Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

3 August 2023

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.

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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 decision made by a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) under regulation 42ZCZN in relation to a proposed amendment to the current Poisons Standard which was referred to an expert advisory committee[1] under subdivision 3D.2 of the Regulations in June 2023.
- the proposed date of effect of the proposed amendment.

In accordance with regulation 42ZCZP, interested persons are invited to make submissions to the Secretary in relation to this interim decision on or before **1 September 2023.**

Submissions should 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.

Defined terms

In this notice the following defined terms are used in addition to those above:

- the *Therapeutic Goods Act 1989* (Cth) (the **Act**)
- the Scheduling Policy Framework 2018 (the **SPF**)
- the Scheduling handbook: Guidance for amending the Poisons Standard (the **Handbook**)
- the Therapeutic Goods Administration (the **TGA**).

Note: additional terms are also be defined for individual decisions.

[1] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

Interim decision on a proposed amendment referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (ACMS-ACCS #34, June 2023)

Interim decision in relation to lead

Proposal

A final decision to amend the Poisons Standard was published in September 2021 (the **2021 Decision**[2]) relevantly amended the scheduling of lead to reduce the maximum permissible level of lead in paints to 90 mg/kg (equivalent to 90 ppm or 0.009%). Anti-fouling and anti-corrosive paints were exempted from the 2021 Decision and retained the previous maximum permissible level of 0.1%. The delegate of the 2021 Decision foreshadowed that the exemption in relation to anti-fouling and anti-corrosive paints would be repealed by 1 October 2023, in effect providing a two-year transition period for industry to develop paints that are compliant with the 0.009% level.

An application was received in December 2022[3] to amend the limit of lead in anti-fouling paints to 600 mg/kg (equivalent to 600 ppm or 0.06%). The applicant did not propose a change to the limit for anti-corrosive paints.

Because the application sought to amend a future version of the Poisons Standard (being the version that was foreshadowed to be in force on 1 October 2023), rather than the current Poisons Standard, the application was not valid. This amendment is instead proceeding as a Secretary-initiated amendment under section 52D of the Act.

Interim decision

The Delegate has, on their own initiative, made an interim decision[4] to make the following amendments to the Poisons Standard:[5]

PART 2, DIVISION 9, SECTION 66 – Amend Section

(2) 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) must not be manufactured, supplied or used.

(3) A paint (other than an anti-fouling ~~or anti-corrosive~~ paint) or tinter containing more than 0.009% lead (calculated as a percentage of the element present in the non-volatile content of the paint) must not be manufactured, supplied or used.

[2] www.tga.gov.au/sites/default/files/notice-final-decisions-amend-or-not-amend-the-current-poisons-standard.pdf
[3] https://consultations.tga.gov.au/tga/scheduling-pre-meeting-june-2023/user_uploads/june-pre-meeting-public-notice-acms--42-acms-accs--34-1.pdf
[4] Pursuant to regulation 42ZCZN of the Regulations
[5] Amendments to the Poisons Standard are made to the current Poisons Standard, Therapeutic Goods (Poisons Standard—July 2023) Instrument 2023.

Schedule 10 – Amend Entry

LEAD COMPOUNDS

a) in anti-fouling ~~or anti-corrosive~~ paints **except** in preparations containing 0.1% 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 0.009% or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive.

Materials considered

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

- the application to amend the current Poisons Standard with respect to lead (the **Application**)
- the 17 public submissions, with 9 including a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions)**
- the advice received from the 34th meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**)
- the Delegate's 2021 Decision to amend the Poisons Standard in relation to lead (in paint) in September 2021 and the materials considered in making those decisions
- subsection 52E(1) of the Act, 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 SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that the transition period of the 2021 Decision be extended by 2 years to **1 October 2025**.

Members agreed that the relevant matters under subsection 52E(1) of the Act 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

Risks:

– Work health and safety (WHS) issues for workers involved in the maintenance of ocean-going vessels:

§ Exposure to lead in paint can come from multiple sources e.g. manufacture, application, removal and aging painted surfaces where crumbling and flaking can release lead into the environment.

- § Inhalation of nanoparticulate lead during hull preparation/cleaning/sanding.
- § Fumes from low boiling solvent mixture.

– Release of lead into local environment from dry-docks or maintenance facilities, causing localised contamination and potential exposure to humans in surrounding environs.

– In poorly regulated setting exposure is more likely.

– Lead is an accumulative toxin and there is no 'safe' lower level.

Benefits:

– Copper-based antifouling paints are the most efficacious and long-lasting paints in the Australian maritime economy. Cuprous oxide (Cu_2O) is the most effective. They reduce fuel consumption of ocean-going vessels and minimise the risk of the spread of unwanted bio-organisms into Australian waters.

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

– Cuprous oxide-based antifouling paints are used globally on all sizes of ocean-going vessels. Economic factors support prominent use of recycled copper, which can contain significant levels of lead as a contaminant.

– General consumer exposure will be limited because the anti-fouling paint is only used on vessel hulls, below the waterline.

– The 600 ppm limit appears to only be necessary for anti-fouling paints with cuprous oxide as the main biocide.

– There are several grades of recycled copper, using the better grades will yield lower lead levels.

– Polymer-based products, and other currently approved anti-fouling paints that do not contain cuprous oxide should be required to conform to the 90ppm limit.

c) the toxicity of a substance

– There is no safe lower limit for lead exposure in humans. Lead has known cumulative toxic effects affecting multiple body systems.

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

– Anti-fouling paints are regulated by the APVMA. Requirements include labelling mandating the use of PPE (overalls, washable hat, gloves, eye protection, respirator if spray painting) and handwashing after use.

e) the potential for abuse of a substance

– *Nil.*

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

– Exemption of anti-fouling paints from the scheduling framework and reliance on APVMA product registration alone to protect public health is not supported. New standard would ensure a set (lower) level for industry to comply with.

– The standards governing permissible lead content of these paints are widely variable, but 600ppm is accepted in the US, UK and Europe.

- A 90 ppm limit is considered technically feasible for manufacturers to achieve for almost all types of paint but is currently unachievable.
- Recent data suggests that for the next two decades over 80% of global copper demand will continue to come from primary (refined ore) sources.
- The potential consequences of servicing overseas:
  - more ships painted with higher lead levels would arrive in Australia
  - loss of Australian jobs in the industry if servicing went offshore.

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

I have made an interim decision to amend the scheduling of lead as it pertains to anti-corrosive paints. The introduction of a 0.009% limit on lead in anti-corrosive paints, as foreshadowed in the 2021 Decision, is given effect by this amendment and will be implemented on 1 October 2023.

I have also made an interim decision to not amend the scheduling of lead as it pertains to anti-fouling paints. The scheduling of lead will retain the permissible maximum level of lead in anti-fouling paints of 0.1%. However, it is anticipated that consideration will be given to reducing the permissible maximum level of lead in anti-fouling paints to 0.06% by 1 October 2026, and further reduced to 0.009% by 1 October 2029.

Anti-corrosive paints

Anti-corrosive paints are typically based on zinc and are unlikely to contain significant levels of lead as an impurity. Therefore, I have decided to retain this element of the 2021 Decision, for the reasons given in that decision, and make the intended amendments with regards to lead in anti-corrosive paints on 1 October 2023.

I note that there is no objection in the submissions to the implementation of a 0.009% limit on lead in anti-corrosive paints, as outlined in the 2021 Decision.

Anti-fouling paints

I agree with the Committee's findings on the relevant provisions of section 52E of the Act. While the interim decision is to extend the implementation of the reduced limit for lead in anti-fouling paint, with reference to s 52E(1)(c) of the Act, I reiterate the 2021 Decision that lead is a substance with known cumulative toxicity to humans with no regulatory threshold for human exposure below which is considered safe. I agree with the Committee that public health policy makers have a responsibility to reduce the potential for human exposure to lead wherever possible, including through controls in the Poisons Standard.

The main consideration in deferring the foreshadowed repeal of the 0.1% limit in relation to anti-fouling paints in 2021 Decision is to ensure that industry has sufficient time to develop innovative and safe alternatives to the anti-fouling paints that are currently available. The 2021 Decision recognised that reduction of the limit for lead in anti-fouling paints may be problematic on the basis that manufacture uses recycled copper, which typically contains traces of lead as an impurity from its use in solder.

The 2021 Decision was made with the intention that manufacturers would source alternative materials or methods for producing anti-fouling paints during the two-year transition period, such that the 0.009% limit on lead content could be achieved by 1 October 2023. I recognise that despite

the transition period of the 2021 Decision, copper compounds remain the predominant active ingredient for anti-fouling paints and there are few alternatives available.

The Australian Pesticides and Veterinary Medicines Authority (APVMA), which is the regulator for anti-fouling paints in Australia, lists 43 anti-fouling products on the Public Chemical Registration Information System (PubCRIS). All contain one or more copper compounds, such as cuprous oxide, cuprous thiocyanate and/or copper pyrithione. The use of recycled copper in these preparations means it is unlikely that the intended 0.009% limit for lead would be able to be met by industry by 1 October 2023.

I have noted the submission from an industry body stating that that virgin (mined) copper, which is of higher purity and contains lower levels of impurities including lead, is currently not adequately accessible or economically viable for use by manufacturers of anti-fouling paints. While scheduling decisions are based on considerations of the effects of a substance on human health rather than economic factors, in my considerations of s 52E(1)(a) of the Act I recognise the importance of anti-fouling paints in Australian industry. Reduction in the practice of using anti-fouling paints on watercraft in Australia has potential detrimental effects or risks, such as increased fuel consumption and the introduction of undesirable bio-organisms, both of which can have flow-on effects to human health. I also recognise the concerns expressed in the application and the submissions that without access to viable anti-fouling paint alternatives in the Australian market there will likely be offshore transfer of work involving such products to countries with less stringent restrictions. This may present little (if any) benefit to the health of Australians in terms of the intent of this decision, as watercraft bearing anti-fouling paints with excessive levels of lead would still be free to re-enter Australian waters and potentially release contaminants to local waterways.

I have considered the risk to public health from exposure to lead in anti-fouling paints and I have decided that extending the transition period is not likely to unduly increase the risk to Australian public health.

An extended transition period provides scope for industry to scale-down the production of paints which may be non-compliant with the new limits on lead at each stage and minimises the risk of inappropriate disposal of existing non-compliant products. This has the potential to minimise the release of lead from disposed anti-fouling paints into the environment and hence contributes to lowering the probability of human exposure to lead from these products.

In considering the risk to public health from extending the transition period for the lower lead limit, I recognise that there are significantly reduced exposure pathways from anti-fouling paints compared to other paints. The key population at risk is shipyard workers during maintenance activities on watercraft. However, in making this decision I have taken into consideration s 52E(1)(d) of the Act. Of particular relevance is that the exposure to lead for those working on the removal or application of anti-fouling paints in dry dock is significantly mitigated under work health and safety laws, through the use of engineering controls such as wet abrasion and vacuuming, and the use of personal protective equipment (PPE) such as masks and gloves. This supports the points raised in the application regarding the reduced potential for human exposure to lead in anti-fouling paints and has contributed to my decision to extend the transition timeframes from the 2021 Decision.

Pursuant to s 52E(1)(b) of the Act, I have considered the data provided in the submissions from the Boating Industry Association[6] which indicated that 85% of boats in Australia are under 6m long, and 62% are constructed from aluminium. Therefore, I consider the risk of exposure to lead from maintenance activities on watercraft to be low and to a small population, as small watercraft are predominantly coated with anti-fouling paints based on cuprous thiocyanate which is preferred for

[6] www.bia.org.au/news/boating-data-report-card-launched

use on aluminium hulls. Cuprous thiocyanate contains a lower proportion of copper (and therefore likely to contain a lower level of lead contamination) than other forms of copper-based anti-fouling paints. For larger watercraft, more likely to be coated with anti-fouling paints containing higher levels of lead (cuprous oxide), maintenance activities will be carried out by shipyard workers with enforcement of appropriate PPE measures. This information supports my view that the population most at risk of lead exposure from anti-fouling paints are workers associated with the maintenance of larger vessels, where appropriate engineering controls and PPE are enforced and regulated to mitigate this risk, rather than individuals working on smaller watercraft.

I acknowledge the Committee's advice regarding the revised transition period, however I am of the view that this decision will provide an adequate adjustment period for relevant stakeholders to meet the requirements at each stage of the suggested staggered amendment process.

Future scheduling amendments in relation to lead

In my view, consideration should be given to making further amendments to the scheduling of lead in relation to anti-fouling paints at a later date. In particular:

- to reduce the permissible maximum level of lead in anti-fouling paints to 0.06% by 1 October 2026, and
- to reduce the permissible maximum level of lead in anti-fouling paints to 0.009% by 1 October 2029.

I consider that the 'staggered' approach to the reduction of lead in anti-fouling paints should contribute to the impetus for innovation in this sector. The introduction in the 1990's of global restrictions on the use of tributyl tin – previously the active ingredient of choice in anti-fouling paints despite presenting with undesirable toxic and bio-accumulative effects – catalysed the development of copper-based alternatives for this purpose. I expect that a staggered reduction in the limits applying to the presence of lead in anti-fouling paints will also present a similar opportunity for the development of new and improved products and methods to prevent the fouling of the hulls of watercraft.

Further, a staggered implementation allows adequate time for the proper reformulation of anti-fouling paints by manufacturers and minimises the risk that product quality may be compromised, such as increasing the quantity of other toxic components to make the paints compliant. I consider this to be a likely risk in the face of the current lack of innovation in the space as presented by the applicant.

In the absence of an application to make the above amendments at the appropriate time, a Secretary-initiated amendment to make the above amendments may be proposed, in accordance with the ordinary procedures to amend the Poisons Standard. A person may apply at any time to seek a different scheduling amendment.

Implementation date

1 October 2023

Therapeutic Goods Administration

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