relationship Between its Administration and Sudden Death? (2017); and
- A review by J Hesselink, Transformation and Migration of Healing Rituals from Indigenous Cultures to the West: Amphibian Secretions, the 'Frog Medicine and Toad Medicine' (2019).

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to kambo. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that the written public submission received during the second round of consultation was fully supportive of the interim decision.

Implementation date

1 October 2021

3.2 Final decision in relation to lidocaine

Proposal

The applicant proposed an amendment to expand the current Schedule 5 entry for lidocaine to include specifically targeted injectable solutions, at up to 2% concentration, for the pain relief of lambs or calves undergoing animal husbandry procedures.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the scheduling of lidocaine in the current Poisons Standard as follows:

Schedule 5 – Amend Entry

LIDOCAINE:

a) in aqueous gel preparations containing 4.5 per cent or less of lidocaine, for the dermal spray-on administration to the wounds of animals; or

b) in injectable preparations containing 2 per cent or less of lidocaine when packaged in a container with a tamper resistant cartridge which can only be dispensed through a rubber ring applicator for tail docking and castration of lambs; or castration of calves.

Schedule 4

LIDOCAINE **except**:

a) when included in Schedules 2 or 5;

b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances per dosage unit; or

c) in lozenges containing 30 mg or less of total anaesthetic substances per dosage unit.

Schedule 2

LIDOCAINE in preparations for topical use other than eye drops:

a) containing 10 per cent or less of total local anaesthetic substances, **except:**

i) in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or

ii) in aqueous sprays for oromucosal use containing 0.6 per cent or less of total local anaeasthetic substances; or

b) in divided preparations containing 200 mg or less of total local anaesthetic substances, **except** in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

Index

Schedule 5
Schedule 4
Schedule 2

Materials considered

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

- The application to amend the current Poisons Standard with respect to lidocaine;
- The 91 public submissions, including 29 written submissions, 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 #27);
- The 22 public submissions, including 14 written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse 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.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to lidocaine, including a minor wording change described below. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations.

In making my decision, I note that 13 of 14 submissions were fully supportive of the interim decision. One of these submissions requested that the new Schedule 6 entry uses the term "container" instead of "bottle". I consider that this wording is more consistent with other Poisons Standard entries, and may allow further innovations in product design. I also note that the new wording has no bearing on the safety features that are integral to the Schedule 6 entry. Due to the potential benefits and low risk, I have decided to implement this minor editorial change as part of my final decision.

I have also considered the opposing submission, from the Australian Veterinary Association, which argued that the packaging of the drug is not tamper proof and does not prevent misuse. The submission also raised that veterinarians are well placed to prescribe lidocaine, and that rescheduling to Schedule 5 disallows assessment of risks and therapeutic need by a medical professional. I note that many of these points were raised in the pre-meeting consultation and discussed in the interim decision. I reiterate that, though it is better classified as 'tamper resistant' rather than 'tamper proof', the product design sufficiently mitigates the risks of diversion. It is also used for procedures that are typically performed by farmers or contractors, and do not require consultation with a veterinarian. As such, the rescheduling of lidocaine is appropriate.

Implementation date

1 October 2021

3.3 Final decision in relation to hemp seed oil

Proposal

The applicant proposed an amendment to the existing Schedule 9 entries for cannabis and tetrahydrocannabinols to exclude hemp seed oil for oral consumption from scheduling when compliant with the Food Standards Code.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the scheduling of hemp seed oil in the current Poisons Standard as follows:

CANNABIS

Schedule 9 – Amend Entry

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~~ 75 mg/kg or less of cannabidiol ~~cannabinoids, including~~ and ~~20~~ 10 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.~~

Schedule 8 – Amend Entry

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[1], 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*,

except ~~when~~:

i) when 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) when separately specified in the NABIXIMOLS entry in this Schedule; or

iii) when captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or

iv) hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.

Appendix D, Item 1 (Poisons available only from or on the prescription or order of an authorised medical practitioner)

CANNABIS for human use.

Appendix K

CANNABIS **except** cannabidiol when included in Schedule 4 or Schedule 3

Index

CANNABIS
cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS

Schedule 9
Schedule 8
Appendix D, Item 1
Appendix K

[1] "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

TETRAHYDROCANNABINOLS

Schedule 9 – Amend Entry

TETRAHYDROCANNABINOLS and their alkyl homologues, **except**:

a) when included in Schedule 4 or Schedule 8; or

b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or

c) in hemp seed oil at a concentration of 10 mg/kg or less. ~~in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of total 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.~~

Schedule 8 – Amend Entry

TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:

a) included in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or

b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

c) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989,*

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; or

iv) in hemp seed oil at a concentration of 10 mg/kg or less.

Appendix D, Item 1 (Poisons available only from or on the prescription or order of an authorised medical practitioner)

TETRAHYDROCANNABINOLS for human use.

Appendix K

TETRAHYDROCANNABINOLS **except** cannabidiol when included in Schedule 4 or Schedule 3

Index

TETRAHYDROCANNABINOLS
cross reference: CANNABIS, HEMP SEED OIL, NABIXIMOLS

Schedule 9
Schedule 8

Appendix D, Item 1
Appendix K

CANNABIDIOL

Schedule 4 – Amend entry

CANNABIDIOL in preparations for therapeutic use or analytical and scientific research where:

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;

except when:

i) included in Schedule 3; or

ii) in hemp seed oil at a concentration of 75 mg/kg or less.

Schedule 3

CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Australian Register of Therapeutic Goods when:

a) the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and

b) the cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and

c) 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 of which tetrahydrocannabinol (THC) can only comprise 1 per cent of the total cannabinoid content; and

d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and

e) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and

f) in packs containing not more than 30 days' supply; and

g) for persons aged 18 years and over.

Appendix F, Part 3

Poison	Warning Statements	Safety Direction
CANNABIDIOL when included in Schedule 3.	67, 111	
67: Do not use if pregnant or likely to become pregnant. 111: Do not use if breastfeeding or planning to breastfeed		

Index

CANNABIDIOL
cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

Schedule 4
Schedule 3
Appendix F, Part 3

HEMP SEED OIL

Index – New Entry

HEMP SEED OIL
cross reference: CANNABIDIOL, CANNABIS, TETRAHYDROCANNABINOLS

Materials considered

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

- The application to amend the current Poisons Standard with respect to hemp seed oil;
- The 101 public submissions, including 9 written submissions, 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 #27);
- The four public submissions, including two written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (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.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to hemp seed oil. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that three of the four public submissions received during the second round of consultation were not opposed to the interim decision.

Implementation date

1 October 2021

4 Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #30, March 2021)

4.1 Final decision in relation to lead (in paint)

Proposal

Three applicants proposed an amendment to the Schedule 10 entry for lead compounds to reduce the permissible level in paints from 0.1% to 0.009%.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the current Poisons Standard in relation to lead as follows:

PART 2, SECTION SEVEN/Appendix I – Amend Section

(2) A person must not manufacture, sell, supply or use:

a) an anti-fouling or anti-corrosive paint containing more than 0.1% Lead (the proportion of Lead for the purposes of this section is calculated as a percentage of the element present in the non-volatile content of the paint); or

b) a paint (other than an anti-fouling or anti-corrosive paint) or tinter containing more than ~~0.1~~ 0.009% Lead (the proportion of Lead for the purposes of this section is calculated as a percentage of the element present in the non-volatile content of the paint).

Schedule 10 – Amend Entry

LEAD COMPOUNDS:

a) in anti-fouling or anti-corrosive paints **except** in preparations containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint; or

b) in paints (other than anti-fouling or anti-corrosive paints), tinters, inks or ink additives **except** in preparations containing ~~0.1~~ 0.009 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive.

Schedule 6

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

LEAD COMPOUNDS in preparations for use as hair cosmetics.

Schedule 4

LEAD for human therapeutic use.

Appendix E, Part 2

POISON	STANDARD STATEMENTS
LEAD COMPOUNDS	
• in hair cosmetics	**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).
• in other preparations	**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.

Appendix B, Part 3

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
LEAD METALLIC	-	a – Low Toxicity	7.1 – Any use

Index

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

Schedule 4

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

LEAD METALLIC

Appendix B, Part 3

Materials considered

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

- The applicants' proposals to amend the current Poisons Standard with respect to lead;
- The 72 public submissions, including three written submissions, 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 #30);
- The four public submissions, including three written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (c) the toxicity 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);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- *Global elimination of lead paint: why and how countries should take action - Technical brief*, World Health Organization 14 August 2020.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to lead. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions,

published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that none of the four public submissions were opposed to the decision to reduce the permissible level of lead in paints (other than anti-fouling or anti-corrosive paints) to 0.009 percent.

The written submissions, though supportive of the interim decision, expressed concern regarding the proposed implementation date for amendments to the scheduling of anti-fouling and anticorrosion paints. The Lead Education and Abatement Design Group raised the issue that it does not take two years to order purer zinc or copper sources for use in these paints. They also noted that the extended date could result in Australia being behind comparable countries in eliminating lead from paint. After considering these points, I reiterate that there are significantly reduced exposure pathways from anti-fouling and anticorrosion paints compared to other paints, and that the impact on industry, necessitates a longer transition period in comparison to other paints. For these reasons, the exemption of anticorrosion and anti-fouling paints from this current amendment, will be removed on 1 October 2023.

I also note that Chemistry Australia and the Australian Paint Manufacturers Federation (APMF) did not support the proposed amendments to anti-fouling paints. They expressed the view that the decision undermines the APVMA's safety assessment of anti-fouling paints and suggested that the proposed changes would be akin to a ban of copper-based products. The APMF further raised that the amendments to anti-corrosive paints would raise costs and impact several industries where the risk of exposure is minimal. Both submissions requested a further round of public consultation.

In response to these concerns, I would reiterate that lead is a substance with known cumulative toxicity to humans. There is no regulatory threshold for human exposure, below which is considered safe. Instead, international standards highlight the need to reduce exposure to lead from various sources to as low as possible or eliminated altogether, e.g. WHO, 2011[1]; OECD, 1999[2]. In a similar manner, the United Nations Environment Program has endorsed lower limits for the presence of lead in paint. This limit has already been adopted by several countries for some or all types of paints and coatings.

Consistent with the advice received from Advisory Committee on Chemicals Scheduling, I have decided to amend the Poisons Standard to reduce the permissible level of lead in paints to 0.009 percent with an implementation date of 1 October 2021, except for anticorrosion and anti-fouling paints. For anticorrosion and anti-fouling paints, this exemption will be removed on 1 October 2023. This will allow an additional 2 years for this industry to meet the new permissible level and ensure that users of anticorrosion and anti-fouling paints and people in general coming into contact with their products, are protected from exposure to lead.

Implementation date

1 October 2021

4.2 Final decision in relation to cyflumetofen

Proposal

The applicant proposed a new entry for cyflumetofen in Schedule 6 of the Poisons Standard.

[1] WHO, 2011. Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Lead. https://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=3511
[2] OECD, 1999. Phasing lead out of gasoline: An examination of policy approaches in different countries. https://www.oecd.org/env/ehs/risk-management/1937036.pdf

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the current Poisons Standard in relation to cyflumetofen as follows:

Schedule 5 – New Entry

CYFLUMETOFEN

Index – New Entry

CYFLUMETOFEN

Schedule 5

Materials considered

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

- The application to amend the current Poisons Standard with respect to cyflumetofen;
- The 54 public submissions, including no written submissions, 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 #30);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation 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.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to cyflumetofen. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses, if provided, received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that no public submissions were received during the second round of consultation.

Implementation date

1 October 2021

4.3 Final decision in relation to isocycloseram

Proposal

The applicant proposed a new entry for isocycloseram in Schedule 6 of the Poisons Standard.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the current Poisons Standard in relation to isocycloseram as follows:

Schedule 6 – New Entry

ISOCYCLOSERAM

Index – New Entry

ISOCYCLOSERAM

Schedule 6

Materials considered

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

- The application to amend the current Poisons Standard with respect to isocycloseram;
- The 53 public submissions (no written submissions) 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 #30);
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation 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.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to isocycloseram. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses, if provided, received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that no public submissions were received during the second round of consultation.

Implementation date

1 October 2021

4.4 Final decision in relation to 1,4-benzenediamine, 2-(methoxymethyl)-

Proposal

The applicant proposed to create entries for 1,4-benzenediamine, 2-(methoxymethyl)- in Schedule 6 (with labelling conditions and a cut-off limit) and Schedule 10 of the Poisons

Standard. The substance is currently captured by group entries for phenylenediamines in Schedules 6 and 10.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision not to amend the current Poisons Standard in relation to 1,4-benzenediamine, 2-(methoxymethyl)-.

Materials considered

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

- The application to amend the current Poisons Standard with respect to 1,4-benzenediamine, 2-(methoxymethyl)-;
- The public report on the substance, compiled by NICNAS in August 2018;
- The 58 public submissions, including one written submission, 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 #30);
- The two public submissions, including one written submission, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of the *Therapeutic Goods Act 1989,* in particular (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; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation 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.

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

I have made a final decision to confirm my interim decision not to amend the current Poisons Standard with respect to 1,4-benzenediamine, 2-(methoxymethyl)-. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 20 July 2021 under regulation 42ZCZP of the Regulations. I note that public submissions received during the second round of consultation were not opposed to the interim decision.