Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Notice of final decision to amend the current Poisons Standard in relation to nicotinic acid

20 January 2025

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Contents

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] 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 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 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]

Schedule 5 – New Entry

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

Schedule 4 – Amend Entry

NICOTINIC ACID in preparations:

(a) for human therapeutic use **except:**

i. when separately specified in these Schedules; or

ii. in preparations containing 100 mg or less of nicotinic acid per dosage unit; or

iii. nicotinamide.

(b) for animal therapeutic use when packed and labelled for injection.

Index – Amend entry

NICOTINIC ACID
cross reference: NICOTINAMIDE
Schedule 5
Schedule 4
Schedule 3

[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.

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 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]

No submissions were received in response to the consultation on 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

[3] https://www.tga.gov.au/sites/default/files/scheduling-handbook-guidance-amending-poisons-standard.pdf

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