



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Notice of final decision to amend (or not amend) the current Poisons Standard in relation to lead

18 September 2023

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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 of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS, this notice publishes:

- the decision made by a delegate¹ of the Secretary of the Department of Health and Aged Care (the **Delegate**) pursuant to r 42ZCZR
- the reasons for the final decision, and
- the date of effect of the decision.

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**), and
- the Therapeutic Goods Administration (the **TGA**).

Note: additional terms are also defined for individual decisions.

¹ For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

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

Final decision in relation to lead

Proposal

A final decision to amend the Poisons Standard was published in September 2021 (the [2021 Decision](#)) 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of the 2021 Decision foreshadowed that the exemption in relation to anti-fouling and anti-corrosive paints would be repealed by 1 October 2023, in effect providing a two-year transition period for industry to develop paints that are compliant with the 0.009% level.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 2022² 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. The amendment instead proceeded as a Secretary-initiated amendment under section 52D of the Act.

Final decision

The Delegate has made a final decision³ to confirm the interim decision and amend the current Poisons Standard in relation to lead as follows:

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.

Schedule 10 – Amend Entry

LEAD COMPOUNDS

² [consultations.tga.gov.au/tga/scheduling-pre-meeting-june-2023/user_uploads/june-pre-meeting-public-notice-acms--42-acms-accs--34-1.pdf](https://www.consultations.tga.gov.au/tga/scheduling-pre-meeting-june-2023/user_uploads/june-pre-meeting-public-notice-acms--42-acms-accs--34-1.pdf)

³ Pursuant to r 42ZCZR of the Regulations

- 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 final 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 received in response to the [pre-meeting consultation](#) under regulation 42ZCZK of the Regulations.
- 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.
- The [interim decision](#) to amend the Poisons Standard in relation to lead (in paint) in July 2023 under regulation 42ZCZN of the Regulations and the materials considered in making the interim decisions (the **interim decision**).
- The 2 public submissions received in response to the [interim decision consultation](#) under regulation 42ZCZP of the Regulations (the **Submissions**).
- Subsection 52E(1) of the Act, 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 (f) any other matters considered necessary to protect public health.
- the SPF and the Handbook.

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 Submissions, both of which were in support of the interim decision.

I would like to reaffirm my view that consideration should be given to making further amendments to the scheduling of lead in relation to anti-fouling paints. 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.

This 'staggered' approach to the reduction of lead in anti-fouling paints should contribute to the impetus for innovation in this sector. I anticipate that this will present ample opportunity for the development of new and improved products and methods to prevent the fouling of watercraft hulls.

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.

Implementation date

1 October 2023

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>