|  |
| --- |
| Notice of final decision to amend the current Poisons Standard in relation to nicotinic acid |
| 20 January 2025 |

**Copyright**

© Commonwealth of Australia 2025
This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to tga.copyright@tga.gov.au.

Contents

[Notice of final decision to amend (or not amend) the current Poisons Standard 4](#_Toc187314777)

[Final decision in relation to nicotinic acid 5](#_Toc187314778)

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

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

* the decision made by a delegate[[1]](#footnote-1) of the Secretary of the Department of Health and Aged Care (the Delegate) pursuant to regulation 42ZCZW
* 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](https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals) 2018 (the SPF)
* the Scheduling handbook, [Guidance for amending the Poisons Standard](https://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard) (the Handbook) and
* the Therapeutic Goods Administration (the TGA).

Note: additional terms are also defined for individual decisions.

### Final decision in relation to nicotinic acid

***Proposal***

The Delegate received an application to create a new Schedule 5 entry for the use of nicotinic acid as an agricultural chemical and to amend the Schedule 4 entry to include preparations for animal therapeutic use when packed and labelled for injection.

***Final decision***

Pursuant to regulation 42ZCZW of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to nicotinic acid as follows:[[2]](#footnote-2)

**Schedule 5 – New Entry**

NICOTINIC ACID when packed and labelled for use as an agricultural chemical.

**Schedule 4 – Amend Entry**

NICOTINIC ACID in preparations:

1. for human therapeutic use **except:**
2. when separately specified in these Schedules; or
3. in preparations containing 100 mg or less of nicotinic acid per dosage unit; or
4. nicotinamide.
5. for animal therapeutic use when packed and labelled for injection.

**Index – Amend entry**

**NICOTINIC ACID**

cross reference: NICOTINAMIDE

Schedule 5
Schedule 4
Schedule 3

***Materials considered***

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

* the application to amend the current Poisons Standard with respect to nicotinic acid (the Application)
* the [interim decision](https://www.tga.gov.au/resources/publication/scheduling-decisions-interim/notice-and-invitation-comment-interim-decisions-amend-current-poisons-standard-relation-intravenous-potassium-salts-iv-and-nicotinic-acid) relating to nicotinic acid and the materials considered as part of the interim decision, as published on 13 December 2024
* 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; and (f) any other matters considered necessary to protect public health.
* pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
* the Handbook.[[3]](#footnote-3)

No submissions were received in response to the [consultation on interim decision](https://consultations.tga.gov.au/tga/nicotinic-acid-and-iv-potassium-interim-decision) taken under regulation 42ZCZV of the Regulations.

***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 nicotinic acid. In making my final decision, I have considered the material in the interim decision. No submissions were received from the public consultation on my interim decision.

My reasons for making the final decision are in alignment with those set out in the interim decision. The interim decision notes that the use of nicotinic acid as an agricultural chemical has a low potential for causing harm and with appropriate labelling is consistent with the SPF factors for Schedule 5. The interim decision also outlines the need for veterinary oversight for injectable formulations containing nicotinic acid that are used for animal therapeutic use. This is due to the risks and complexity of injectable formulations. Injecting animals requires specialised handling for administration e.g. precise vein access, accurate control of the injection rate and needle stability, elements which are consistent with Scheduling Factor 2 for Schedule 4 of the SPF.

I remain of the opinion that the current scheduling of nicotinic acid should be amended to create a Schedule 5 entry for nicotinic acid packed and labelled for use as an agricultural chemical while veterinary medicines containing nicotinic acid and are administered by injection should be restricted to Schedule 4.

The decision to create a Schedule 5 entry for nicotinic acid use as an agricultural chemical under Schedule 5, strikes a balance between consumer or industry accessibility and risk mitigation through appropriate packaging with warnings and safety directions on the label. I have decided to confirm the implementation date of 1 February 2025, which was specified in the interim decision.

***Implementation date***

1 February 2025

|  |
| --- |
| Therapeutic Goods Administration |
| PO Box 100 Woden ACT 2606 AustraliaEmail: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605[**https://www.tga.gov.au**](https://www.tga.gov.au) |
|  |

1. For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth). [↑](#footnote-ref-1)
2. Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard. [↑](#footnote-ref-2)
3. <https://www.tga.gov.au/sites/default/files/scheduling-handbook-guidance-amending-poisons-standard.pdf> [↑](#footnote-ref-3)