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Agricultural and veterinary chemicals

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The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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Assistant Director, Communications  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

Email: [communications@apvma.gov.au](mailto:communications@apvma.gov.au)  
Website: [apvma.gov.au](http://www.apvma.gov.au)

General information

The APVMA Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

Distribution and subscription

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APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

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Agricultural chemical products and approved labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

Table 1: Agricultural products based on existing active constituents

| Application no. | 135349 |
| --- | --- |
| Product name | Kelpie Diquat 200SL Herbicide |
| Active constituent/s | 200 g/L diquat present as diquat dibromide monohydrate |
| Applicant name | Sinochem International Australia Pty. Ltd. |
| Applicant ACN | 160 164 616 |
| Date of registration | 2 August 2022 |
| Product registration no. | 92386 |
| Label approval no. | 92386/135349 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 200 g/L diquat SL product for pre-harvest crop desiccation and the control of a wide range of broadleaf weeds in certain crops as per directions for use for application through aircraft and ground equipment |

| Application no. | 135703 |
| --- | --- |
| Product name | Akoprid 350 Insecticide |
| Active constituent | 350 g/L imidacloprid |
| Applicant name | AAKO Australia Pty Ltd |
| Applicant ACN | 122 279 109 |
| Date of registration | 3 August 2022 |
| Product registration no. | 92491 |
| Label approval no. | 92491/135703 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 350 g/L imidacloprid suspension concentrate product for the control of various insect pests of cotton, fruit, vegetables, ornamentals, and turf as a foliar spray and as a soil-applied treatment for the control of various canegrubs in sugarcane, certain pests in apples and citrus, and silverleaf whitefly in various vegetable crops and an injection treatment for control of certain pests in bananas |

| Application no. | 131802 |
| --- | --- |
| Product name | Genfarm Picolinafen 750 WG Herbicide |
| Active constituent | 750 g/kg picolinafen |
| Applicant name | Nutrien Ag Solutions Limited |
| Applicant ACN | 008 743 217 |
| Date of registration | 8 August 2022 |
| Product registration no. | 91313 |
| Label approval no. | 91313/131802 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 750 g/kg picolinafen herbicide for the control of wild radish in field peas and narrowleaf lupins |

| Application no. | 131794 |
| --- | --- |
| Product name | Optima Ant & Cockroach Granules |
| Active constituent | 0.15 g/kg fipronil |
| Applicant name | Lifeguard Sciences (Pty) Ltd |
| Applicant ACN | N/A |
| Date of registration | 10 August 2022 |
| Product registration no. | 91312 |
| Label approval no. | 91312/131794 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration and label approval of a 0.15 g/kg fipronil ready-to-use granular bait for the control of ants, cockroaches and crickets |

| Application no. | 135497 |
| --- | --- |
| Product name | Aquatic Elements Liquid Pool Chlorine |
| Active constituent | 125 g/L available chlorine (CI) present as sodium hypochlorite |
| Applicant name | Aquatic Elements Pty Ltd |
| Applicant ACN | 134 196 679 |
| Date of registration | 11 August 2022 |
| Product registration no. | 92435 |
| Label approval no. | 92435/135497 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 125 g/L sodium hypochlorite product for the control of algae and bacteria in swimming pools |

Table 2: Variations of registration

|  |  |
| --- | --- |
| Application no. | 136325 |
| Product name | Nufarm 2,4-D Ester 680 Herbicide |
| Active constituent | 680 g/L 2,4-D present as the 2-ethylhexyl ester |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of variation | 21 July 2022 |
| Product registration no. | 60938 |
| Label approval no. | 60938/136325 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from ‘Nufarm Estercide Xtra 680 Herbicide’ to ‘Nufarm 2,4-D Ester 680 Herbicide’ |

|  |  |
| --- | --- |
| Application no. | 136355 |
| Product name | Penncozeb 750 DF Fungicide |
| Active constituent | 750 g/kg mancozeb |
| Applicant name | UPL Australia Pty Ltd |
| Applicant ACN | 066 391 384 |
| Date of variation | 25 July 2022 |
| Product registration no. | 53987 |
| Label approval no. | 53987/136355 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to update the first aid instructions, safety directions and safety directions appearing on a label to reflect the current FAISD Handbook |

|  |  |
| --- | --- |
| Application no. | 136356 |
| Product name | Vendex Miticide |
| Active constituent | 550 g/L fenbutatin oxide |
| Applicant name | UPL Australia Pty Ltd |
| Applicant ACN | 066 391 384 |
| Date of variation | 25 July 2022 |
| Product registration no. | 68860 |
| Label approval no. | 68860/136356 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook |

|  |  |
| --- | --- |
| Application no. | 136374 |
| Product name | Viraban Broad Spectrum Virucidal, Bactericidal and Fungicidal Powder Disinfectant |
| Active constituents | 504 g/kg potassium peroxymonosulfate triple salt, 150 g/kg sodium dodecylbenzene sulphonate, 15 g/kg sodium chloride |
| Applicant name | Elanco Australasia Pty Ltd |
| Applicant ACN | 076 745 198 |
| Date of variation | 26 July 2022 |
| Product registration no. | 65013 |
| Label approval no. | 65013/136374 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook |

|  |  |
| --- | --- |
| Application no. | 136389 |
| Product name | Zoono Z-71 “Ready To Use” Poultry Guard Sanitiser and Protectant |
| Active constituent | 0.67 g/L quaternary ammonium compound |
| Applicant name | Zoono Group Limited |
| Applicant ACN | 006 645 754 |
| Date of variation | 27 July 2022 |
| Product registration no. | 89529 |
| Label approval no. | 89529/136389 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to change the distinguishing name that appears on the label from ‘YP VET 21 Surface Sanitiser and Protectant’ to ‘Xtend RTU Surface Sanitiser and Protectant’ |

| Application no. | 135369 |
| --- | --- |
| Product name | Trio Prosulfocarb 800 EC Herbicide |
| Active constituent/s | 800 g/L prosulfocarb |
| Applicant name | CTS Chemicals Pty Ltd |
| Applicant ACN | 605 759 644 |
| Date of registration | 1 August 2022 |
| Product registration no. | 90161 |
| Label approval no. | 90161/135369 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of product registration and label approval to update the constituent and mode of action label statements |

| Application no. | 135291 |
| --- | --- |
| Product name | Oxstar Herbicide Coated Fertiliser |
| Active constituent/s | 10 g/kg oxadiazon |
| Applicant name | Turf Culture Pty Ltd |
| Applicant ACN | 117 986 615 |
| Date of variation | 1 August 2022 |
| Product registration no. | 83464 |
| Label approval no. | 83464/135291 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration, label approval and label conditions to include a new label for home garden use |

| Application no. | 134424 |
| --- | --- |
| Product name | Genfarm Propyzamide 500 WG Selective Herbicide |
| Active constituent | 500 g/kg propyzamide |
| Applicant name | Nutrien Ag Solutions Limited |
| Applicant ACN | 008 743 217 |
| Date of variation | 2 August 2022 |
| Product registration no. | 66962 |
| Label approval no. | 66962/134424 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to add use pattern for control of certain grasses and broad leaf weeds in canola |

| Application no. | 135361 |
| --- | --- |
| Product name | Thermacell Zone Mosquito Repellent |
| Active constituent | 43.8 g/L metofluthrin |
| Applicant name | Thermacell Repellents Inc. |
| Applicant ACN | N/A |
| Date of variation | 3 August 2022 |
| Product registration no. | 89453 |
| Label approval no. | 89453/135361 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of product registration and label approval to amend the net contents, update the constituent statements and make minor changes to the label |

|  |  |
| --- | --- |
| Application no. | 136464 |
| Product name | Nufarm Chlorthal-Dimethyl 900 Herbicide |
| Active constituent | 900 g/kg chlorthal dimethyl |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of variation | 3 August 2022 |
| Product registration no. | 59137 |
| Label approval no. | 59137/136464 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from ‘Nufarm Dacthal 900 Pre-Emergence Herbicide’ to ‘Nufarm Chlorthal-Dimethyl 900 Herbicide’ |

| Application no. | 135454 |
| --- | --- |
| Product name | KDPC Prethal 750WG Herbicide |
| Active constituent | 750 g/kg chlorthal dimethyl |
| Applicant name | KD Plant Care Pty Ltd |
| Applicant ACN | 134 592 804 |
| Date of variation | 4 August 2022 |
| Product registration no. | 67445 |
| Label approval no. | 67445/135454 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to add a grazing WHP and remove uses for perennial grasses and lucerne |

| Application no. | 135460 |
| --- | --- |
| Product name | Accensi Thiram/Thiabendazole Fungicidal Liquid Seed Dressing |
| Active constituents | 360 g/L thiram, 200 g/L thiabendazole |
| Applicant name | Accensi Pty Ltd |
| Applicant ACN | 079 875 184 |
| Date of variation | 5 August 2022 |
| Product registration no. | 64451 |
| Label approval no. | 64451/135460 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label to add use in peanuts for control of pre-emergence seedling rot (*Rhizopus spp.*) and seedling blight (*Aspergillus spp.*) |

| Application no. | 135382 |
| --- | --- |
| Product name | Palmero 750 WG Herbicide |
| Active constituent | 750 g/kg isoxaflutole |
| Applicant name | ADAMA Australia Pty Ltd |
| Applicant ACN | 050 328 973 |
| Date of variation | 5 August 2022 |
| Product registration no. | 68600 |
| Label approval no. | 68600/135382 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to registration particular and label particulars to include use in fallow and to add the control of turnip weed in sugarcane |

| Application no. | 135462 |
| --- | --- |
| Product name | Tecto Flowable SC Fungicide |
| Active constituent | 500 g/L thiabendazole |
| Applicant name | Syngenta Australia Pty Ltd |
| Applicant ACN | 002 933 717 |
| Date of variation | 5 August 2022 |
| Product registration no. | 49910 |
| Label approval no. | 49910/135462 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of product registration and label to add uses in sweet potato as part of the permit to label project |

| Application no. | 135742 |
| --- | --- |
| Product name | Lawthal 750WG Herbicide |
| Active constituent | 750 g/kg chlorthal-dimethyl |
| Applicant name | Nutrien Ag Solutions Limited |
| Applicant ACN | 008 743 217 |
| Date of variation | 5 August 2022 |
| Product registration no. | 83116 |
| Label approval no. | 83116/135742 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of product registration and label approval to remove uses in lucerne and perennial grass pasture and to add the grazing restraint 'DO NOT graze any treated areas or cut for stock food' |

|  |  |
| --- | --- |
| Application no. | 136503 |
| Product name | Proleaf T Seed Treatment |
| Active constituents | 150 g/L triadimenol, 4 g/L triflumuron |
| Applicant name | Arysta LifeScience Australia Pty Ltd |
| Applicant ACN | 005 225 507 |
| Date of variation | 5 August 2022 |
| Product registration no. | 54162 |
| Label approval no. | 54162/136503 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to update the first aid instructions appearing on a label to reflect the current FAISD Handbook |

| Application no. | 135435 |
| --- | --- |
| Product name | Hemani Chlorthal 750 WG Herbicide |
| Active constituent | 750 g/kg chlorthal dimethyl |
| Applicant name | Hemani Australia Pty Ltd |
| Applicant ACN | 634 346 357 |
| Date of variation | 9 August 2022 |
| Product registration no. | 85327 |
| Label approval no. | 85327/135435 |
| Description of the application and its purpose, including the intended use of the chemical product | To vary registration particulars and label to add a grazing WHP and delete uses for perennial grasses and lucerne |

| Application no. | 133464 |
| --- | --- |
| Product name | Electra 225 Insecticide |
| Active constituent | 225 g/L methomyl (an anti-cholinesterase compound) |
| Applicant name | ADAMA Australia Pty Ltd |
| Applicant ACN | 050 328 973 |
| Date of variation | 10 August 2022 |
| Product registration no. | 48910 |
| Label approval no. | 48910/133464 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of product registration and label approval to extend the use in various additional crops/situations |

| Application no. | 131481 |
| --- | --- |
| Product name | Aduleth Termiticide |
| Active constituent/s | 8.8 g/L bifenthrin |
| Applicant name | The White Ant Co. Pty. Ltd. |
| Applicant ACN | 100 706 009 |
| Date of variation | 12 August 2022 |
| Product registration no. | 65633 |
| Label approval no. | 65633/131481 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the particulars of registration and label approval to update the label hazard and safety direction statements |

Table 3: Variation of label approval

| Application no. | 135377 |
| --- | --- |
| Product name | Farmalinx Clearview 200 GR Herbicide |
| Active constituent | 200 g/kg tebuthiuron |
| Applicant name | Farmalinx Pty Ltd |
| Applicant ACN | 134 353 245 |
| Date of variation | 5 August 2022 |
| Product registration no. | 69043 |
| Label approval no. | 69043/135377 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to particulars of label, to vary the states in the directions for use table and add ground and aerial application |

| Application no. | 135829 |
| --- | --- |
| Product name | Imtrade Chemphos 400 Fungicide |
| Active constituent | 400 g/L phosphonic acid |
| Applicant name | Imtrade Australia Pty Ltd |
| Applicant ACN | 090 151 134 |
| Date of variation | 9 August 2022 |
| Product registration no. | 54077 |
| Label approval no. | 54077/135829 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of label approval to add a timing restriction for use in grapes ‘do not apply after E-L 33’ |

| Application no. | 135828 |
| --- | --- |
| Product name | Imtrade Dominator 600 Fungicide |
| Active constituent | 600 g/L phosphorous (phosphonic) acid as mono-di K phosphonate |
| Applicant name | Imtrade Australia Pty Ltd |
| Applicant ACN | 090 151 134 |
| Date of variation | 10 August 2022 |
| Product registration no. | 56975 |
| Label approval no. | 56975/135828 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of label approval to add a timing restriction for use in grapes ‘do not apply after E-L 33’ |

Veterinary chemical products and approved labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

Table 4: Veterinary products based on existing active constituents

| Application no. | 134411 |
| --- | --- |
| Product name | Clavox L Broad Spectrum Antibiotic Tablets |
| Active constituent | 500 mg/tablet amoxycillin (as the trihydrate), 125 mg/tablet clavulanic acid (as potassium clavulanate) |
| Applicant name | Abbey Laboratories Pty Ltd |
| Applicant ACN | 156 000 430 |
| Date of variation | 1 August 2022 |
| Product registration no. | 92071 |
| Label approval no. | 92071/134411 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 500 mg amoxycillin (as the trihydrate), 125 mg clavulanic acid (as potassium clavulanate) tablet for the treatment of bacterial infections sensitive to clavulanic acid and amoxycillin in large dogs |

| Application no. | 132153 |
| --- | --- |
| Product name | Praziquantel 50 mg Tablet |
| Active constituent | 50 mg/tablet praziquantel |
| Applicant name | Ashish Life Science Pvt Ltd |
| Applicant ACN | N/A |
| Date of variation | 2 August 2022 |
| Product registration no. | 91414 |
| Label approval no. | 91414/132153 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 50 mg/tb praziquantel tablet for the control of tapeworms in dogs and cats |

| Application no. | 134410 |
| --- | --- |
| Product name | Clavox S Broad Spectrum Antibiotic Tablets |
| Active constituent | 50 mg/tablet amoxycillin (as the trihydrate), 12.5 mg/tablet clavulanic acid (as potassium clavulanate) |
| Applicant name | Abbey Laboratories Pty Ltd |
| Applicant ACN | 156 000 430 |
| Date of variation | 2 August 2022 |
| Product registration no. | 92070 |
| Label approval no. | 92070/134410 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 50 mg amoxycillin (as the trihydrate), 12.5 mg clavulanic acid (as potassium clavulanate) tablet for the treatment of bacterial infections sensitive to clavulanic acid and amoxycillin in cats and small dogs |

| Application no. | 134754 |
| --- | --- |
| Product name | Prazimax Duo Broad Spectrum Antiparasitic Paste for Horses |
| Active constituent | 77.5 mg/g praziquantel, 15.5 mg/g ivermectin |
| Applicant name | Abbey Laboratories Pty Ltd |
| Applicant ACN | 156 000 430 |
| Date of variation | 2 August 2022 |
| Product registration no. | 92178 |
| Label approval no. | 92178/134754 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of 15.5 mg/g ivermectin and 77.5 mg/g praziquantel paste product for oral administration to treat and control intestinal round worms (including larval stages of *Strongylus vulgaris* in intestinal arteries and benzimidazole resistant strongyles), lungworms, tapeworms, bots, and skin lesions caused by *Habronema* and *Draschia spp*. (summer sores) and *Onchocerca spp*. microfilariae (*Cutaneous onchocerciasis*) in horses |

| Application no. | 135472 |
| --- | --- |
| Product name | Equacare Joint Health Powder for Horses |
| Active constituent | 500 g/kg glucosamine hydrochloride |
| Applicant name | Equacare Pty Ltd |
| Applicant ACN | 650 408 861 |
| Date of variation | 2 August 2022 |
| Product registration no. | 92430 |
| Label approval no. | 92430/135472 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 500 g/kg glucosamine hydrochloride powder product to help improve joint health and function in horses |

| Application no. | 136016 |
| --- | --- |
| Product name | Acti-trace Injection for Cattle |
| Active constituent | 40 g/L zinc as disodium zinc EDTA, 15 g/L copper as disodium copper EDTA, 10 g/L manganese as disodium manganese EDTA, 5 g/L selenium as sodium selenite |
| Applicant name | Virbac (Australia) Pty Ltd |
| Applicant ACN | 003 268 871 |
| Date of variation | 2 August 2022 |
| Product registration no. | 92616 |
| Label approval no. | 92616/136016 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 40 g/L zinc as disodium zinc EDTA, 15 g/L copper as disodium copper EDTA, 10 g/L manganese as disodium manganese EDTA and 5 g/L selenium as sodium selenite injectable product for use in beef and dairy cattle to supplement zinc, copper, selenium and manganese |

| Application no. | 134557 |
| --- | --- |
| Product name | Azacalm Neuroleptic Injection for Pigs |
| Active constituent | 40 mg/mL azaperone |
| Applicant name | Vetpharm Laboratories IP Pty Ltd |
| Applicant ACN | 654 406 756 |
| Date of variation | 9 August 2022 |
| Product registration no. | 92117 |
| Label approval no. | 92117/134557 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of 40 mg/mL azaperone injectable parental solution product for psychomotor sedation in pigs |

Table 5: Variations of registration

| Application no. | 135353 |
| --- | --- |
| Product name | Troy Vitamin B12 Injection |
| Active constituent | 1 mg/mL cyanocobalamin |
| Applicant name | Troy Laboratories Pty Ltd |
| Applicant ACN | 000 283 769 |
| Date of variation | 2 August 2022 |
| Product registration no. | 52509 |
| Label approval no. | 52509/135353 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of relevant particulars of the product and label to amend the claim as well as update the label to the current Veterinary Labelling Code |

| Application no. | 135338 |
| --- | --- |
| Product name | Entrodox 100 g Microgranulate Feed Additive |
| Active constituent | 100 g/kg olaquindox |
| Applicant name | Dox-al Australia Pty Ltd |
| Applicant ACN | 079 454 265 |
| Date of variation | 3 August 2022 |
| Product registration no. | 49013 |
| Label approval no. | 49013/135338 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the conditions of the label approval by aligning to the current Veterinary Labelling Code |

| Application no. | 135339 |
| --- | --- |
| Product name | Ilium Meloxicam Anti-Inflammatory Oral Suspension for Dogs |
| Active constituent | 1.5 mg/mL meloxicam |
| Applicant name | Troy Laboratories Pty Ltd |
| Applicant ACN | 000 283 769 |
| Date of variation | 5 August 2022 |
| Product registration no. | 60023 |
| Label approval no. | 60023/135339 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the relevant particulars of the product and label by updating the dosing instructions and marketed label name |

| Application no. | 135342 |
| --- | --- |
| Product name | Ilium Meloxicam 0.5 Anti-Inflammatory Oral Suspension for Cats |
| Active constituent | 0.5 mg/mL meloxicam |
| Applicant name | Troy Laboratories Pty Ltd |
| Applicant ACN | 000 283 769 |
| Date of variation | 5 August 2022 |
| Product registration no. | 63845 |
| Label approval no. | 63845/135342 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the relevant particulars of the product and label by updating the dosing instructions and marketed label name |

| Application no. | 133057 |
| --- | --- |
| Product name | Nobivac Flex DHP Live Vaccine |
| Active constituent | ≥4.0 log10 TCID50 canine distemper virus strain onderstepoort, ≥4.0 log10 TCID50 canine adenovirus type 2 strain Manhattan, ≥7.0 log10 TCID50 canine parvovirus strain 154 |
| Applicant name | Intervet Australia Pty Ltd |
| Applicant ACN | 008 467 034 |
| Date of variation | 9 August 2022 |
| Product registration no. | 59043 |
| Label approval no. | 59043/133057 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of the relevant particulars of the product and the label to update claims and dosage and administration |

| Application no. | 133059 |
| --- | --- |
| Product name | Nobivac Flex DHPPi Live Vaccine |
| Active constituent | ≥4.0 log10 TCID50 canine distemper virus strain onderstepoort, ≥4.0 log10 TCID50 canine adenovirus type 2 strain Manhattan, ≥7.0 log10 TCID50 canine parvovirus strain 154, ≥5.5 log10 TCID50 canine parainfluenza strain cornell |
| Applicant name | Intervet Australia Pty Ltd |
| Applicant ACN | 008 467 034 |
| Date of variation | 9 August 2022 |
| Product registration no. | 56912 |
| Label approval no. | 56912/133059 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of the relevant particulars of the product and the label to update claims and dosage and administration |

Approved active constituents

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

Table 6: Active constituent

| Application no. | 132681 |
| --- | --- |
| Active constituent/s | Praziquantel |
| Applicant name | Ashish Life Science Pvt Ltd |
| Applicant ACN | N/A |
| Date of approval | 2 August 2022 |
| Approval no. | 91575 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent praziquantel for use in veterinary chemical products |

| Application no. | 134119 |
| --- | --- |
| Active constituent/s | Isoxaflutole |
| Applicant name | Asynagro Company Limited |
| Applicant ACN | N/A |
| Date of approval | 2 August 2022 |
| Approval no. | 91995 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent isoxaflutole for use in agricultural chemical products |

| Application no. | 135275 |
| --- | --- |
| Active constituent/s | Methadone hydrochloride |
| Applicant name | Avet Health Pty Ltd |
| Applicant ACN | 616 838 101 |
| Date of approval | 2 August 2022 |
| Approval no. | 92359 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent methadone hydrochloride for use in veterinary chemical products |

| Application no. | 133600 |
| --- | --- |
| Active constituent | Clethodim |
| Applicant name | Yun Cropcare Co Ltd |
| Applicant ACN | N/A |
| Date of approval | 3 August 2022 |
| Approval no. | 91828 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent clethodim for use in agricultural chemical products |

| Application no. | 134582 |
| --- | --- |
| Active constituent/s | Selamectin |
| Applicant name | Redcap Solutions Pty Ltd |
| Applicant ACN | 095 863 899 |
| Date of approval | 3 August 2022 |
| Approval no. | 92127 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent selamectin for use in veterinary chemical products |

| Application no. | 132680 |
| --- | --- |
| Active constituent/s | Clethodim |
| Applicant name | Imtrade Australia Pty Ltd |
| Applicant ACN | 090 151 134 |
| Date of approval | 4 August 2022 |
| Approval no. | 91574 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent clethodim for use in agricultural chemical products |

| Application no. | 134793 |
| --- | --- |
| Active constituent/s | Diazepam |
| Applicant name | Avet Health Pty Ltd |
| Applicant ACN | 616 838 101 |
| Date of approval | 8 August 2022 |
| Approval no. | 92189 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent diazepam for use in veterinary chemical products |

| Application no. | 134823 |
| --- | --- |
| Active constituent/s | Phenylbutazone |
| Applicant name | Avet Health Pty Ltd |
| Applicant ACN | 616 838 101 |
| Date of approval | 8 August 2022 |
| Approval no. | 92197 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent phenylbutazone for use in veterinary chemical products |

| Application no. | 128548 |
| --- | --- |
| Active constituent/s | cis-Jasmone |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of approval | 9 August 2022 |
| Approval no. | 90325 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent cis-jasmone for use in agricultural chemical products |

| Application no. | 132783 |
| --- | --- |
| Active constituent/s | Propiconazole |
| Applicant name | Syngenta Australia Pty Ltd |
| Applicant ACN | 002 933 717 |
| Date of approval | 10 August 2022 |
| Approval no. | 91597 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent propiconazole for use in agricultural chemical products |

Table 7: Variations of active constituent

| Application no. | 132823 |
| --- | --- |
| Active constituent/s | Altrenogest |
| Applicant name | Ceva Animal Health Pty Ltd |
| Applicant ACN | 002 692 426 |
| Date of variation | 3 August 2022 |
| Approval no. | 82896 |
| Description of the application and its purpose, including the intended use of the active constituent | Variation of relevant particulars or conditions of an approved active constituent |

| Application no. | 132465 |
| --- | --- |
| Active constituent/s | Oil of lemon eucalyptus (hydrated, cyclized) |
| Applicant name | Citrefine International Ltd |
| Applicant ACN | N/A |
| Date of variation | 10 August 2022 |
| Approval no. | 54942 |
| Description of the application and its purpose, including the intended use of the active constituent | Variation to add and remove a manufacturing site for the existing approval |

Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019. The MRL Standard lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The MRL Standard also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the MRL Standard and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 6) 2022.

The amendments will be incorporated into the compilation of the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019.

The MRL Standard is accessible via the [Federal Register of Legislation website.](https://www.legislation.gov.au/Series/F2019L01105)

For further information please contact:

MRL Contact Officer

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**Phone:** +61 2 6770 2300

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

Proposal to amend Schedule 20 in the Australian New Zealand Food Standards Code

In the previous notice on page 20 of APVMA Gazette No. 17, the APVMA gazetted amendments which it has approved to vary maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out in the APVMA’s MRL Standard.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument 2022 (No. 6)) to MRLs into Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The agreement between the Australian Government and the New Zealand Government concerning a Joint Food Standards System excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

A Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) will be made.

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.

Proposed variation to Schedule 20 in the Australia New Zealand Food Standards Code

23 August 2022

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments but are not subject to disallowance or sunsetting.

To commence: on gazettal of variation

**[1]** The table to section S20–3 in Schedule 20 is varied by

[1.1] omitting from each of the following chemicals, the foods and associated MRLs

| Agvet chemical: Aminocyclopyrachlor | |
| --- | --- |
| Permitted residue: Aminocyclopyrachlor | |
| Mammalian fats [except milk fats] | 0.05 |

| Agvet chemical: Flupyradifurone | |
| --- | --- |
| Permitted residue: Flupyradifurone | |
| Avocado | 0.7 |

[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

| Agvet chemical: Aminocyclopyrachlor | |
| --- | --- |
| Permitted residue: Aminocyclopyrachlor | |
| Meat (mammalian) [in the fat] | 0.05 |

| Agvet chemical: Amitraz | |
| --- | --- |
| Permitted residue:  Sum of amitraz and N-(2,4-dimethylphenyl)-n′-methylformamidine, expressed as N-(2,4-dimethylphenyl)-N′-methylformamidine | |
| Honey | 0.2 |

| Agvet chemical: Buprofezin | |
| --- | --- |
| Permitted residue: Buprofezin | |
| Basil | 5 |
| Chives, Chinese | 2 |
| Garlic chives | 2 |
| Marjoram (oregano) | 5 |
| Mints | 5 |
| Thyme | 5 |

| Agvet chemical: Flupyradifurone | |
| --- | --- |
| Permitted residue: Flupyradifurone | |
| Assorted tropical and sub-tropical fruits – inedible peel [except banana; mango; papaya; pineapple] | 1.5 |
| Olives for oil production | 1 |
| Table olives | 1 |

| Agvet chemical:  Fluxapyroxad | |
| --- | --- |
| Permitted residue:  Fluxapyroxad | |
| Pomegranate | T0.3 |

| Agvet chemical:  Pyraclostrobin | |
| --- | --- |
| Permitted residue—commodities of plant origin:  Pyraclostrobin  Permitted residue—commodities of animal origin:  Sum of pyraclostrobin and metabolites hydrolysed to 1-(4-chloro-phenyl)-1H-pyrazol-3-ol, expressed as pyraclostrobin | |
| Pomegranate | T0.3 |

| Agvet chemical:  Quizalofop-ethyl | |
| --- | --- |
| Permitted residue:  Sum of quizalofop-ethyl and quizalofop acid and other esters, expressed as quizalofop-ethyl | |
| Barley | \*0.02 |

[1.3] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

| Agvet chemical: Aminocyclopyrachlor | |
| --- | --- |
| Permitted residue: Aminocyclopyrachlor | |
| Edible offal (mammalian) | 0.5 |
| Milks | 0.02 |

| Agvet chemical: Imazapic | |
| --- | --- |
| Permitted residue: Sum of imazapic and its hydroxymethyl derivative | |
| Oats | 0.05 |

| Agvet chemical: Imazapyr | |
| --- | --- |
| Permitted residue: Imazapyr | |
| Oats | 0.1 |

Invitation for submissions

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA.

Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials and surveys. Technical information should be in sufficient detail to allow independent scientific assessment.

Submissions must be made in writing and should be clearly marked as a ‘submission on the proposed amendment to Schedule 20’ and quote the correct amendment number.

Deadline for public submissions

Submissions must be received by 20 September 2022 (28 days from date Gazette published). Submissions received after this deadline will only be considered by prior arrangement or if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

Please note: submissions will be published on the APVMA’s website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the [public consultation coversheet](https://apvma.gov.au/node/72856)).

Please lodge your submission using the [public consultation coversheet](https://apvma.gov.au/node/72856), which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

For further information please contact:

MRL Contact Officer

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**Phone:** +61 2 6770 2300

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

Privacy

For information on how the APVMA manages personal information when you make a submission, see our [Privacy Policy](https://apvma.gov.au/node/59876).

Variations to Schedule 20 of the Australian New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA MRL Standard, and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Schedule 20 – Maximum residue limits of the Australia New Zealand Food Standards Code. This notice pertains to proposals (No. 3) gazetted on 17 May 2022 (No. APVMA 10).

Submissions have been sought on these proposals and the APVMA has written separately to each person or organisation that made a submission. All matters raised in the submissions have been resolved.

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Schedule 20. A copy of the Amendment Instrument (No. APVMA 3, 2022) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the [Federal Register of Legislation](http://www.legislation.gov.au/).

Based on dietary exposure assessments and current health standards, the APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied that these MRLs are not harmful to public health. MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health by minimising residues in foods consistent with the effective control of pests and diseases.

The agreement between the Australian Government and the New Zealand Government concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

A Sanitary and Phytosanitary notification to the World Trade Organization (WTO) was also made in relation to the variations to MRLs in Schedule 20 and no comment was received in response to that notice.

A copy of these variations has been given to FSANZ.

The variations take effect as from the date of this notice.

This notice is published in accordance with subsection 82(7) of the *Food Standards Australia New Zealand Act 1991*.

For further information please contact:

MRL Contact Officer

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**Phone:** +61 2 6770 2300

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

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***Australia New Zealand  
Food Standards Code* —   
Schedule 20 — Maximum residue limits Variation Instrument No. APVMA 4, 2022**

I, Sheila Logan, delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Sheila Logan

Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this Eighteenth day of August 2022

**Part 1 Preliminary**

**1 Name of instrument**

This instrument is the *Australia New Zealand Food Standards Code — Schedule 20 − Maximum residue limits Variation Instrument No. APVMA 4, 2022* (Amendment Instrument*)*.

**2 Commencement**

In accordance with subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this instrument commences on the day it is published in the *Gazette.*

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia Agricultural and Veterinary Chemicals Gazette.

**3 Object**

The object of this instrument is for the APVMA to make variations to Schedule 20 − Maximum residue limits in the *Australia New Zealand Food Standards* *Code* to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

**4 Interpretation**

In this instrument: —

APVMA means the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and

Principal Instrument means Schedule 20–Maximum residue limits in theAustralia New Zealand Food Standard Code as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the Code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that Code. Schedule 20 was published in the *Food Standards Gazette* FSC 96 on Thursday 10 April 2015 and was registered as a legislative instrument on 1 April 2015 (F2015L00468).

**Part 2 Variations to Schedule 20–  
Maximum Residue Limits**

**5 Variations to Schedule 20**

The Schedule to this instrument sets out the variations made to the Principal Instrument by this instrument.

**Schedule**

Variations to Schedule 20 – Maximum residue limits

**[1]** The table to section S20–3 in Schedule 20 is varied by

[1.1] omitting from each of the following chemicals, the foods and associated MRLs

| Agvet chemical: Fluopyram | |
| --- | --- |
| Permitted residue—commodities of plant origin: Fluopyram  Permitted residue—commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram | |
| Almonds | 0.05 |
| Tree nuts | 0.05 |

| Agvet chemical: Fluroxypyr | |
| --- | --- |
| Permitted residue: Fluroxypyr | |
| Cereal grains | 0.2 |

[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

| Agvet chemical: Bifenthrin | |
| --- | --- |
| Permitted residue: Bifenthrin | |
| Fig | T1 |

| Agvet chemical: Diflufenican | |
| --- | --- |
| Permitted residue: Diflufenican | |
| Safflower seed | T\*0.05 |

| Agvet chemical: Fluopyram | |
| --- | --- |
| Permitted residue—commodities of plant origin: Fluopyram  Permitted residue—commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram | |
| Tree nuts [except walnuts] | 0.05 |
| Walnuts | T0.07 |

| Agvet chemical: Fluroxypyr | |
| --- | --- |
| Permitted residue: Fluroxypyr | |
| Cereal grains [except rice bran, unprocessed] | 0.2 |

| ***Agvet chemical: Prothioconazole*** | |
| --- | --- |
| Permitted residue—commodities of plant origin: Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as Prothioconazole  Permitted residue—commodities of animal origin: Sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole | |
| Sunflower seed | \*0.02 |

|  |  |
| --- | --- |
| Agvet chemical: Tebuconazole | |
| Permitted residue: Tebuconazole | |
| Sunflower seed | 0.1 |

| Agvet chemical: Tetraniliprole | |
| --- | --- |
| Permitted residue: Tetraniliprole | |
| Fig | T0.5 |

| Agvet chemical: Trifludimoxazin | |
| --- | --- |
| Permitted residue: Trifludimoxazin | |
| Oats | \*0.01 |
| Triticale | \*0.01 |

[1.3] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

| Agvet chemical: Indoxacarb | |
| --- | --- |
| Permitted residue: Sum of indoxacarb and its R-isomer | |
| Macadamia nuts | 0.03 |

| ***Agvet chemical: Thiabendazole*** | |
| --- | --- |
| Permitted residue—commodities of plant origin: Thiabendazole  Permitted residue—commodities of animal origin: Sum of thiabendazole and 5-hydroxylthiabendazole, expressed as thiabendazole | |
| Taro | T50 |

New legislative instrument – Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022

The [Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022](https://www.legislation.gov.au/Details/F2022L01068) is a new legislative instrument made on 9 August 2022 under section 6E of the Agvet Code. The instrument commenced on 16 August 2022, the day after it was registered on the Federal Register of Legislation.

As required by regulation 8AF(1) of the Agricultural and Veterinary Chemicals Code Regulations (the Regulations), the proposal to establish the new standard was released for public consultation on the APVMA [website](https://apvma.gov.au/node/99936) and in the [APVMA Gazette](https://apvma.gov.au/node/100101) on 3 May 2022. Comments received in response to the public consultation were generally supportive of the new standard and were [published on the APVMA website](https://apvma.gov.au/node/99936). Some minor changes from the draft standard were made in response to the comments.

Under regulation 8AF(4) of the Regulations, the APVMA must publish a notice in the APVMA Gazette and on its website when it makes a standard under section 6E of the Code, stating that the standard has been made. This notice was also [published on the APVMA website](https://apvma.gov.au/node/104066) on 23 August 2022.

Under recent changes made to the Agvet Code, section 5AA states that concentrations of constituents in registered chemical products must not differ from the concentrations entered into the Register at the time of product registration by more than the extent prescribed by the Regulations (the prescribed extent).

Regulation 41(2) of the Regulations states that the prescribed extent is the extent permitted by the standards prescribed by Regulation 42.

In turn, Regulation 42(3) specifies the standard prescribed for a chemical product as being the standard published in any of a ‘cascade’ of publications, with a publication higher in the cascade taking precedence over one lower down. The publications are, in order, a standard specified in an Order made under section 7 of the *Agricultural and Veterinary Chemicals Code Act 1994* (of which there are none currently), a standard made under section 6E of the Code (as has been done), a standard published for a listed chemical product, a monograph in the British, European or US Pharmacopoeia, or a specification published by the Food and Agriculture Organization (FAO) and/or the World Health Organisation (WHO).

Establishment of the standard for allowable variations in concentrations of constituents in agricultural chemical products as a standard under section 6E of the Agvet Code gives the APVMA full control over the standard.

The standard prescribes the extent of the allowable variation in the concentrations of constituents (including active and non-active constituents) in registered agricultural chemical products. The standard does not cover veterinary chemical products – it is envisaged that a similar standard will be created for veterinary chemical products in the future.

The allowable variations for concentrations of active constituents of agricultural chemical products are the same as those listed in the [guideline for chemistry and manufacture requirements for agricultural chemical products](https://apvma.gov.au/node/1045). These allowable variations are already applied in the chemistry assessment of agricultural chemical products and inclusion in a standard under section 6E of the Code gives them a more formal status.

The allowable variations for concentrations of non-active constituents of agricultural chemical products are harmonised with regulations of overseas authorities, including the [US EPA](https://www.govinfo.gov/app/details/CFR-2004-title40-vol22/CFR-2004-title40-vol22-sec158-175) and [New Zealand Ministry of Primary Industries](https://www.mpi.govt.nz/dmsdocument/19448-Chemistry-and-Manufacture-of-Agricultural-Chemicals). Until now, there has been no defined allowable variation in the concentrations of non-active constituents, which has created challenges for the APVMA and industry.

In addition, the standard includes provision for applicants to nominate non-standard allowable variations for the concentrations of both active and non-active constituents, where this can be justified and will allow the APVMA to be satisfied with respect to the safety, efficacy and trade criteria.

There are no changes to processes for registration or assessment of agricultural chemical products in conjunction with the new standard, beyond any consideration needed for a ‘non-standard’ allowable variation as discussed in the previous paragraph.

It should be noted that the standard allows for reasonable variation from concentrations in the registered chemical product that are expected from normal variability in manufacturing processes, and in analytical methods. It does not allow the ‘target’, nominal, or declared concentrations of constituents to be varied from those on the Register without appropriate application to the APVMA for variation of relevant particulars of the product under an item 12 or 14 (Schedule 6, Part 2, Clause 2.1 of the Regulations) as appropriate, even where such a change is within the allowable variations defined in the standard.

Further, this standard does not specify a level of difference in concentrations that constitute closely similar product formulations.

The standard will be updated from time to time as required. All such changes will be consulted on as required by regulation 8AF.

Enquiries about the new legislative instrument may be directed to [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au).

Links to the relevant legislative references are provided below:

* [*Agricultural and Veterinary Chemicals Code Act 1994*](https://www.legislation.gov.au/Series/C2004A04723)
* [Agricultural and Veterinary Chemicals Code Regulations 1995](https://www.legislation.gov.au/Series/F1996B00288).

Notice of cancellation at the request of the holder

At the request of the holder, in accordance with section 42(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), the APVMA has cancelled the approvals and/or registrations set out in Table 8:

Table 8: Active constituent approval/product registration/label approval cancelled at the request of the holder

| Approval or registration number | Name | Type of approval or registration | Holder | Reason for cancellation (if relevant pursuant to s 45A(3)) | Date of cancellation |
| --- | --- | --- | --- | --- | --- |
| 48734 | Methomyl | Active constituent approval | Corteva Agriscience Australia Pty Ltd | N/A | 8 August 2022 |
| 54077/0309 54077/0801 54077/0909 | Imtrade Chemphos 400 Fungicide | Label approval | Imtrade Australia Pty Ltd | May not meet labelling criteria | 9 August 2022 |
| 56975/0403 56975/54898 | Imtrade Dominator 600 Fungicide | Label approval | Imtrade Australia Pty Ltd | May not meet labelling criteria | 10 August 2022 |
| 59137/133001 | Nufarm Dacthal 900 Pre-Emergence Herbicide | Label approval | Nufarm Australia Limited | May not meet labelling criteria | 21 July 2022 |
| 59137/113217  59137/107851  59137/58737  59137/1105  59137/1104 | Dacthal 900 WG Pre-Emergence Herbicide | Label approval | Nufarm Australia Limited | May not meet labelling criteria | 21 July 2022 |
| 67445/56048 | KDCP Prethal 750WG Herbicide | Label approval | KD Plant Care Pty Ltd | May not meet labelling criteria | 4 August 2022 |
| 69085/59935 | Ezycrop Chlorthal 750 WG Herbicide | Label approval | Ezycrop Pty Ltd | May not meet labelling criteria | 27 July 2022 |
| 81334/102842 | MacPhersons Chlorthal 900WG Herbicide | Label approval | EuroChem Pty Ltd | May not meet labelling criteria | 12 July 2022 |
| 83116/107561 | Relyon Lawthal 750WG Herbicide | Label approval | Nutrien Ag Solutions Limited | May not meet labelling criteria | 5 August 2022 |
| 83116/113127 | Lawthal 750WG Herbicide | Label approval | Nutrien Ag Solutions Limited | May not meet labelling criteria | 5 August 2022 |
| 84082/109657  84082/113647 | Conquest Concydone 500 SC Fungicide | Label approval | Conquest Crop Protection Pty Ltd | N/A | 19 July 2022 |
| 88705/122051 | Titan Chlorthal 900WG Pre-Emergence Herbicide | Label approval | Titan Ag Pty Ltd | May not meet labelling criteria | 20 July 2022 |

In accordance with section 45A(1)(b) of the Agvet Code, the APVMA publishes this notice of the cancellation, including the following instructions which set out how a person can deal with the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 8.

Instructions

Instructions for persons who possess, have custody of or use the cancelled active constituent, cancelled product, or the product bearing a cancelled label under section 45B(3) of the Agvet Code.

A person who possesses, has custody of or uses the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 8 in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 45B(3) of the Agvet Code to possess, have custody of or use the cancelled active constituent, cancelled product or product bearing a cancelled label, in accordance with those instructions.

Possession or custody

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 8 in accordance with its label instructions for 12 months from the date of cancellation.

Use, supply or otherwise deal with

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in Table 8 according to its label instructions, including any conditions relating to shelf life or expiry date, for 12 months after the date of cancellation.

A person may supply or cause to be supplied at wholesale or retail level the cancelled active constituent, cancelled product, or product bearing a cancelled label referred to in Table 8, for 12 months after the date of cancellation.

Contraventions

After the day that is 12 months from the date of cancellation it will be an offence against the Agvet Code to have possession or custody of the cancelled active constituents, cancelled products or products bearing a cancelled label with the intention to supply, or to supply the cancelled active constituent, cancelled product, or product bearing a cancelled label.

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled active constituents, cancelled products or products bearing the cancelled label listed in Table 8 in a manner that contravenes the above instructions.

APVMA contact

For any enquiries or further information about this matter, please contact:

Chemical Review

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**Phone:** +61 2 6770 2400

**Email:** [chemicalreview@apvma.gov.au](mailto:chemicalreview@apvma.gov.au)

More information

The APVMA publishes a list of [voluntary cancellations at the request of the holder](https://apvma.gov.au/node/69446) on its website, and provides a [subscription option](https://apvma.us2.list-manage.com/subscribe?u=f09f7f9ed2a2867a19b99e2e4&id=a025640240) to be notified by email when the list is updated.