Consultation: Proposed Amendments to the Poisons Standard – ACCS, ACMS and Joint ACCS/ACMS meetings, November 2017

Invitation to comment

The TGA is seeking comments from interested parties on the following proposed amendments to the Poisons Standard referred by the delegate for scheduling advice to the Advisory Committee on Chemicals Scheduling (ACCS), the Advisory Committee on Medicines Scheduling (ACMS) and the Joint ACCS-ACMS.

1. Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Chemicals Scheduling (ACCS).

Substance	Proposal	
1-Deoxy-1-(methylamino)-D-glucitol *N*-C10-16 acyl derivatives	CAS number	173145-38-5
	Alternative names	D-glucitol, 1-deoxy-1-(methylamino)-, *N*-C10-16 acyl derivatives (CAS); lauroyl/myristoyl methyl glucamide (INCI); C12-14 linear glucose amide; lauryl methyl glucamide.
	Applicant	National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under their IMAP program
	Current scheduling	New substance not previously considered by the scheduling committee
	Proposed scheduling	To create a new Schedule 6 entry 1-deoxy-1-(methylamino)-D-glucitol *N*-C10-16 acyl derivatives to restrict the use in cosmetic rinse-off and household cleaning preparations and to create new entries in Appendices E and F.
	Key uses/expected use	Cosmetic rinse-off and in household cleaning preparations
	Reasons for proposal	Identified uses in cosmetic and domestic products in the Australian marketplace: • 1-Deoxy-1-(methylamino)-D-glucitol *N*-C10-16 acyl derivatives is used as a surfactant in rinse-off cosmetics at a concentration ≤ 7% and household cleaning products at a concentration ≤ 12%. Widespread and repeated public exposure is expected through the use of products containing the chemical. • Shown to cause irreversible eye damage and severe eye

Substance	Proposal	
		irritation. • Similar substances have recently been listed in Schedule 6 of the Poisons Standard. International restrictions. • Reported use overseas is in cosmetic products however the maximum concentration of the substance in products is not known (Personal Care Products Council, 2017).
Phenyl methyl pyrazolone	CAS number	89-25-8
	Alternative names	3*H*-pyrazol-3-one, 2,4-dihydro-5-methyl-2-phenyl- (CAS); 5-methyl-2-phenyl-4*H*-pyrazol-3-one (IUPAC); 3*H*-pyrazol-3-one, 2,4-dihydro-5-methyl-2-phenyl- (AICS); 3-methyl-1-phenyl-5-pyrazolone (EINECS); evaravone; radicut; norphenazone; norantipyrine; MCI 186
	Applicant	National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under their IMAP program
	Current scheduling	New substance not previously considered by the scheduling committee
	Proposed scheduling	To create a new entry in Schedule 5 or 6 for phenyl methyl pyrazolone for hair dye and eyebrow/eyelash preparations with an exemption cut-off of 0.25% and to create new entries in Appendices E and F.
	Key uses/expected use	Cosmetic and domestic
	Reasons for proposal	Identified uses in cosmetic products in the Australian marketplace: • Included in permanent and semi-permanent hair dye formulations. International regulations: • Use is reported overseas in cosmetic and domestic products at concentrations up to 0.25%. • The Association of Southeast Asian Nations (ASEAN), European Union and New Zealand restrict its concentration for use in oxidative hair dyes to a maximum of 0.25%; • According to the Scientific Committee on Consumer Products (SCCP) opinion (2006) phenyl methyl pyrazolone is considered to be safe as oxidative hair dye ingredient when used up to 0.25% in the finished cosmetic product, apart from

Substance	Proposal	
		its sensitising potential
Fluralaner	CAS number	864731-61-3
	Alternative names	4-[(5*RS*)-5-(3,5-dichlorophenyl)-4,5-dihydro-5-(trifluoromethyl)-1,2-oxazol-3-yl]-*N*-[2-oxo-2-(2,2,2-trifluoroethylamino)ethyl]-*o*-toluamide (IUPAC); rac-4-[(5*R*)-5-(3,5-dichlorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-2-methyl-*N*-{2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl}benzamide (PIN); A-1443
	Applicant	Australian Pesticides and Veterinary Medicines Authority (APVMA)
	Current scheduling	**Schedule 5** FLURALANER for the treatment and prevention of flea infestations and control of ticks in dogs in oral divided preparations each containing 1400 mg or less of fluralaner per dosage unit.
	Proposed scheduling	To amend the current entry for fluralaner in Schedule 5 to include topical or oral veterinary use for cats and dogs.
	Key uses/expected use	Veterinary insecticide; systemic ectoparasiticide
	Reasons for proposal	Scheduling application is for related product(s). Advice from the APVMA is that there are no objections on human health grounds for registration of the product(s).
Afidopyropen	CAS Number	915972-17-7
	Alternative names	[(3*S*,4*R*,4a*R*,6*S*,6a*S*,12*R*,12a*S*,12b*S*)-3-(cyclopropylcarbonyloxy)-1,2,3,4,4a,5,6,6a,12a,12b-decahydro-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(3-pyridyl)-11*H*,12*H*-benzo[*f*]pyrano[4,3-*b*]chromen-4-yl]methyl cyclopropanecarboxylate (IUPAC); [(3*S*,4*R*,4a*R*,6*S*,6a*S*,12*R*,12a*S*,12b*S*)-3-[(cyclopropylcarbonyl)oxy]-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(3-pyridinyl)-2*H*,11*H*-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl cyclopropanecarboxylate (CAS)
	Applicant	Australian Pesticides and Veterinary Medicines Authority (APVMA)
	Current scheduling	New substance not previously considered by the scheduling committee

Substance	Proposal	
	Proposed scheduling	To exempt afidopyropen from scheduling.
	Key uses/expected use	Agricultural insecticide
	Reasons for proposal	Scheduling application is for the active ingredient and related product(s). Advice from the APVMA is that there are no objections on human health grounds for approval of the active constituent or registration of the product(s).
Silver oxide	CAS Number	20667-12-3
	Alternative names	Silver monoxide; argentous oxide; silver rust; 1S/2Ag.O (InChI); silver (I) oxide (IUPAC); silver oxide (CAS)
	Applicant	Australian Pesticides and Veterinary Medicines Authority (APVMA)
	Current scheduling	New substance not previously considered by the scheduling committee
	Proposed scheduling	To exempt silver oxide from scheduling.
	Key uses/expected use	Spa pool sanitiser
	Reasons for proposal	Scheduling application is for the active ingredient and related product(s). Advice from the APVMA is that there are no objections on human health grounds for approval of the active constituent or registration of the product(s).
Alpha-cypermethrin	CAS Number	67375-30-8
	Alternative names	Alphamethrin; (*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (IUPAC); (*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-rel-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate (CAS)
	Applicant	Australian Pesticides and Veterinary Medicines Authority (APVMA)

Substance	Proposal	
	Current scheduling	**Schedule 7** ALPHA-CYPERMETHRIN **except** when included in Schedule 5 or 6. **Schedule 6** ALPHA-CYPERMETHRIN: a) in aqueous preparations containing 25 per cent or less of alpha-cypermethrin; or b) in other preparations containing 10 per cent or less of alpha-cypermethrin, **except** when included in Schedule 5. **Schedule 5** ALPHA-CYPERMETHRIN: a) in aqueous preparations containing 3 per cent or less of alpha-cypermethrin; or b) in other preparations containing 1.5 per cent or less of alpha-cypermethrin.
	Proposed scheduling	To amend the current entry for alpha-cypermethrin in Schedule 6 to increase the cut-off in aqueous preparations from 25 per cent or less to 30 per cent or less.
	Key uses/expected use	Commercial agricultural insecticide
	Reasons for proposal	Scheduling application is for related product(s). Advice from the APVMA is that there are no objections on human health grounds for registration of the product(s).
Dinotefuran	CAS Number	165252-70-0
	Alternative names	1-Methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine (IUPAC); *N*-methyl-*N′*-nitro-*N″*-[(tetrahydro-3-furanyl)methyl]guanidine (CAS); 2-methyl-1-nitro-3-(oxolan-3-ylmethyl)guanidine; 1-methyl-2-nitro-3-((tetrahydrofuran-3-yl)methyl)guanidine; *N* (*RS*)-1-methyl-2-nitro-3-[(tetrahydro-3-furanyl) methyl] guanidine; MTI-446
	Applicant	Australian Pesticides and Veterinary Medicines Authority (APVMA)

Substance	Proposal	
	Current scheduling	**Schedule 5** DINOTEFURAN.
	Proposed scheduling	To amend the current entry for dinotefuran in Schedule 5 to exclude preparations containing 10 per cent or less of dinotefuran.
	Key uses/expected use	Insecticide
	Reasons for proposal	Scheduling application is for related product(s). Advice from the APVMA is that there are no objections on human health grounds for registration of the product(s).
Metofluthrin	CAS Number	240494-70-6
	Alternative names	[2,3,5,6-Tetrafluoro-4-(methoxymethyl)phenyl]methyl 2,2-dimethyl-3-[(*E*)-prop-1-enyl]cyclopropane-1-carboxylate (IUPAC); (2,3,5,6-tetrafluoro-4-methoxymethylphenyl)methyl-2,2-dimethyl-3-(1-propenyl)cyclopropanecarboxylate
	Applicant	Australian Pesticides and Veterinary Medicines Authority (APVMA)
	Current scheduling	**Schedule 6** METOFLUTHRIN **except** when included in Schedule 5. **Schedule 5** METOFLUTHRIN: a) in impregnated fabric mosquito repellent preparations for use in a vaporiser containing 15 mg or less of metofluthrin per disk; or b) when impregnated into a polyethylene slow release matrix containing 250 mg or less of metofluthrin for use as a mosquito repellent.
	Proposed scheduling	To amend the current entry for metofluthrin in Schedule 5 to remove "*as a mosquito repellent*" in subclause b) '*when impregnated into a polyethylene slow release matrix containing 250 mg or less of metofluthrin'*.
	Key uses/expected use	Insect repellent

Substance	Proposal	
	Reasons for proposal	Scheduling application is for related product(s). Advice from the APVMA is that there are no objections on human health grounds for registration of the product(s).

2. Proposed amendments referred by the delegates to the Joint Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS) for scheduling advice.

Substance	Proposal	
Salts of boric acid	CAS numbers and names	1330-43-4 Boric acid ($H_2B_4O_7$), disodium salt; boron sodium oxide, ($B_4Na_2O_7$) (CAS); sodium borate (INCI); disodium tetraborate; sodium borate anhydrous; disodium tetraborate, anhydrous
		1332-77-0 Boric acid ($H_2B_4O_7$), dipotassium salt; boron potassium oxide ($B_4K_2O_7$) (CAS); potassium tetraborate; potassium borate; dipotassium tetraborate
		26038-87-9 Boric acid (H_3BO_3), compd. with 2-aminoethanol; monoethanolamine, boric acid salt; Boric acid (H_3BO_3), compd. with 2-aminoethanol (1:?) (CAS); MEA-borate (INCI)
		26038-90-4 Boric acid (H_3BO_3), compd. with 1-amino-2-propanol (1:?) (CAS); MIPA-borate (INCI); boric acid, monoisopropanolamine salt; 1-aminopropan-2-ol, compound with orthoboric acid; orthoboric acid isopropanolamine salt
		68003-13-4 Boric acid (H_3BO_3), compd. with 1-amino-2-propanol (1:1) (CAS); MIPA-borate (INCI); Isopropanolamine borate; (2-hydroxypropyl)ammonium dihydrogen orthoborate
	Applicant	National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under their IMAP program
	Current scheduling	**Schedule 4** BORON, including boric acid and borax, for human therapeutic use **except**: a) in preparations for internal use containing 6 mg or less of boron per recommended daily dose; b) in preparations for dermal use containing 0.35 per cent or less of boron, which are not for

Substance	Proposal	
		paediatric or antifungal use; or c) when present as an excipient. **Schedule 5** BORIC ACID (excluding its salts) and BORAX **except**: a) when included in Schedule 4; b) in preparations, other than insect baits, containing 1 per cent or less of boron; or c) in hand cleaning preparations. **Appendix E, Part 2** BORIC ACID Standard statements: A (For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once)). **Index** **BORON** cross reference: BORATES, BORAX, BORIC ACID, BORON COMPOUNDS Schedule 4
	Proposed scheduling	To amend the current entry for boric acid in Schedule 5, removing "*excluding its salts*" so the salts of boric acid are captured by the entry
	Key uses/expected use	Cosmetics, domestic and therapeutic
	Reasons for proposal	Although there is no specifically identified use in cosmetic and domestic products in the Australian marketplace, the chemicals are known to be used in cosmetic and domestic products internationally. International regulations: • Use is reported overseas in cosmetic and domestic products at concentrations up to 30% (CAS Nos. 1330-43-4, 1332-77-0). • The European Union concentration restrictions for boric acid in cosmetics include up to 5% when used in talc, up to 3% in 'other products' and up to 0.1% in oral products. • In Canada, the cosmetic ingredient hotlist restricts the use of the chemicals identified by the CAS Nos. 1330-43-4 26038-90-4 and 68003-13-4 to a maximum concentration of 0.1% (as a

Substance	Proposal		
		pH adjuster) and 5% (in other cosmetic products).	
Helium	CAS Number	7440-59-7	
	Applicant	Australian Competition and Consumer Commission (ACCC)	
	Current scheduling	New substance not previously considered by the scheduling committee	
	Proposed scheduling	To create new entries in Schedules 6 and 7 and Appendices E and F for helium with cut-offs. The proposal also requires helium gas to be in pressurised gas canisters or cylinders containing an aversive when being sold to or hired by consumers intended for household or domestic use.	
	Key uses/expected use	Domestic, commercial, medical and industrial	
	Reasons for proposal	• To mitigate public health risks by asphyxiation.	
Polihexanide	CAS number	28757-47-3	27083-27-8
	Alternative names	1-(diaminomethylidene)-2-hexylguanidine (IUPAC); poly(iminocarbonimidoylimino carbonimidoyl imino-1,6-hexanediyl); polyhexamethylene biguanide (PHMB)	2-[6-[[amino-(cyanoamino)methylidene]amino]hexyl]-1-cyanoguanidine; hexane-1,6-diamine; hydrochloride (IUPAC); *N,N'''*-1,6-hexanediylbis[*N*'-cyanoguanidine polymer with 1,6-hexanediamine, hydrochloride; polyhexamethylene biguanide (PHMB) hydrochloride; polyhexamethlenebiguanidine
	Applicant	National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under their IMAP program	
	Current scheduling	**Schedule 6** POLIHEXANIDE **except**: a) in preparations containing 5 per cent or less of polihexanide; or b) when packed and labelled for therapeutic use.	

Substance	Proposal	
		Appendix E, Part 2 POLIHEXANIDE Standard Statement: E1 (If in eyes, wash out immediately with water). **Appendix F, Part 3** POLIHEXANIDE Safety Directions: 1 (Avoid contact with eyes); 4 (Avoid contact with skin); 8 (Avoid breathing dust (or) vapour (or) spray mist).
	Proposed scheduling	To amend the Schedule 6 entry cut-off of polihexanide from 5 per cent to 0.3 per cent or less of polihexanide, and to amend the Appendix F, Part 3 entry to include Warning Statement 28 (Repeated exposure may cause sensitisation).
	Key uses/expected use	Cosmetic, domestic, veterinary and medical
	Reasons for proposal	No identified uses in cosmetic and domestic products in the Australian marketplace. International regulations: • European Union and New Zealand restrictions allow maximum concentration of 0.3 per cent when used as a preservative in cosmetic products.
Cimicoxib	CAS Number	265114-23-6
	Alternative names	4-[4-Chloro-5-(3-fluoro-4-methoxyphenyl)-1*H*-imidazol-1-yl]benzenesulfonamide (IUPAC); benzenesulfinamide, 4-[4-chloro-5-(3-fluoro-4-methoxyphenyl)-1*H*-imidazole-1-yl] (CAS); UR-8880
	Applicant	Australian Pesticides and Veterinary Medicines Authority (APVMA)
	Current scheduling	New substance not previously considered by the scheduling committee
	Proposed scheduling	To create a new entry for cimicoxib in Schedule 4 for veterinary use.
	Key uses/expected use	Veterinary: non-steroidal anti-inflammatory drug and selective cyclooxygenase-2 (COX-2) inhibitor

Substance	Proposal	
	Reasons for proposal	Scheduling application is for the active ingredient and related product(s). Advice from the APVMA is that there are no objections on human health grounds for approval of the active constituent or registration of the product(s).

3. Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling (ACMS).

Substance	Proposal
Hyaluronic acid	A request has been made to amend the Schedule 4 entry for hyaluronic acid to include '*d) for intra-articular injection.*'
Cardarine	A request has been made to create a new Schedule 9 or Schedule 4 entry for cardarine (GW501516).
Stenabolic (SR9009) and other synthetic REV-ERB agonists	A request has been made to create a new Schedule 4 or Schedule 9 entry for stenabolic (SR9009) and other synthetic REV-ERB agonists, including SR9011, GSK2945, GSK0999, GSK5072 and GSK2667.
Ibutamoren	A request has been made to create a new Schedule 4 entry for ibutamoren (Nutrobal). The proposal is also to include ibutamoren (Nutrobal) in Appendix D, Part 5 due to its potential for misuse and abuse in sports doping.
Cathinones, methylone (MDMC) and alpha-pyrrolidinovalerophenone (alpha-PVP)	A request has been made to: • Create a new Schedule 4 and Appendix D, or Schedule 9 entry for alpha-pyrrolidinovalerophenone (alpha-PVP); • Create a new Schedule 4 and Appendix D, or Schedule 9 entry for methylone (MDMC); AND • Amend the Schedule 9 entry for cathinone to cathinones **except** when separately specified in these Schedules; OR • Create a new Schedule 4 and Appendix D, or Schedule 9 entry for synthetic cathinones **except** when separately specified in these Schedules.
Melanotan II	A request has been made to create a new Schedule 10 entry for melanotan II for cosmetic or therapeutic use.

Substance	Proposal
Clotrimazole	A request has been made to: • Amend the Schedule 2 entry for clotrimazole to include the phrase "*in vaginal preparations*"; • Delete the Schedule 3 entry and Appendix H listing for clotrimazole; • Amend the Schedule 4 entry for clotrimazole to delete the reference to Schedule 3; and • Amend the Appendix F listing for clotrimazole to change the reference from Schedule 3 to Schedule 2.
Orphenadrine	A request has been made to reschedule orphenadrine from Schedule 4 to Schedule 3 when compounded with paracetamol in oral preparations containing 35 mg or less of orphenadrine per dosage unit in packs containing 24 or less dosage units when used for the relief of pain associated with skeletal muscle spasm in adults and children over 12 years of age.
Ibuprofen	A request has been made to: • Amend the Schedule 2 entry for ibuprofen to restrict no more than 30 dosage units when in divided preparations containing 200 mg or less of ibuprofen in a primary pack (down from current 100 dosage units); • Delete the exemptions in the Schedule 2 entry for ibuprofen that currently allow general sale of up to 25 dosage units of 200 mg ibuprofen; and • Amend the Schedule 3 entry for ibuprofen to allow up to 100 dosage units containing 200 mg or less of ibuprofen in a primary pack.

Timetable

Document released for consultation on 6 September 2017.

Interested parties should respond by close of business 6 October 2017.

Feedback will be released following consideration of submissions. (See 'What will happen').

About the consultation

This consultation is inviting public submissions under subsection 42ZCZK/42ZCZL of the *Therapeutic Goods Regulations 1990* (the Regulations).

The delegate of the Secretary of the Department of Health hereby gives notice that the proposed amendments to the current Poisons Standard contained in this notice will be referred for scheduling advice to relevant expert advisory committees.

Accordingly, the above scheduling proposals are open for public submissions. Submissions must be relevant to the proposed amendment, must address a matter mentioned in section 52E of the *Therapeutic Goods Act 1989* and be received by the closing date.

Content of submissions

Submissions may address any, or all, of the proposed amendments to the Poisons Standard or other identified issues.

In addition, submissions might include:

- Suggested improvements.
- Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
- An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

How to respond

All submissions should be accompanied by a TGA submission coversheet. Submissions must include full personal or organisational contact details (including address, telephone number and email).

- Print version: Consultation submission coversheet (Microsoft Word,61kb)

Electronic submissions are preferred:

- Submissions regarding substances referred to the ACMS or Joint ACCS-ACMS should be emailed to medicines.scheduling@health.gov.au. Please include 'Proposed Amendments to the Poisons Standard (Medicines)' in the subject line of the email.
- Submissions regarding substances referred to the ACCS should be emailed to chemicals.scheduling@health.gov.au. Please include 'Proposed Amendments to the Poisons Standard (Chemicals)' in the subject line of the email.

What will happen

All submissions will be placed on the TGA Internet site unless marked confidential or indicated otherwise in the submission coversheet (see Privacy information).

Submissions will be reviewed by the TGA and published on the TGA Internet website: feedback on submissions will be provided through the TGA Internet site: https://www.tga.gov.au/public-submissions-scheduling-matters.

Scheduling decisions made by the medicines and/or chemicals delegates following consideration of submissions from interested parties, along with advice from the Advisory Committee on Chemicals Scheduling (ACCS), the Advisory Committee on Medicines Scheduling (ACMS) and the Joint ACCS-ACMS will be published on the TGA website as interim decisions.

Privacy information

- The TGA collects your personal information in this submission in order to:
  - contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available.

  - help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).

- The TGA will disclose your name and (if applicable) your designation/work title on the TGA Internet site (i.e. make this information publicly available) if you consent to the publication of your name on the TGA Internet site (please complete the coversheet).
- Any text within the body of your submission that you want to remain confidential should be clearly marked 'IN CONFIDENCE'.
- Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Enquiries

Any questions relating to submissions should be directed by email to medicines.scheduling@health.gov.au (for substances referred to the ACMS or Joint ACCS-ACMS) or chemicals.scheduling@health.gov.au (for substances referred to the ACCS).