Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

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

2 June 2026

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Contents

Notice of final decisions 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 publishes:

- the decisions made by a delegate[1] of the Secretary of the Department of Health and Aged Care (the **Delegate**) pursuant to regulations 42ZCZU.
- the reasons for the final decisions and
- the date of effect of those decisions.

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 decisions on proposed amendments to the current Poisons Standard under regulation 42ZCZU

In my capacity as a delegate of the Secretary for the purpose of regulation 42ZCZU of the Regulations, I have made final decisions under regulation 42ZCZU with respect to the following substances:

- *Bacillus paralicheniformis*
- Dimethyl Disulfide
- Enflicoxib sodium
- Spidoxamat

Final decision in relation to *Bacillus paralicheniformis*

Final Decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to *Bacillus paralicheniformis* as follows:[2]

Appendix B, Clause 3 – New Entry

Substances exempt in certain uses				
Item	Column 1 Substance	Column 2 Area, sub-area or sub-sub-area of use	Column 3 Reason for inclusion	Column 4 Date of inclusion
22	BACILLUS PARALICHENIFORMIS	1.10	a	Jun 2026

Index – New Entry

BACILLUS PARALICHENIFORMIS

Appendix B, Clause 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 *Bacillus paralicheniformis* (the **Application**)
- 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 (f) any other matters considered necessary to protect public health.

[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.

- pursuant to paragraph 52E(2)(a) of the Act, the SPF
- the Handbook.

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

The proposal is to amend the current Poisons Standard to include *Bacillus paralicheniformis* (*B. paralicheniformis*) in Appendix B, Clause 3 of the Poisons Standard. Appendix B lists substances considered not to require control by scheduling.

In determining that this matter will be a delegate-only decision I have taken into account the information provided in the Application, and the matters outlined under s 52E of the Act and the SPF. My reasons for making the final decision follow.

B. paralicheniformis) is a bacterium proposed for use in the control of root-knot nematode (*Meloidogyne* spp.) in a wide range of vegetables such as fruiting, root and tuber vegetables. Root-knot nematode infestations can severely impact nutrient uptake, leading to stalled plant growth and diminished crop yield.[3]

The genus *Bacillus* are gram-positive, rod-shaped bacteria which are ubiquitous in soil and commonly found in water, air, food and feed. *B. paralicheniformis* strain FMCH001 is one of two biological control agents in a new product yet to be registered for agricultural use.

With regard to subsection 52E(1)(a) of the Act, *B. paralicheniformis* possesses very little inherent risk associated with its use due to the absence of information indicating its pathogenicity, infectivity and toxicity as determined through toxicological analysis. *B. paralicheniformis* is a common additive in feed for livestock with potential use in human probiotics. The substance's benefit of use includes its effectiveness in preventing root-knot nematodes, which will in turn improve crop yield and size of produce.

Regarding s 52E(1)(b) and (d) of the Act, the nematicide product will be available as a suspension concentrate formulation in bottles ranging from 50 mL to 10 L net content, sealed with a screw cap and is intended for professional use as part of an integrated pest management program. The product will be applied at a rate of 1 L/ha via drip irrigation into the root zone, in-furrow spray or plant hole drench. Direct seeded crops can receive banded boom application at plant emergence from the planted rows, with or prior to irrigation or rainfall. The extent of its use is to control the occurrence of root-knot nematode in several different families of vegetables including brassica, legume, cucurbits, bulbs, root and tuber, stalk and stem, fruiting and leafy vegetables.

In consideration of s 52E(1)(c) of the Act, *B. paralicheniformis* does not meet the criteria for any scheduling factor classification with regards to acute oral, dermal, inhalation and eye toxicity. The acute oral and dermal acute toxicity endpoints (LD_{50}, rat) are greater than 5,000 mg/kg bw with no deaths recorded. It is slightly irritating to the eyes and has a low potential for skin sensitisation. *B. paralicheniformis* was not mutagenic or cytotoxic in various cell culture systems. No long-term repeat-dose toxicity studies, carcinogenicity, reproductive or developmental studies were undertaken as a result of the absence of significant findings from the acute toxicity and infectivity/pathogenicity studies. Moreover, the establishment of either an Acute Reference Dose (ARfD) or Acceptable Daily Intake (ADI) was not required. *B. paralicheniformis* has a long history of safe use, e.g. in the food industry for enzyme production, as a probiotic in livestock feed and in agriculture as a plant growth-promoting bacterium. It has only rarely been implicated in human infections and has also been added to European Food Safety Authority's (EFSA) list of Qualified Presumption of Safety (QPS)[4] recommended microorganisms intentionally added to food in 2022. Several *Bacillus* spp. including

[3] Business Queensland (2025). Root-knot nematode. Available at: www.business.qld.gov.au/industries/farms-fishing-forestry/agriculture/biosecurity/plants/insects/horticultural/root-knot-nematode [date accessed: 24/04/2026]

[4] EFSA Panel on Biological Hazards (BIOHAZ) et al. (2023). Update of the list of qualified presumption of safety (QPS) recommended microorganisms intentionally added to food or feed as notified to EFSA. In: EFSA Journal [Internet]. Available at: www.doi.org/10.2903/j.efsa.2023.7747.

B. subtilis – the other active in the nematicide product under consideration – are currently considered not to require control by scheduling due to their low toxicity.

A human health risk assessment for the *B. paralicheniformis* product was prepared by the Australian Pesticides and Veterinary Medicine Authority (APVMA) and submitted alongside the application. The assessment raised no objections on human health grounds to the approval of the active constituent or the product. As the product is intended for commercial professional use only, the potential risks associated with skin and eye exposure will be addressed by the APVMA, and through appropriate labelling and the use of applicable personal protective equipment.

Overall, I am satisfied that the risks associated with the use of this 'substance' are low enough to not require control through scheduling. Therefore, I have decided to include *B. paralicheniformis* in Appendix B—'Substances considered not to require control by scheduling', under Clause 3 as a biological control agent for use in agriculture. This amendment to the Poisons Standard was not referred to an expert advisory committee for advice.

Implementation date

1 October 2026

Final decision in relation to dimethyl disulfide

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to dimethyl disulfide as follows:[5]

Schedule 6 – New entry

DIMETHYL DISULFIDE for agricultural use as a soil fumigant.

Index – New entry

DIMETHYL DISULFIDE

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 dimethyl disulfide (the **Application**)
- 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 (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.

[5] 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.

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

The Application is to amend the current Poisons Standard to create an entry for dimethyl disulfide under Poisons (Schedule 6) classification. Dimethyl disulfide is not currently listed in the Poisons Standard.

In determining that this matter will be a delegate-only decision I have taken into account the information provided by the Australian Pesticides and Veterinary Medicine Authority (APVMA), and the matters outlined under s 52E of the Act and the SPF. My reasons for making the final decision are as follows.

Dimethyl disulfide is an organic and volatile chemical compound. This compound is used as a pre-plant soil fumigant for controlling nematodes, weeds, insects and soil borne pathogens. It exhibits broad-spectrum activity with non-selective characteristics due to its complex mode of action. The mechanism of action involves disruption of mitochondrial function, activation of ATP-sensitive potassium channels, and inhibition of cytochrome oxidase.

Dimethyl disulfide is also used as a flavouring agent and the safety evaluation of its use in food has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives evaluations (JEFCA). Results from JECFA suggest a low level of toxicity when administered orally. JEFCA indicated that the threshold for human intake is 1,800 µg per day.[6]

Dimethyl disulfide is regulated by the United States Environmental Protection Agency (EPA), and, in Europe, by the European Food Safety Authority (EFSA) in collaboration with the European Chemicals Agency (ECHA) for use as a soil fumigant. Due to its toxicity, flammability, environmental risks, and occupational hazards, its use in industry and pesticides is permitted under strict safety and labelling requirements.

With regard to 52E (1) (a) and (b) of the Act, I have considered that dimethyl disulfide is for agricultural use and effectively controls a wide range of pests, leading to improvements in crop production and reduced management time to grow a crop. The applicant indicated that dimethyl disulfide has the potential to be a safer alternative than some soil fumigants registered for the same use such as methyl bromide or methyl iodide (iodomethane) which are Dangerous poisons (Schedule 7).

With regard to 52E (1) (c) of the Act, the APVMA provided a Human Health Risk Assessment (HHRA) for both dimethyl disulfide and the intended product containing this substance.

Dimethyl disulfide has moderate acute oral, low dermal and low inhalational acute toxicity in rats. It is a slight irritant to skin, a moderate irritant to the eyes in rabbits, and is a skin sensitiser based on the results of a local lymph node assay in mice.

Repeat-dose toxicity studies in animals by the inhalation route demonstrated that the most sensitive outcome was concentration dependent nasal irritation. The concentration at which nasal irritation occurs is similar for a single exposure and for repeat exposure.[7] Systemic toxicity (reduced body weight and food consumption) was only observed following repeat exposure at higher doses.

Crops grown after dimethyl disulfide soil treatment showed no toxicologically significant residues that could contribute to dietary exposure.

With regard to 52E (1) (d) of the Act, I have considered the formulated product is intended for agricultural professional use only. The HHRA indicated that considering the potential toxicological hazard, use pattern and likelihood of handler exposure, the directions for use, first aid instructions and safety directions should appear on the product label.

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[6] https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/2319

[7] European Food Safety Authority (EFSA), Anastassiadou, M., Arena, M., Auteri, D., Barmaz, S., Brancato, A., Bura, L., Carrasco Cabrera, L., Chaideftou, E., Chiusolo, A., Court Marques, D., Crivellente, F., De Lentdecker, C., Egsmose, M., Fait, G., Ferreira, L., Greco, L., Ippolito, A., Istace, F., Jarrah, S., … Villamar-Bouza, L. (2019). Peer review of the pesticide risk assessment of the active substance dimethyl disulfide. EFSA journal. European Food Safety Authority, 17(11), e05905. https://doi.org/10.2903/j.efsa.2019.5905

Regarding 52E(1)(f) of the Act, the proposed application of dimethyl disulfide is not expected to result in a significant change in the concentration of dimethyl disulfide present in human food. Consequently, this usage should have minimal impact on dietary exposure levels and is considered to pose an acceptable risk for a Schedule 6 poison.

Based on the above considerations and the information provided, I have decided to amend the Poisons (Schedule 6) entry for dimethyl disulfide in the current Poisons Standard in the manner set out above. The proposed amendment was not referred to an expert advisory committee.

Implementation date

1 October 2026

Final decision in relation to enflicoxib sodium

Final Decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to enflicoxib sodium as follows:[8]

Schedule 4 – New Entry

ENFLICOXIB

Index – New Entry

ENFLICOXIB

Schedule 4

Materials considered

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

- the application to amend the current Poisons Standard with respect to enflicoxib (the **Application**)
- 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
- the Handbook.

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

The Application is to amend the current Poisons Standard to create a Prescription animal remedy (Schedule 4) entry for enflicoxib. Enflicoxib is the active ingredient of a currently unregistered veterinary medicine and is not included in the current Poisons Standard.

[8] 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

In determining that this matter will be a delegate-only decision I have taken into account the information provided in the Application, and the matters outlined under s 52E of the Act and the SPF. My reasons for making the final decision follow.

Enflicoxib is a new pyrazoline derivative that belongs to the cyclooxygenase inhibitor (COXIB) class of the non-steroidal anti-inflammatory drugs (NSAID). Enflicoxib is a selective inhibitor of cyclooxygenase-2 (COX-2) enzyme which plays a major role in the synthesis of prostaglandins responsible for mediating the pain and inflammatory response in tissues and organs. The product is intended solely for veterinary use in dogs for the ongoing management of pain and inflammation associated with osteoarthritis.

In relation to subsection 52E(1)(a) of the Act, I note that enflicoxib's principal benefit is its use for the management of osteoarthritis in dogs. Osteoarthritis is a chronic and progressive condition that significantly compromises mobility, welfare and quality of life and generally requires veterinary diagnosis, treatment planning and long-term management (Schedule 4, scheduling factor 1). Enflicoxib may provide sustained analgesic and anti-inflammatory effects that can improve comfort and mobility in affected animals, supporting its therapeutic role in the management of this condition.

The principal risks from enflicoxib include gastrointestinal irritation, ulceration and bleeding which is consistent with the risk profile of other human and veterinary nonsteroidal anti-inflammatory drugs. Repeat-dose toxicity studies identified the gastrointestinal tract as the primary target organ at higher dose levels, and these risks are dose-related and well characterised. These adverse events are clinically significant and require veterinary assessment, monitoring and intervention to minimise harm (Schedule 4, scheduling factor 4). I consider that these risks can be appropriately managed by qualified veterinarians through diagnosis, prescribing and ongoing clinical supervision.

With regard to subsection 52E(1)(b) and (d) of the Act, enflicoxib is intended for oral administration to dogs by their owners under the direction of a veterinarian. The products will be available in tablet form containing 15 mg, 30 mg, 45 mg, 70 mg or 100 mg of enflicoxib per tablet. Tablets will be available in pack sizes of 4, 5, 10, 12, 20, 24, 50 or 100 tablets and packed in child resistant aluminium blister strips inside a standard carton box with a product leaflet. The product will be administered at an initial loading dose of 8 mg enflicoxib/kg bw followed by a maintenance dose of 4 mg/kg bw per week. Since osteoarthritis is a chronic condition, the use pattern of enflicoxib is expected to be long term.

Enflicoxib has been approved for veterinary use in overseas jurisdictions, including the European Union and the United Kingdom. While the overseas usage can provide additional information on its safety and efficacy profile, enflicoxib however, is a new active constituent in Australia and that there is limited local experience of this substance under normal clinical conditions (Schedule 4, scheduling factor 8). Several COX-2 inhibitors e.g. firocoxib, mavacoxib, robenacoxib and cimicoxib are currently classified as Schedule 4 substances without any concentration, dose or preparation exceptions.

In relation to subsection 52E(1)(c) of the Act, enflicoxib has low acute oral toxicity in laboratory animals (LD_{50} > 2,000 mg/kg bodyweight). Short-term repeat-dose toxicity studies in rats and dogs identified dose-related gastrointestinal toxicity, including ulceration and bleeding, at higher exposure levels. Target animal safety studies in dogs demonstrated that enflicoxib was generally well tolerated at up to 5 times the recommended therapeutic dose over a 7-month period, with gastrointestinal effects decreasing over time under controlled veterinary use. Genotoxicity studies were negative. No neurotoxicity, reproductive and developmental toxicity studies or long-term toxicity/carcinogenicity studies were provided, consistent with its intended use in non-food producing animals.

With regard to subsection 52E(1)(e) of the Act, there is no known misuse or abuse potential of the active constituent, enflicoxib.

Enflicoxib is formulated as non-divisible, film-coated tablets in child-resistant blister packaging which will limit accidental exposure. The Australian Pesticides and Veterinary Medicines Authority's (APVMA) Human Health Risk Assessment considered that accidental exposure to 100 mg enflicoxib (highest does table) in children equates to half of the dose of celecoxib – a COX-2 inhibitor approved for use in children and adults. Schedule 4 classification will require a signal heading 'PRESCRIPTION ANIMAL REMEDY' and cautionary statement 'KEEP OUT OF REACH OF CHILDREN'. I concur with the APVMA risk assessment's conclusion the human exposure is expected to be limited and

accidental and human health risks are acceptable when used in accordance with the directions for use and adhering to the safety directions.

Overall, based on the above considerations, I am of the view that the therapeutic benefits of enflicoxib outweigh its risks. Therefore, I have decided to amend the current Poisons Standard in relation to enflicoxib in the manner set out above. The proposed amendment was not referred to an expert advisory committee.

Implementation date

1 June 2026

Final decision in relation to spidoxamat

Final Decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to spidoxamat as follows.[9]

Schedule 5 – New Entry

SPIDOXAMAT

Index – New Entry

SPIDOXAMAT

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 spidoxamat (the **Application**)
- 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.
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

The Application is to amend the current Poisons Standard to create a new entry for spidoxamat as a Caution (Schedule 5) substance. Spidoxamat is one of active constituents for a new insecticide and is not listed in the current Poisons Standard.

In determining that this matter will be a delegate-only decision, I have taken into account the information provided in the Application and the matters outlined under s 52E of the Act and the SPF. My reasons for making the final decision follow.

[9] 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.

Spidoxamat is a tetramic acid analogue belonging to the broader chemical class of insecticides known as 'ketoenols'. Other systemic insecticides of this chemical class, such as spirotetramat and spiropidion have previously been approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Spidoxamat, spirotetramat and spiropidion all target insect growth and development by inhibiting acetyl coenzyme A carboxylase involved in the first step of lipid biosynthesis subsequently leading to death.

In relation to s 52E(1)(a), (b) and (d) of the Act, I note that the formulated product containing spidoxamat is intended for the control of a range of insect pests in cotton. The product is a water-dispersible granule formulation containing aconcentration of 24 g/kg spidoxamat available in packs of 700 g to 100 kg. The product will be applied mechanically by professional users using ground boom or aerial application methods at a rate of 700 g to 1 kg/ha with a maximum of two applications per season at an interval of 10–14 days. The applicant estimated that approximately 125,000 kg of the active constituent will be manufactured or imported during the first 2 years following registration. The product is not expected to replace any existing products currently available on the market.

In relation to s 52E(1)(c) of the Act, spidoxamat, has low acute toxicity by the oral (LD_{50} >2,000 mg/kg bw with no deaths), dermal (LD_{50} >2,000 mg/kg bw with no deaths) and inhalation (LC_{50} >2,150 mg/m^3; 4 h with nose-only exposure and no deaths) routes in the rat. Spidoxamat is a slight eye irritant (rabbit) but is not a skin irritant (rabbit) or a skin sensitiser (mouse local lymph node assay). The toxicological findings are aligned with scheduling factor 1 for classification in Schedule 5.

Spidoxamat did not demonstrate neurotoxic, immunotoxic, developmental, or reproductive toxicity potential in the repeat dose toxicity studies in animals. It was examined for its genotoxic potential in an adequate range of *in vitro* and *in vivo* tests and was found to be negative in all tests. Metabolites and impurities of spidoxamat were tested for genotoxicity in in vitro and all were negative. These findings are consistent with a Schedule 5 classification (scheduling factor 2).

Repeat-dose studies with spidoxamat caused urinary calculi formation in mice, rats and dogs that was linked to its poor solubility at low urinary pH. In the combined chronic toxicity and carcinogenicity studies, spidoxamat showed evidence of urothelial carcinomas of the kidney in rats and urinary bladder in mice. Noting that the formation of urinary calculi and associated toxicity leading to urothelial carcinomas has a threshold and non-genotoxic mode of action, the Australian Pesticides and Veterinary Medicines Authority (APVMA) assessment of spidoxamat concluded that spidoxamat is unlikely to pose a carcinogenic risk to humans based on the established mode of action and lack of genotoxicity. APVMA proposed an acceptable daily intake (ADI) of 0.09 mg/kg bw/day for spidoxamat, based on a no observed adverse effect level (NOAEL) of 9.1 mg/kg bw/day in a sub-chronic (90-day) dietary toxicity study in dogs and an uncertainty factor of 100. An acute reference dose (ARfD) was not determined based on its low acute oral toxicity and the lack of evidence for neurotoxicity or developmental toxicity attributable to a single exposure. The ADI is considered adequately protective of the effects of spidoxamat on the kidney and urinary tract.

Overall, in consideration of the toxicological profile and likely human exposure associated with the use of spidoxamat, the APVMA's Human Health Risk Assessment (HHRA) concluded the human health risk posed by spidoxamat to be acceptable. I concur with the APVMA's toxicology assessments and HHRA findings.

Based on the above considerations and the information provided in the application, I have decided to amend the current Poisons Standard in the manner laid out above. The proposed amendment was not referred to an expert advisory committee.

Implementation date

1 June 2026

Therapeutic Goods Administration

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