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Gazette

**Agricultural and
Veterinary Chemicals**

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**Australian Pesticides and
Veterinary Medicines Authority**

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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GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) 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

The *APVMA Gazette* is published in electronic format only and is available from the [APVMA website](http://apvma.gov.au).

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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.

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	120326
Product name:	Entrust Organic Insecticide
Active constituent/s:	240g/L spinosad
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of use:	For the control of various insect pests in fruit, herbs, ornamentals, vegetables, and forestry
Date of registration:	7 July 2020
Product registration no.:	88118
Label approval no.:	88118/120326

Application no.:	124840
Product name:	Chemblend Permethrin 500 Timber and Pest Termiticide and Insecticide
Active constituent/s:	500 g/L permethrin 25:75
Applicant name:	Vaughany Holdings Pty Ltd
Applicant ACN:	630 311 036
Summary of use:	For the control of insect pests in a range of situations including timber, household and industrial situations
Date of registration:	7 July 2020
Product registration no.:	89427
Label approval no.:	89427/124840

Application no.:	121930
Product name:	4Farmers Glyphosate 510 Herbicide
Active constituent/s:	510g/L glyphosate present as the isopropylamine salt
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of use:	For the control of a wide range of annual and perennial weeds in agricultural situations
Date of registration:	7 July 2020
Product registration no.:	88662
Label approval no.:	88662/121930

Application no.:	121835
Product name:	Imtrade Ellias Plus 400 EC Insecticide
Active constituent/s:	400g/L alpha-cypermethrin
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control of insect pests of cereals, cotton, grain legumes, oilseeds, pastures, pome and stone fruits, trees and ornamentals, tobacco and vegetables
Date of registration:	8 July 2020
Product registration no.:	88617

Label approval no.:	88617/121835
Application no:	124887
Product name:	Ciperkey Insecticide
Active constituent/s:	100 g/L alpha-cypermethrin
Applicant name:	Industrial Quimica Key S A
Applicant ACN:	N/A
Summary of use:	For the control of certain insect pests, including heliothis (<i>Helicoverpa spp.</i>) on various crops and red legged earth mite and blue oat mite on certain field crops and pastures and certain insect pests on fruit and vegetable crops
Date of registration:	9 July 2020
Product registration no.:	89446
Label approval no.:	89446/124887

Application no.:	120354
Product name:	Biflex Professional 240 Wood Treatment Insecticide
Active constituent/s:	240 g/L bifenthrin
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of use:	For the protection of timber and timber-based products from damage by borers and termites
Date of registration:	9 July 2020
Product registration no.:	88129
Label approval no.:	88129/120354

Application no.:	125064
Product name:	Relyon Fluazifop Post-emergence Selective Herbicide
Active constituent/s:	212 g/L fluazifop-p present as the butyl ester
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use:	For the control of certain grasses in crops as indicated in the directions for use
Date of registration:	10 July 2020
Product registration no.:	89494
Label approval no.:	89494/125064

Application no.:	125059
Product name:	Relyon Captan 900 WG Fungicide
Active constituent/s:	900 g/kg captan
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use:	For the control of certain diseases in a range of fruit crops, turf and ornamentals
Date of registration:	10 July 2020
Product registration no.:	89490
Label approval no.:	89490/125059

Application no.:	125024
Product name:	Virkill S Broad Spectrum Disinfectant
Active constituent/s:	504 g/kg potassium peroxomonosulfate triple salt, 150 g/kg sodium dodecyl benzene sulphonate, 15 g/kg sodium chloride
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For broad spectrum control of viruses, bacteria and fungi for use on machinery, equipment, animal accommodation and vehicles
Date of registration:	10 July 2020
Product registration no.:	89487
Label approval no.:	89487/125024

Application no.:	123835
Product name:	Eezi Pool Smart Pool Booster For Pool Sanitisation
Active constituent/s:	75 g/kg copper present as copper sulphate pentahydrate
Applicant name:	Eezi Pool Australia Pty Ltd
Applicant ACN:	632 990 320
Summary of use:	To be used as an additive with chlorine to reduce the pool chlorine demand and boost the control of algae in pool water
Date of registration:	13 July 2020
Product registration no.:	89173
Label approval no.:	89173/123835
Application no.:	125892
Product name:	Pastoral Ag Pindone Oat Rabbit Bait
Active constituent/s:	0.5 g/kg pindone present as the sodium salt
Applicant name:	Freezone Public Health Pty Ltd
Applicant ACN:	132 080 098
Summary of use:	For the control of rabbits in accordance with the directions of the appropriate state or territory government department, under the appropriate state or territory legislation
Date of registration:	14 July 2020
Product registration no.:	89721
Label approval no.:	89721/125892
Application no.:	122247
Product name:	Imtrade Ecdypro 700 WP Insecticide
Active constituent/s:	700 g/kg tebufenozide
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control of light brown apple moth on apples, pears, citrus and grapevines; and for control of various insect pests of avocado, custard apple, kiwifruit, longan, lychee, macadamia, and eucalyptus
Date of registration:	14 July 2020
Product registration no.:	88780
Label approval no.:	88780/122247
Application no.:	122676
Product name:	Gemini Fungicide
Active constituent/s:	500 g/L fluazinam
Applicant name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of use:	For the control various diseases in turf
Date of registration:	14 July 2020
Product registration no.:	88849
Label approval no.:	88849/122676
Application no.:	121179
Product name:	Maxunitech Progress 420 EC Fungicide
Active constituent/s:	210 g/L prothioconazole, 210 g/L tebuconazole
Applicant name:	Max(Rudong) Chemicals Co Ltd
Applicant ACN:	N/A
Summary of use:	For the control of various diseases in barley and canola
Date of registration:	15 July 2020
Product registration no.:	88389
Label approval no.:	88389/121179

Application no.:	124167
Product name:	Vitalyse Maintenance Algaecide
Active constituent/s:	40 g/L copper (Cu) present as triethanolamine complex
Applicant name:	Focus Products Pty Ltd
Applicant ACN:	073 540 520
Summary of use:	For the control of algae in swimming pools
Date of registration:	15 July 2020
Product registration no.:	89249
Label approval no.:	89249/124167

Application no.:	120572
Product name:	Surefire Carbendazim 500 SC Fungicide
Active constituent/s:	500 g/L carbendazim
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of fungal diseases in macadamia and pulse crops
Date of registration:	16 July 2020
Product registration no.:	88209
Label approval no.:	88209/120572

Application no.:	124975
Product name:	eChem Trifluralin 480 Herbicide
Active constituent/s:	480 g/L trifluralin
Applicant name:	eChem (Aust) Pty Ltd
Applicant ACN:	089 133 095
Summary of use:	For the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
Date of registration:	16 July 2020
Product registration no.:	89469
Label approval no.:	89469/124975

Application no.:	126061
Product name:	Aqua Des Sanitiser
Active constituent/s:	282 g/L hydrogen peroxide, 85 g/L acetic acid, 56 g/L peroxyacetic acid
Applicant name:	Solvay Interlox Pty Ltd
Applicant ACN:	000 882 137
Summary of use:	For use in sanitising/disinfecting of dairies and other milk processing plant, animal housing and beverage manufacturing industries
Date of registration:	16 July 2020
Product registration no.:	89776
Label approval no.:	89776/126061

Application no.:	122591
Product name:	Farmalinx Iodosulfuron Herbicide
Active constituent/s:	100 g/kg iodosulfuron-methyl-sodium
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the post-emergent control of certain broadleaf weeds and grasses in turf and for the suppression of winter grass and bahia grass
Date of registration:	16 July 2020
Product registration no.:	88829
Label approval no.:	88829/122591

Application no.:	122543
Product name:	Imtrade Boost 250 SC Plant Growth Regulator
Active constituent/s:	250 g/L paclobutrazol
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of variation:	To update the statement of claims, directions for use and general instructions to add avocado and turf
Date of variation:	16 July 2020
Product registration no.:	66861
Label approval no.:	66861/122543

Application no.:	121065
Product name:	Farmalinx Weapon Herbicide
Active constituent/s:	875 g/kg terbuthylazine
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the control of weeds in forestry
Date of registration:	17 July 2020
Product registration no.:	88367
Label approval no.:	88367/121065

2. VARIATIONS OF REGISTRATION

Application no.:	125983
Product name:	Herbi Blue Spray Marker Dye
Active constituent/s:	90 g/L CI acid blue 9, disodium salt (hidacid azure blue 65%)
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To remove the use with boom spray application from the instructions
Date of variation:	23 June 2020
Product registration no.:	66398
Label approval no.:	66398/125983

Application no.:	126047
Product name:	Relyon Di-Par 250 SC Herbicide
Active constituent/s:	135 g/L paraquat present as paraquat dichloride, 115 g/L diquat present as diquat dibromide
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Sprayquick Herbicide' to 'Relyon Di-Par 250 SC Herbicide'
Date of variation:	29 June 2020
Product registration no.:	81790
Label approval no.:	81790/126047

Application no.:	126079
Product name:	Relyon Terbu M Herbicide
Active constituent/s:	275 g/L terbutryn, 160 g/L MCPA present as the potassium salt
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Perturb MA Herbicide' to 'Relyon Terbu M Herbicide'
Date of variation:	30 June 2020
Product registration no.:	83143
Label approval no.:	83143/126079
Application no.:	126082
Product name:	Relyon Imazethapyr 700 WG Herbicide
Active constituent/s:	700 g/kg imazethapyr
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Splice 700WG Herbicide' to 'Relyon Imazethapyr 700 WG Herbicide'
Date of variation:	30 June 2020
Product registration no.:	82942
Label approval no.:	82942/126082
Application no.:	126083
Product name:	Relyon Simagen 900 WG Herbicide
Active constituent/s:	900 g/kg simazine
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Simazon 900WG Herbicide' to 'Relyon Simagen 900 WG Herbicide'
Date of variation:	30 June 2020
Product registration no.:	81787
Label approval no.:	81787/126083
Application no.:	126095
Product name:	Reylon Isoxaflutole 750 WG Herbicide
Active constituent/s:	750 g/kg isoxaflutole
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Steady 750WG Herbicide' to 'Relyon Isoxaflutole 750 WG Herbicide'
Date of variation:	30 June 2020
Product registration no.:	82230
Label approval no.:	82230/126095
Application no.:	126096
Product name:	Relyon Hexazinone 250 SL Herbicide
Active constituent/s:	250 g/L hexazinone
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Velcat 250SL Herbicide' to 'Relyon Hexazinone 250 SL Herbicide'
Date of variation:	30 June 2020
Product registration no.:	86415
Label approval no.:	86415/126096

Application no.:	124826
Product name:	AC Tussel Selective Herbicide
Active constituent/s:	240 g/L clodinafop-propargyl, 60 g/L cloquintocet-mexyl
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of variation:	To update the first aid instructions and remove reference to D-C-Trate from the label
Date of variation:	7 July 2020
Product registration no.:	65369
Label approval no.:	65369/124826
Application no.:	124874
Product name:	Azoxy 250 Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of variation:	To include new uses
Date of variation:	13 July 2020
Product registration no.:	66927
Label approval no.:	66927/124874
Application no.:	124846
Product name:	Maxim 100 FS Fungicide Seed Treatment
Active constituent/s:	100 g/L fludioxonil
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To add control of rhizoctonia in broccoli to product containing fludioxonil 100
Date of variation:	13 July 2020
Product registration no.:	51407
Label approval no.:	51407/124846
Application no.:	120390
Product name:	Bobcat I-Maxx Herbicide
Active constituent/s:	125 g/L hexazinone, 25 g/L imazapic present as the ammonium salt
Applicant name:	Adama Australia Pty Ltd
Applicant ACN:	050 328 973
Summary of variation:	To extend the use pattern to include suppression of various weeds and add spot spraying of guinea grass
Date of variation:	13 July 2020
Product registration no.:	69698
Label approval no.:	69698/120390
Application no.:	121981
Product name:	Sprayphos 600 Systemic Fungicide
Active constituent/s:	600 g/L phosphorous (phosphonic) acid present as mono (and) dipotassium phosphite
Applicant name:	Foliar Fertilizers Pty Ltd
Applicant ACN:	007 974 496
Summary of variation:	For control of phytophthora in almond, macadamia, walnut, and chestnuts
Date of variation:	14 July 2020
Product registration no.:	65178
Label approval no.:	65178/121981

Application no.:	123802
Product name:	Sporekill Agricultural Disinfectant
Active constituent/s:	120 g/L didecyl dimethyl ammonium chloride
Applicant name:	Grochem Australia Pty Ltd
Applicant ACN:	169 400 033
Summary of variation:	To add uses in poultry sheds and for the control of the spread of Panama disease in bananas
Date of variation:	14 July 2020
Product registration no.:	51141
Label approval no.:	51141/123802

Application no.:	124972
Product name:	Affinity Force Herbicide
Active constituent/s:	240 g/L carfentrazone-ethyl
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of variation:	To add uses in rice
Date of variation:	15 July 2020
Product registration no.:	62003
Label approval no.:	62003/124972

Application no.:	121998
Product name:	Sundew TaserPRO 800 WP Insecticide
Active constituent/s:	800 g/kg bendiocarb
Applicant name:	Sundew Solutions Pty Ltd
Applicant ACN:	135 400 261
Summary of variation:	To extend turf use to include control of earthworms
Date of variation:	15 July 2020
Product registration no.:	80649
Label approval no.:	80649/121998

Application no.:	124977
Product name:	Switch Fungicide
Active constituent/s:	375 g/kg cyprodinil, 250 g/kg fludioxonil
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To add uses in nursery stock and ornamentals, cut flowers, pyrethrum crops, lettuce, capsicum, and alliums to product containing fludioxonil 250 g/L and cyprodinil 375 g/L
Date of variation:	16 July 2020
Product registration no.:	51797
Label approval no.:	51797/124977

Application no.:	123736
Product name:	Surefire Invictus 500 WG Fungicide
Active constituent/s:	500 g/kg trifloxystrobin
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of variation:	To add use in strawberries
Date of variation:	16 July 2020
Product registration no.:	85778
Label approval no.:	85778/123736

3. LABEL APPROVAL

Application no.:	125382
Product name:	Biocover Horticultural Oil
Active constituent/s:	840 g/L petroleum oil
Applicant name:	Agnova Technologies Pty Ltd
Applicant ACN:	097 705 158
Summary of use:	To approve a new label for the product 'BIOCOVER HORTICULTURAL OIL ' with the label name 'JMS Stylet Oil® Horticultural Mineral Oil'
Date of approval:	14 July 2020
Label approval no.:	59091/125382

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.

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	125068
Product name:	Purina Totalcare Flea & Tick Control Plus For Small Dogs
Active constituent/s:	100 g/L fipronil, 90 g/L (S)-methoprene
Applicant name:	Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of use:	For the treatment and prevention of flea infestation (<i>Ctenocephalides</i> spp.), and control of brown dog ticks (<i>Rhipicephalus sanguineus</i>), paralysis tick (<i>Ixodes holocyclus</i>) and biting lice (<i>Trichodectes canis</i>) on dogs and puppies. Also aids in the control of sarcoptic mange (<i>Sarcoptic scabiei</i> var. <i>canis</i>) in dogs
Date of registration:	14 July 2020
Product registration no.:	89496
Label approval no.:	89496/125068

Application no.:	125069
Product name:	Purina Totalcare Flea & Lice Control Plus For Cats & Kittens
Active constituent/s:	120 g/L (S)-methoprene, 100 g/L fipronil
Applicant name:	Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of use:	For the treatment of flea infestation (<i>Ctenocephalides</i> spp.) and biting lice (<i>Felicola subrostratus</i>) on cats and kittens. May be used for the treatment and control of flea allergy dermatitis in cats
Date of registration:	14 July 2020
Product registration no.:	89497
Label approval no.:	89497/125069

Application no.:	125070
Product name:	Purina Totalcare Flea & Tick Control Plus For Medium Dogs
Active constituent/s:	100 g/L fipronil, 90 g/L (S)-methoprene
Applicant name:	Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of use:	For the treatment and prevention of flea infestation (<i>Ctenocephalides</i> spp.), and control of brown dog ticks (<i>Rhipicephalus sanguineus</i>), paralysis tick (<i>Ixodes holocyclus</i>) and biting lice (<i>Trichodectes canis</i>) on dogs and puppies. Also aids in the control of sarcoptic mange (<i>Sarcoptic scabiei</i> var. <i>canis</i>) in dogs
Date of registration:	14 July 2020
Product registration no.:	89498
Label approval no.:	89498/125070

Application no.:	125071
Product name:	Purina Totalcare Flea & Tick Control Plus For Large, Dogs
Active constituent/s:	100 g/L fipronil, 90 g/L (S)-methoprene
Applicant name:	Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of use:	For the treatment and prevention of flea infestation (<i>Ctenocephalides</i> spp.), and control of brown dog ticks (<i>Rhipicephalus sanguineus</i>), paralysis tick (<i>Ixodes holocyclus</i>) and biting lice (<i>Trichodectes canis</i>) on dogs and puppies. Also aids in the control of sarcoptic mange (<i>Sarcoptic scabiei</i> var. <i>canis</i>) in dogs
Date of registration:	14 July 2020
Product registration no.:	89499
Label approval no.:	89499/125071

Application no.:	124879
Product name:	Purina Procure Flea Shampoo For Dogs
Active constituent/s:	10 g/L piperonyl butoxide, 8 g/L melaleuca oil, 2 g/L permethrin (25:75, cis:trans)
Applicant name:	Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of use:	For killing fleas (<i>Ctenocephalides</i> spp.), aiding in the control of paralysis tick (<i>Ixodes holocyclus</i>) and contains melaleuca alternifolia oil which penetrates the skin, soothing distress caused by skin irritation. It also assists in the control of eczema whilst cleaning and conditioning the dog's coat
Date of registration:	14 July 2020
Product registration no.:	89441
Label approval no.:	89441/124879

Application no.:	124988
Product name:	LincoRx 300 mg/mL
Active constituent/s:	300 mg/mL lincomycin as lincomycin hydrochloride
Applicant name:	Probus Pharmaceuticals Pty Ltd
Applicant ACN:	638193674
Summary of use:	For the treatment of infections sensitive to lincomycin in pigs
Date of registration:	15 July 2020
Product registration no.:	89477
Label approval no.:	89477/124988

2. VARIATIONS OF REGISTRATION

Application no.:	126176
Product name:	Sidewinder Long Acting Injection For Sheep
Active constituent/s:	20g/L moxidectin
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'DYCECTIN LONG LASTING INJECTION FOR SHEEP' to 'SIDEWINDER LONG ACTING INJECTION FOR SHEEP'
Date of variation:	3 July 2020
Product registration no.:	89250
Label approval no.:	89250/126176

Application no.:	122216
Product name:	Apex Benazepril Oral Solution
Active constituent/s:	5 mg/mL benazepril hydrochloride
Applicant name:	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN:	614 716 700
Summary of variation:	To vary the conditions of product registration and update the label to include a new storage condition statement and new pack sizes
Date of variation:	9 July 2020
Product registration no.:	80867
Label approval no.:	80867/122216

Application no.:	120230
Product name:	Alamycin SA 100 Injection
Active constituent/s:	100 mg/mL oxytetracycline hydrochloride
Applicant name:	Norbrook Laboratories Australia Pty Ltd
Applicant ACN:	080 972 596
Summary of variation:	To update withholding periods, trade advice and pack sizes
Date of variation:	13 July 2020
Product registration no.:	51973
Label approval no.:	51973/120230

3. LABEL APPROVAL

Application no.:	125279
Product name:	Starmec Pour-On For Beef And Dairy Cattle
Active constituent/s:	5 g/L ivermectin
Applicant name:	The Hunter River Company Pty Ltd
Applicant ACN:	133 798 615
Summary of variation:	To approve a new label for the product 'Starmec Pour-On for Beef and Dairy Cattle' with the label name 'Pastoral Ag Iverlab Pour-On for Cattle'
Date of variation:	10 July 2020
Product registration no.:	70317
Label approval no.:	70317/125279

4. VARIATION OF LABEL APPROVAL

Application no.:	122792
Product name:	NV Gentamax 100 Injection
Active constituent/s:	100 mg/mL gentamicin (as sulfate)
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Amendment to dosage instructions for horses
Date of variation:	6 July 2020
Product registration no.:	55873
Label approval no.:	55873/122792

Application no.:	125076
Product name:	D-Max Doramectin Injection
Active constituent/s:	10 mg/mL doramectin
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of variation:	Variation to the statements in general directions section of the approved label
Date of variation:	15 July 2020
Product registration no.:	86188
Label approval no.:	86188/125076

Application no.:	124319
Product name:	Porcilis PCV Vaccine
Active constituent/s:	Porcine Circovirus Type 2 ORF2 subunit antigen: ≥ 4.5 log ₂ antibody titre per dose of 2 mL
Applicant name:	Intervet Australia Pty Ltd
Applicant ACN:	008 467 034
Summary of variation:	To update side effects and align label with current label guidelines
Date of variation:	15 July 2020
Product registration no.:	64025
Label approval no.:	64025/124319

Application no.:	124981
Product name:	Elanco Component -H Growth And Finishing Implants For Heifers
Active constituent/s:	200 mg/implant testosterone propionate, 20 mg/implant oestradiol benzoate
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	65441
Label approval no.:	65441/124981

Application no.:	124982
Product name:	Elanco Component -S Growth And Finishing Implants For Steers
Active constituent/s:	200 mg/implant progesterone, 20 mg/implant oestradiol benzoate
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	65444
Label approval no.:	65444/124982

Application no.:	124985
Product name:	Elanco Component TE-200 Growth And Finishing Implants For Heifers And Steers
Active constituent/s:	200 mg/Implant trenbolone acetate, 20 mg/Implant oestradiol
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	65448
Label approval no.:	65448/124985

Application no.:	124994
Product name:	Elanco Component TE-S Growth And Finishing Implants For Steers
Active constituent/s:	140 mg/Implant trenbolone acetate, 28 mg/Implant oestradiol
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	65449
Label approval no.:	65449/124994
Application no.:	124998
Product name:	Elanco AH0973 Component TE-S With Tylan Growth And Finishing Implants For Steers
Active constituent/s:	140 mg/Im trenbolone acetate, 29 mg/Im tylosine tartrate, 28 mg/Im oestradiol
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	62873
Label approval no.:	62873/124998
Application no.:	124997
Product name:	Elanco AH0513 Component TE-200 With Tylan Growth And Finishing Implants For Heifers And Steers
Active constituent/s:	200 mg/Implant trenbolone acetate, 29 mg/Implant tylosine tartrate, 20 mg/Implant oestradiol
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	62874
Label approval no.:	62874/124997
Application no.:	124995
Product name:	Elanco AH0338 Component -H With Tylan Growth And Finishing Implants For Heifers
Active constituent/s:	200 mg/Implant testosterone propionate, 29 mg/Implant tylosine tartrate, 20 mg/Implant oestradiol benzoate
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	62872
Label approval no.:	62872/124995
Application no.:	124996
Product name:	Elanco AH0328 Component S With Tylan Growth And Finishing Implants For Steers
Active constituent/s:	200 mg/Implant progesterone, 29 mg/Implant tylosine tartrate, 20 mg/Implant oestradiol benzoate
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update product label in line with current Veterinary Labelling Code
Date of variation:	16 July 2020
Product registration no.:	62868
Label approval no.:	62868/124996

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.

1. ACTIVE CONSTITUENT

Application no.:	120824
Active constituent/s:	Bifenthrin
Applicant name:	Shandong United Pesticide Industry Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	6 July 2020
Approval no.:	88300

Application no.:	123066
Active constituent/s:	Chlorantraniliprole
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For use in agricultural chemical products
Date of approval:	7 July 2020
Approval no.:	88973

Application no.:	123033
Active constituent/s:	Fluroxypyr-meptyl
Applicant name:	Shanghai E-Tong Chemical Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	7 July 2020
Approval no.:	88963

Application no.:	125941
Active constituent/s:	Trenbolone acetate
Applicant name:	Intervet Australia Pty Ltd
Applicant ACN:	008 467 034
Summary of use:	For use in veterinary chemical products
Date of approval:	8 July 2020
Approval no.:	89740

Application no.:	123813
Active constituent/s:	Fipronil
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of use:	For use in veterinary chemical products
Date of approval:	9 July 2020
Approval no.:	89164

Application no.:	122833
Active constituent/s:	Clethodim
Applicant name:	UPL Australia Pty Ltd
Applicant ACN:	066 391 384
Summary of use:	For use in agricultural chemical products
Date of approval:	9 July 2020
Approval no.:	88913

Application no.:	122687
Active constituent/s:	Trifloxystrobin
Applicant name:	Agrogill Chemicals Pty Ltd
Applicant ACN:	094 672 107
Summary of use:	For use in agricultural chemical products
Date of approval:	9 July 2020
Approval no.:	88856

Application no.:	123085
Active constituent/s:	Amprolium hydrochloride
Applicant name:	Huvepharma EOOD
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	10 July 2020
Approval no.:	88979

Application no.:	123088
Active constituent/s:	Gibberellin A4 A7
Applicant name:	Valent Biosciences A Div Of Sumitomo Chemical Australia
Applicant ACN:	081 096 255
Summary of use:	For use in agricultural chemical products
Date of approval:	10 July 2020
Approval no.:	88981

Application no.:	123152
Active constituent/s:	Cyproconazole
Applicant name:	Sabero Australia Pty Ltd
Applicant ACN:	087 313 059
Summary of use:	For use in agricultural chemical products
Date of approval:	13 July 2020
Approval no.:	89010

Application no.:	124181
Active constituent/s:	Moxidectin
Applicant name:	Intervet Australia Pty Ltd
Applicant ACN:	008 467 034
Summary of use:	For use in veterinary chemical products only
Date of approval:	15 July 2020
Approval no.:	89256

Application no.:	122076
Active constituent/s:	Diquat Dibromide Manufacturing Concentrate
Applicant name:	Foison Scitech Co Limited
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	15 July 2020
Approval no.:	88714

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	124189
Active constituent/s:	Procaine hydrochloride
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	15 July 2020
Approval no.:	56226

Application no.:	124113
Active constituent/s:	L-lysine hydrochloride
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	15 July 2020
Approval no.:	85911

Application no.:	124007
Active constituent/s:	Albendazole
Applicant name:	Jurox Pty Ltd
Applicant ACN:	000 932 230
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	15 July 2020
Approval no.:	83598

New chemical product KENJA 400 SC FUNGICIDE containing isofetamid

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product **KENJA 400 SC FUNGICIDE**, containing a new active constituent isofetamid.

PARTICULARS OF THE APPLICATION

Proposed product name:	KENJA 400 SC FUNGICIDE
Applicant company:	Ishihara Sangyo Kaisha, Ltd
Name of active constituents:	Isofetamid
Signal heading:	Unscheduled (Appendix B)
Summary of proposed use:	For the control of grey mould (<i>Botrytis cinerea</i>) in berries, low growing berries such as strawberries, cane berries including raspberries and bush berries including blueberries in protected and field cropping situations.
Pack sizes:	1–20 L
Withholding period:	Harvest: Nil

SUMMARY OF THE APVMA'S EVALUATION OF KENJA 400 SC FUNGICIDE IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of KENJA 400 SC FUNGICIDE containing the active constituent isofetamid would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - (ii) The APVMA is satisfied that the proposed use of KENJA 400 SC FUNGICIDE containing the active constituent isofetamid will not be an undue hazard to the safety of people using anything containing its residues.
 - (iii) The APVMA is satisfied that the proposed use of KENJA 400 SC FUNGICIDE containing the active constituent isofetamid is not likely to be harmful to human beings if used according to the product label directions.
 - (iv) The APVMA is satisfied that the proposed use of the new products KENJA 400 SC FUNGICIDE containing the active constituent isofetamid, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.
2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.
3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:

- (ii) The APVMA is satisfied that the proposed use of KENJA 400 SC FUNGICIDE would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the [‘Public Consultation’ page](#) on the APVMA website, or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether KENJA 400 SC FUNGICIDE should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

Submissions must be received by the APVMA within **28 days** of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address
- the date you made the submission.

All personal and confidential commercial information (CCI) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au.

Licensing of Veterinary Chemical Manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action with respect to the licensing of the following veterinary chemical manufacturers with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the [APVMA's website](#).

1. NEW LICENCES

Nil

2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agvet Code:

DECHRA VETERINARY PRODUCTS (AUSTRALIA) PTY LTD

Licence number: 2245

ACN: 614 716 700

2 Cal Close

Somersby NSW 2250

Product types: *

- *Category 2:* Tablets, creams / lotion, ointments, gels, granules, pastes, powders, liquids and suspensions

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, relabelling, strip, blister or sachet packaging, dry milling, wet milling, granulation, tableting, analysis and testing (physical), storage and release for supply.

Amended licence issued: 16 July 2020

KATO LABORATORIES PTY LTD

Licence number: 2119

ACN: 000 397 240

61 Chivers Road

Somersby NSW 2250

Product types: *

- *Category 2:* Tablets, pastes, liquids and suspensions

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, packaging, labelling, tableting, analysis and testing (physical and chemical), and storage.

Amended licence issued: 30 January 2020

3. LICENCE CANCELLATIONS

The APVMA has cancelled the following licences under subsection 127(1) of the Agvet Code:

**GIPPSLAND RESEARCH
STATION PTY LTD**

Licence number: 6213

ACN: 167 872 773

Date cancelled: 13 July 2020

110 Fish Creek-Walkerville Road
Fish Creek VIC 3979

**AUSTRALIAN BLISTER
SEALING INCORPORATED
PTY LTD**

Licence number: 6148

ACN: 001 219 003

Date cancelled: 13 July 2020

18 Distribution Place
Seven Hills NSW 2147

4. LICENCE SUSPENSIONS

Nil

5. REVOCATION OF LICENCE CANCELLATION

Nil

6. REVOCATION OF LICENCE SUSPENSION

Nil

APVMA CONTACT

Manufacturing Quality and Licensing
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2301

Email: mls@apvma.gov.au.

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 Australian Pesticides and Veterinary Medicines Authority (APVMA) has cancelled the approvals and/or registrations set out in the table below.

Approval or registration number	Name	Type of approval or registration	Holder	Date of cancellation
69698/101646 69698/61461	Bobcat I-Maxx Herbicide	Label approvals	ADAMA Australia Pty Ltd	13 July 2020
41092/2377 41092/0999 41092/0600 41092/57623	Barmac Broadleaf Weeder Selective Weedkiller	Label approvals	Amgrow Pty Ltd	16 July 2020

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 the above table.

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 the above table 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 the above table 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 the above table 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 the above table, 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 the table above 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.

Change to conditions for the export of phorate

The Australian Government Department of Agriculture, Water and the Environment gives notice that the conditions that apply to the export of the active constituent phorate, and products containing the active constituent phorate, were changed on 17 July 2020 by way of amendment to the Agricultural and Veterinary Chemicals (Administration) Regulations 1995.

The amendment fulfilled Australia's obligations under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the Rotterdam Convention).

In order to meet export notification requirements under the Rotterdam Convention, anyone seeking to export a chemical listed in Annex III must apply to the Department of Agriculture, Water and the Environment for permission to export the chemical (contact details are at the end of this notice). Anyone exporting listed chemicals to countries that are parties to the convention must:

- (i) include the [Harmonised System Customs Code](#) for the chemical (where assigned) on shipping documentation
- (ii) ensure adequate labelling of the chemical including information about:
 - a) risks and/or hazards to human health and the environment
 - b) compliance with relevant international standards applicable to labels
- (iii) provide to the importer (if the chemical is to be used for occupational purposes) a safety data sheet that follows an internationally recognised format, with the most up to date information available, in one of the official languages of the importing party
- (iv) comply with any specified conditions stipulated by the importing country and promulgated by the secretariat to the Rotterdam Convention as advised by the authorised officer. These specified conditions can be found at pic.int/Procedures/ImportResponses/Database/tabid/1370/language/en-US/Default.aspx.

The amendment applies the PIC procedure to all phorate concentrations.

Background

The Rotterdam Convention is an international treaty promoting shared responsibilities and cooperative efforts in the international trade of certain hazardous chemicals. It creates legally-binding obligations for implementing the Prior Informed Consent (PIC) procedure. Annex III of the Rotterdam Convention contains a list of chemicals that are subject to the PIC procedure (also referred to as a listed chemical). The PIC procedure aims to ensure that countries do not export chemicals, for use as pesticides, to other countries that have not provided their consent to receive them. Exporting parties must ensure that the export of a listed chemical does not occur when the importing country has indicated that it does not consent to imports of that chemical.

Enquiries

For further information please contact:

Agvet Chemicals Branch, International and Domestic Policy Section
Department of Agriculture, Water and the Environment

Phone: +61 2 6272 4442

Email: agvetpolicy@agriculture.gov.au.

Final regulatory decisions for certain swimming and spa pool sanitiser products

STATEMENT OF REASONS

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has made the following decisions in respect of swimming and spa pool products containing hydrogen peroxide or polyhexanide hydrochloride under section 41 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (Agvet Code):
 - a) to CANCEL the registrations of the products listed in Appendix A under section 41(1) of the Agvet Code; and
 - b) to CANCEL the label approvals listed in Appendix A under section 41(2) of the Agvet Code.
2. The reasons for these decisions are set out below.

LEGISLATIVE FRAMEWORK

3. The following sections of the Agvet Code were relevant to the cancellation decisions:

Section	Provision
5A	Definition of <i>meets the safety criteria</i>
5B	Definition of <i>meets the efficacy criteria</i>
5D	Definition of <i>meets the labelling criteria</i>
34P	The APVMA must not suspend or cancel an approval or registration unless it has given the holder a written notice that it intends to do so, and has had regard to any submissions made by the person to whom the written notice is given
35	The APVMA must not suspend or cancel an approval or registration unless it has given written notice of the intended action to each coordinator designated for a jurisdiction
41	The APVMA may suspend or cancel the approval of an active constituent for a proposed or existing chemical product, or the registration of a chemical product, if it appears to the APVMA that the product may not meet the safety criteria, the trade criteria or the efficacy criteria. The APVMA may suspend or cancel the approval of a label for containers for a chemical product if it appears to the APVMA that the label may not meet the labelling criteria or may not comply with any requirement prescribed by the regulations

4. Relevant extracts of these provisions are found at Appendix B.

EVIDENCE OR OTHER MATERIAL ON WHICH ANY FINDINGS OF FACT ARE BASED

5. The following were considered and relied upon for the proposed decisions:
 - a) The relevant provisions of the Agvet Code as set out above;
 - b) The relevant provisions of any regulations, standards and determinations;
 - c) The relevant submissions received in response to the proposed regulatory decisions; and,
 - d) The materials listed in the References section below.

DEFINITIONS

6. For the purposes of this statement of reasons:

Hydrogen peroxide is the chemical identified in the Chemicals Abstraction Service as registration number 7722-84-

1. The terms hydroperoxide, oxydol, perhydrol, peroxide hydrogen, superoxol are synonyms of hydrogen peroxide,

Polyhexanide hydrochloride is the chemical identified in the Chemicals Abstraction Service as registration number 28757-47-3. The terms polihexanide, baquacil, cosmocil, lavasept, polyhexamethylene biguanide (abbreviated as PHMB), PHMB polymer, polihexanide hydrochloride, poly(hexamethylene biguanide), poly(hexamethylenebiguanide) hydrochloride, poly(iminocarbonimidoyliminocarbonimidoylimino-1,6-hexanediyl) hydrochloride) are synonyms of polyhexanide hydrochloride,

Products means the registered swimming pool and spa pool products containing hydrogen peroxide or polyhexanide hydrochloride shown in Appendix A,

Labels means the approved labels for the swimming and spa products containing hydrogen peroxide or polyhexanide hydrochloride shown in Appendix A, and

Swimming pool and spa sanitiser means a chemical agent that kills or irreversibly inactivates microorganisms in swimming pools and spas, to reduce pathogenic microorganisms to meet the target performance characteristics defined in the performance criteria for these products (APVMA, 2014).

MATERIAL FINDINGS OF FACT

7. Based on the evidence and other material set out above, the APVMA makes the following findings of fact which are material to the cancellation decisions.

The products do not meet the swimming and spa pool sanitiser performance criteria and therefore do not meet the safety criteria stipulated in section 5A of the Code

8. The potential for infection with and/or transmission of important human pathogens and disease can occur via swimming and spa pool use.
9. The purpose of swimming and spa pool sanitiser products is to mitigate the risks to human health associated with the potential for infection with and/or transmission of important human pathogens and disease during swimming and spa pool use.
10. The swimming and spa pool sanitiser products' failure to mitigate the risks to human health associated with the potential for infection with and/or transmission of important human pathogens and disease during swimming and spa pool use is an effect that is harmful to human beings. Under such circumstances the relevant swimming and spa pool sanitiser products would not meet the safety criteria as defined in section 5A of the Code.
11. The swimming and spa pool sanitiser products' failure to meet the sanitiser performance criteria (APVMA, 2014) means that such a product would not adequately mitigate the risk of infection with and/or transmission of important human pathogens. Accordingly such a product would have effects that are harmful to human beings and would not meet the safety criteria defined in section 5A of the Code.

The anti-bacterial sanitiser performance of hydrogen peroxide ± silver as an active constituent for swimming and spa pools is inadequate in terms of the time it takes to have effect

12. In relation to swimming and spa pool sanitiser products that use hydrogen peroxide as an active constituent, Standards Australia (2002) has noted that hydrogen peroxide can take up to two hours to kill bacteria as compared with the time requirement of 30 seconds to two minutes defined in the APVMA performance criteria.

13. Borgmann-Strahsen (2003) evaluated the antimicrobial properties of hydrogen peroxide at 80 and 150 ppm (mg/L) in simulated swimming pool conditions. Irrespective of whether 150 ppm (mg/L) hydrogen peroxide was used by itself or in combination with 24 ppb of silver nitrate these investigators found that these sanitisers had negligible killing power against *Pseudomonas aeruginosa*, *Escherichia coli* and *Legionella pneumophila* (all of which are specified test organisms in the APVMA performance criteria for pool and spa sanitisers), even following a 30 minute contact period (which is 15 times longer than the test exposure duration specified in the APVMA performance criteria shown (APVMA, 2014)). Notably the concentrations of hydrogen peroxide used by these investigators are consistent with the target maintenance concentrations stipulated on the labels for those products shown in Appendix A (column 6).
14. Broadbent (1996) has noted that due to their poor antimicrobial performance during trial use in public swimming pools, hydrogen peroxide plus ultraviolet light swimming pool sanitiser systems have not been approved for use in public swimming pools in Victoria.
15. A systematic survey of swimming and spa sanitisers and sanitation systems by Wojtowicz (2001) has noted that the use of hydrogen peroxide based products resulted in an accumulation of organic matter, organic carbon, urea and ammonia in the water. These conditions promote the overgrowth of bacteria resulting in unsanitary conditions, ie, the effects were opposite to the actual intended effect of swimming and spa pool sanitisers using hydrogen peroxide as the active constituent. Wojtowicz (2001) concluded that these undesirable conditions were created because of the poor sanitiser performance characteristics of hydrogen peroxide.
16. Based on this information, the products shown in Appendix A that use hydrogen peroxide as the active constituent cannot achieve the minimum antibacterial sanitiser performance characteristics (APVMA, 2014).
17. Furthermore, based on the findings of Wojtowicz (2001), the use of the products shown in Appendix A can produce unsanitary (ie conditions that may transmit, generate or promote disease, injury or sickness to any person) and unsafe conditions, thus producing circumstances that are opposite to the intended effects of using these products.
18. Accordingly, the APVMA has concluded that:
 - a) the products shown in Appendix A that use hydrogen peroxide as the active constituent cannot meet the safety criteria defined in section 5A of the Agvet Code; and
 - b) the poor sanitiser performance characteristics of hydrogen peroxide means that the label directions of the products shown in Appendix A, particularly in relation to the circumstances in which the products should be used, how the products should be used, the times when the product should be used and the frequency of the use of the product are not adequate and therefore do not meet the labelling criteria in section 5D of the Code.

The stipulated use concentration of the hydrogen peroxide active constituent in the swimming and spa pool sanitisers is too low to ensure adequate anti-bacterial sanitiser performance and cannot be safely increased

19. The United States of America Centers for Disease Control and Prevention (CDC, 2018) confirms that 'hydrogen peroxide is not registered by the [US] EPA for use as a disinfectant in recreational water'. To ensure adequate antibacterial sanitiser performance a hydrogen peroxide concentration of around 30,000 ppm (three per cent) is required to disinfect hard surfaces (CDC, 2018). As shown in Column 6 of Appendix A, the label stipulated target maintenance hydrogen peroxide concentrations are 100 to 150 ppm. Label stipulated maintenance concentrations are 200- to 300-fold below those required to achieve adequate antibacterial sanitiser performance.
20. Hydrogen peroxide concentrations of 30,000 ppm (three per cent) are irritant to mucosal tissues (eg the mucosae of the eyes) and may cause vomiting and diarrhoea according to the United States of America Agency for Toxic Substances and Disease Registry (ATSDR, 2014). Therefore the label defined target maintenance hydrogen peroxide concentrations of 100 to 150 ppm cannot be increased to the level required to ensure adequate antibacterial sanitiser performance, because this would result in the co-occurrence of effects that are harmful to human beings (and thus the products would not meet the safety criteria defined in section 5A of the Code).

21. Based on this information the products shown in Appendix A that use hydrogen peroxide as the active constituent cannot achieve the minimum antibacterial sanitiser performance characteristics defined by the APVMA without causing the co-occurrence of effects that are harmful to human beings.
22. Accordingly, the APVMA has concluded that:
- a) the products shown in Appendix A that use hydrogen peroxide as the active constituent cannot meet the safety criteria defined in section 5A of the Agvet Code; and
 - b) The label directions of the products shown in Appendix A, particularly in relation to the circumstances in which the products should be used, how the products should be used, the times when the product should be used and the frequency of the use of the product, are not adequate and therefore do not meet the labelling criteria in section 5D of the Code. It is not possible to vary the label directions of the products shown in Appendix A in such a way that they would meet the safety criteria defined in section 5A of the Code. This is due to the poor sanitiser performance properties of hydrogen peroxide and the co-occurrence of adverse effects on human health associated with the concentrations of hydrogen peroxide that are required to produce adequate sanitiser performance.

The anti-*Legionella* sp. sanitiser performance for polyhexanide hydrochloride-based swimming and spa pool sanitiser products is inadequate

23. Barker et al (1992) evaluated the sanitiser performance of polyhexanide hydrochloride against *Legionella pneumophila* under idealised (ie, optimal) laboratory conditions. These investigators determined that polyhexanide hydrochloride at a concentration of 1 ppm (ie, roughly the same as the label stipulated maintenance concentration as shown in Appendix A) took two hours (ie, 60 times longer than the exposure time stipulated in the APVMA swimming and pool sanitiser performance criteria (APVMA, 2014)) to achieve an approximately 2.5 fold log₁₀ reduction (ie, about a 0.6 times decreased performance compared with that stipulated in the APVMA swimming and pool sanitiser performance criteria (APVMA, 2014)) in *Legionella pneumophila* survival. Furthermore, these investigators demonstrated that after four hours of exposure (ie, 120 times longer than the exposure time stipulated in the APVMA swimming and pool sanitiser performance criteria (APVMA, 2014)) at 1 ppm of polyhexanide hydrochloride did not achieve the 4 fold log₁₀ reduction in *Legionella pneumophila* survival required by the APVMA swimming and pool sanitiser performance criteria (APVMA, 2014). Based on the findings of Barker et al (1992), polyhexanide hydrochloride at the maintenance concentrations stipulated in Appendix A cannot achieve the required sanitiser performance criteria for swimming and spa pool sanitiser products.
24. Based on the findings of Barker et al (1992), the products shown in Appendix A that use polyhexanide hydrochloride as the active constituent do not have adequate sanitiser performance against *Legionella pneumophila*.
25. Given the adverse impact of *Legionella pneumophila* infection in human beings, the APVMA has concluded that the products shown in Appendix A that use hydrogen peroxide as the active constituent have harmful effects on human beings because these products do not control the risk of *Legionella pneumophila* infection associated with spa pool use. Accordingly, these products do not meet the safety criteria defined in section 5A of the Code.
26. Furthermore, based on the information presented in Barker et al (1992), the APVMA has concluded that the label directions of the products shown in Appendix A, particularly in relation to the circumstances in which the products should be used, how the products should be used, the times when the product should be used and the frequency of the use of the product are not adequate and therefore do not meet the labelling criteria in section 5D of the Code. It is not possible to vary the label directions of the products shown in Appendix A in such a way that they would meet the safety criteria defined in section 5A of the Code. This is due to the poor anti-*Legionella pneumophila* sanitiser performance properties of polyhexanide hydrochloride.

CONCLUSIONS

27. On the basis of the evidence set out above, the APVMA has determined that:

- a) the products shown in Appendix A do not meet the safety criteria as set out in section 5A of the Code, and
- b) the label approvals shown in Appendix A do not meet the labelling criteria as set out in section 5D of the Code.

28. Accordingly, the APVMA has decided to:

- c) CANCEL the registration of the swimming and spa pool products shown in Appendix A because they do not meet the safety criteria defined in section 5A of the Code; and
- d) CANCEL the approval of the swimming and spa pool product labels shown in Appendix A because they do not meet the labelling criteria defined in section 5D of the Code.

REFERENCES

Agency for Toxic Substances and Disease Registry (ATSDR) (2014), *Medical management guidelines for hydrogen peroxide*, available at atsdr.cdc.gov/mmg/mmg.asp?id=304&tid=55.

Australian Pesticides and Veterinary Medicines Authority (APVMA) (2014), *Target performance characteristics of effective sanitisers against the recommended test organisms—swimming and spa pools*, available at apvma.gov.au/node/1039.

Barker J, Brown MR, Collier PJ, Farrell I, Gilbert P (1992), Relationship between *Legionella pneumophila* and *Acanthamoeba polyphaga*: physiological status and susceptibility to chemical inactivation, *Applied and Environmental Microbiology*, 58:2420–2425.

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Broadbent, C (1996), Guidance on water quality for heated spas, *National Environmental Health Forum Monographs, Water Series No 2*, Adelaide: South Australian Health Commission, ISBN 0646294768.

Centers for Disease Control and Prevention (CDC) (2018), *Annex to the 2018 Model Aquatic Health Code, 3rd Edition*, available at: cdc.gov/mahc/pdf/2018-MAHC-Annex-Clean-508.pdf.

Romanowski, EG, Yates, KA, O'Connor, KE, Mah, FS, Shanks, RM, and Kowalski, RP (2013), Evaluation of polyhexamethylene biguanide (PHMB) as a disinfectant for adenovirus, *JAMA Ophthalmology*, 13:495–498.

Standards Australia (2002), *Water Management for Public Swimming Pools and Spas*, HB 241–2002.

Wojtowicz, JA (2001), Survey of Swimming Pool/Spa Sanitizers and Sanitation Systems, *Journal of the Swimming Pool and Spa Industry*, 4:121–141.

APPENDIX A—PRODUCTS AND LABELS

The registered products affected by the final decision are shown in the table below. All approved labels are affected.

Product number	Label number	Name	Holder	Containing the active constituent	Target maintenance concentration of active constituent in recreational water
39380	39380/60778 39380/51826 39380/02	Poppit Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm
50276	50276/0198	Spa Protector Bacteriacide & Clarifier	Pool Ranger Pty Ltd	hydrogen peroxide	100 ppm
57606	57606/RV0518C	Aquafresh By Lo-Chlor Pool Sanitiser	M I International Pty Ltd	polyhexanide hydrochloride	1.2 ppm
59949	59949/RV0518D	Aquaspa By Lo-Chlor Spa Sanitiser	M I International Pty Ltd	polyhexanide hydrochloride	1.2 ppm
61106	61106/RV0518E	Clark Rubber Filtrite Sanit-Eezy For Family Pools Eezy Sanitiser	Clark Rubber Franchising Pty Ltd	polyhexanide hydrochloride	1.2 ppm
62939	62939/62431	Spa Protector Pool & Spa Sanitiser	Pool Ranger Pty Ltd	hydrogen peroxide	100 ppm
64278	64278/RV0518F	Nature Spa Water Treatment & Sanitiser	Enviro Spa & Pool Pty Ltd	polyhexanide hydrochloride	1.2 ppm
64823	64823/RV0518G	Clark Rubber Filtrite Sanit-Eezy Eezy Sanitiser	Clark Rubber Franchising Pty Ltd	polyhexanide hydrochloride	1.2 ppm
65577	65577/51342	Pureblue Spa Protector	United Eastern Chemicals Pty Ltd	hydrogen peroxide	100 ppm
66624	66624/RV0518H	Crystal Waters Spa Sanitiser	M I International Pty Ltd	polyhexanide hydrochloride	1.2 ppm
66943	66943/RV0518I	Crystal Waters Pool Sanitiser	M I International Pty Ltd	polyhexanide hydrochloride	1.2 ppm
68964	68964/RV0518J	Filtrite Sanit-Eezy Eezy Sanitiser for Spas Spa Sanitiser	Clark Rubber Franchising Pty Ltd	polyhexanide hydrochloride	1.2 ppm
69425	69425/60768	Perox598 Chlorine Free Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm

Product number	Label number	Name	Holder	Containing the active constituent	Target maintenance concentration of active constituent in recreational water
69472	69472/60901	Peroxsil595 Chlorine Free Pool Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm
69473	69473/60902	Peroxypure 598 Chlorine Free Pool Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm
69474	69474/62951	Peroxypure395 Chlorine Free Pool Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm
69706	69706/61474	Zodiac Spa Sanifresh Bactericide And Clarifier	Fluidra Group Australia Pty Ltd	hydrogen peroxide	100 ppm
70221	70221/62763	Ultrasil Chlorine Free Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm
70441	70441/63462	Perox395 Chlorine Free Pool Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm
70448	70448/63472	Peroxsil395 Chlorine Free Pool Sanitiser	Waterco Limited	hydrogen peroxide	100 ppm
82162	82162/RV0518K	Spa Soft Spa Sanitiser	M I International Pty Ltd	polyhexanide hydrochloride	1.2 ppm
87715	87715/119060	Spa Fresh Active Spa Sanitiser	M I International Pty Ltd	polyhexanide hydrochloride	1.2 ppm
88288	88288/120764	Pool And Spa Sanitiser	The Pops Group Pty Ltd	hydrogen peroxide	100 ppm

APPENDIX B—LEGISLATIVE FRAMEWORK

AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994 (CTH)

4. Definition of ‘agricultural chemical product’

1. This section defines what is meant by an agricultural chemical product for the purposes of this Code.
2. Subject to subsections (3) and (4), an agricultural chemical product is a substance or mixture of substances that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:
 - a) destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or a thing; or
 - b) destroying a plant; or
 - c) modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or
 - d) modifying an effect of another agricultural chemical product; or
 - e) attracting a pest for the purpose of destroying it.
3. An agricultural chemical product includes a substance or mixture of substances declared by the regulations to be an agricultural chemical product.
4. An agricultural chemical product does not include:
 - a) a veterinary chemical product; or
 - b) a substance or mixture of substances declared by the regulations not to be an agricultural chemical product.

Section 5A Definition of ‘meets the safety criteria’

1. An active constituent or chemical product ***meets the safety criteria*** if use of the constituent or product, in accordance with any instructions approved, or to be approved, by the APVMA for the constituent or product or contained in an established standard:
 - a) is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
 - b) is not, or would not be, likely to have an effect that is harmful to human beings; and
 - c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment.
2. For the purposes of being satisfied as to whether an active constituent meets the safety criteria, the APVMA:
 - a) must have regard to the following:
 - (i) the toxicity of the constituent and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;
 - (ii) the method by which the constituent is, or is proposed to be, manufactured;
 - (iii) the extent to which the constituent will contain impurities;
 - (iv) whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis;

- (v) any conditions to which its approval is, or would be, subject;
 - (vi) any relevant particulars that are, or would be, entered in the Record for the constituent;
 - (vii) whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection (1);
 - (viii) any matters prescribed by the regulations; and
- b) may have regard to such other matters as it thinks relevant.
3. For the purposes of being satisfied as to whether a chemical product meets the safety criteria, the APVMA:
- a) must have regard to the following:
 - (i) the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;
 - (ii) the relevant poison classification of the product under the law in force in this jurisdiction;
 - (iii) how the product is formulated;
 - (iv) the composition and form of the constituents of the product;
 - (v) any conditions to which its registration is, or would be, subject;
 - (vi) any relevant particulars that are, or would be, entered in the Register for the product;
 - (vii) whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
 - (viii) any matters prescribed by the regulations; and
 - b) may have regard to one or more of the following:
 - (i) the acceptable daily intake of each constituent contained in the product;
 - (ii) any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under subsection 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under subsection 82(4) of that Act;
 - (iii) whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves;
 - (iv) the stability of the product;
 - (v) the specifications for containers for the product;
 - (vi) such other matters as it thinks relevant.

Section 5D Definition of ‘meets the labelling criteria’

1. A label for containers for a chemical product **meets the labelling criteria** if the label contains adequate instructions relating to such of the following as are appropriate:
 - a) the circumstances in which the product should be used;
 - b) how the product should be used;
 - c) the times when the product should be used;
 - d) the frequency of the use of the product;
 - e) the withholding period after the use of the product;
 - f) the re-entry period after the use of the product;
 - g) the disposal of the product when it is no longer required;
 - h) the disposal of containers of the product;
 - i) the safe handling of the product and first aid in the event of an accident caused by the handling of the product;
 - j) any matters prescribed by the regulations.
2. For the purposes of being satisfied as to whether a label meets the labelling criteria, the APVMA must have regard to the following:
 - a) any conditions to which its approval is, or would be, subject;
 - b) any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label;
 - c) whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).

Section 34P Notice of proposed suspension or cancellation to be given to holder

1. The APVMA must not suspend or cancel an approval or registration unless it has given the holder a written notice that:
 - a) states that the APVMA proposes to suspend or cancel the approval, or suspend or cancel the registration, as the case may be; and
 - b) sets out the reasons for the proposed suspension or cancellation; and
 - c) invites the holder to make, within a reasonable period specified in the notice, submissions to the APVMA in relation to the proposed suspension or cancellation.
2. The APVMA must not make a decision relating to the proposed suspension or cancellation, as the case may be, until it has had regard to any submission made by the person in response to an invitation under paragraph (1)(c).
3. A written notice under subsection (1) must specify the period of the suspension.
4. Subsection (1) does not apply to a suspension or cancellation under section 34AA, 35A, 39 or 42.

Section 35 Notice of proposed suspension or cancellation to be given to co-ordinators

1. Subject to subsection (2), the APVMA must not suspend or cancel an approval or registration unless:
 - a) it has given notice of the proposed suspension or cancellation to each co-ordinator designated for a jurisdiction; and

- b) a period of 10 working days, or any other period that the APVMA thinks adequate in a particular case, has elapsed since the notice was given.

2. Subsection (1) does not apply to a suspension or cancellation under section 35A.

Section 41 Suspension or cancellation of approval or registration for non-compliance with criteria for approval or registration or prescribed requirements

1. The APVMA may suspend or cancel the approval of an active constituent for a proposed or existing chemical product, or the registration of a chemical product, if it appears to the APVMA:
 - a) for an active constituent—that the constituent may not meet the safety criteria; or
 - b) for a chemical product—that the product may not meet the safety criteria, the trade criteria or the efficacy criteria; or
 - c) that the constituent or product may not comply with any requirement prescribed by the regulations.
2. The APVMA may suspend or cancel the approval of a label for containers for a chemical product if it appears to the APVMA that the label may not meet the labelling criteria or may not comply with any requirement prescribed by the regulations.

AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995

Regulation 8AB Safety criteria—chemical products

1. For subparagraph 5A(3)(a)(vii) of the Code, the following are prescribed matters for a chemical product:
 - a) for all chemical products—the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product;
 - b) for a product manufactured in Australia—whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code;
 - c) for a product manufactured outside Australia—whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code;
 - d) for a molluscicide in the form of a bait and of which the active constituent is metaldehyde:
 - (i) whether the product contains sufficient green pigment or dye to colour the bait a distinctive green colour; and
 - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
 - e) for a molluscicide in the form of a bait and of which the active constituent is methiocarb:
 - (i) whether the product contains sufficient blue pigment or dye to colour the bait a distinctive blue colour; and
 - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
 - f) for an agricultural chemical product to be applied to seeds to be stored before planting or sowing—whether the product contains sufficient pigment or dye to colour the seed to enable the seed to be readily distinguished from seed to which the product has not been applied.
2. However, paragraphs (1)(b) and (c) do not apply if the product is prescribed under subregulation 59(1) for the purposes of section 120A of the Code

Regulation 8AE Labelling criteria

1. For paragraph 5D(1)(j) of the Code, the following are prescribed matters:
 - a) for a chemical product that is a veterinary chemical product—the duration of any treatment using the product;
 - b) the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia;
 - c) the appropriate signal words (if any) required by the current Poisons Standard;
 - d) for a chemical product that is a date-controlled chemical product—the storage of containers for the product;
 - e) any other matter determined by the APVMA CEO under subregulation (2).
2. For paragraph 6(2)(c) of the Act, the APVMA CEO may determine matters in relation to which a label must contain adequate instructions.

Notice of cancellation of the registration of certain spa and pool sanitiser products and associated label approvals

In accordance with section 41(1)(b) and 41(2) of the Agricultural and Veterinary Chemical Code scheduled to the *Agricultural and Veterinary Chemical Code Act 1994* (the Agvet Code), the Australian Pesticides and Veterinary Medicines Authority (APVMA) has cancelled the product registrations and label approvals in the table below.

Product registration number(s)	Label approval number(s)	Product name	Holder	Date of cancellation
39380	39380/60778 39380/51826 39380/02	Poppit Sanitiser	Waterco Limited	28 July 2020
50276	50276/0198	Spa Protector Bacteriacide & Clarifier	Pool Ranger Pty Ltd	28 July 2020
57606	57606/RV0518C	Aquafresh By Lo-Chlor Pool Sanitiser	M I International Pty Ltd	28 July 2020
59949	59949/RV0518D	Aquaspa By Lo-Chlor Spa Sanitiser	M I International Pty Ltd	28 July 2020
61106	61106/RV0518E	Clark Rubber Filtrite Sanit-Eezy For Family Pools Eezy Sanitiser	Clark Rubber Franchising Pty Ltd	28 July 2020
62939	62939/62431	Spa Protector Pool & Spa Sanitiser	Pool Ranger Pty Ltd	28 July 2020
64278	64278/RV0518F	Nature Spa Water Treatment & Sanitiser	Enviro Spa & Pool Pty Ltd	28 July 2020
64823	64823/RV0518G	Clark Rubber Filtrite Sanit-Eezy Eezy Sanitiser	Clark Rubber Franchising Pty Ltd	28 July 2020
65577	65577/51342	Pureblue Spa Protector	United Eastern Chemicals Pty Ltd	28 July 2020
66624	66624/RV0518H	Crystal Waters Spa Sanitiser	M I International Pty Ltd	28 July 2020
66943	66943/RV0518I	Crystal Waters Pool Sanitiser	M I International Pty Ltd	28 July 2020
68964	68964/RV0518J	Filtrite Sanit-Eezy Eezy Sanitiser For Spas Spa Sanitiser	Clark Rubber Franchising Pty Ltd	28 July 2020
69425	69425/60768	Perox598 Chlorine Free Sanitiser	Waterco Limited	28 July 2020
69472	69472/60901	Peroxsil595 Chlorine Free Pool Sanitiser	Waterco Limited	28 July 2020

Product registration number(s)	Label approval number(s)	Product name	Holder	Date of cancellation
69473	69473/60902	Peroxypure 598 Chlorine Free Pool Sanitiser	Waterco Limited	28 July 2020
69474	69474/62951	Peroxypure395 Chlorine Free Pool Sanitiser	Waterco Limited	28 July 2020
69706	69706/61474	Zodiac Spa Sanifresh Bactericide And Clarifier	Fluidra Group Australia Pty Ltd	28 July 2020
70221	70221/62763	Ultrasil Chlorine Free Sanitiser	Waterco Limited	28 July 2020
70441	70441/63462	Perox395 Chlorine Free Pool Sanitiser	Waterco Limited	28 July 2020
70448	70448/63472	Peroxsil395 Chlorine Free Pool Sanitiser	Waterco Limited	28 July 2020
82162	82162/RV0518K	Spa Soft Spa Sanitiser	M I International Pty Ltd	28 July 2020
87715	87715/119060	Spa Fresh Active Spa Sanitiser	M I International Pty Ltd	28 July 2020
88288	88288/120764	Pool And Spa Sanitiser	The Pops Group Pty Ltd	28 July 2020

BRIEF REASONS FOR DECISIONS

Pursuant to section 41(1) of the Agvet Code the APVMA is not satisfied that the products listed in the table above meet the safety criteria set out in section 5A of the Agvet Code.

Pursuant to section 41(2) the APVMA is also not satisfied that the labels listed in the table above meet the labelling criteria set out in section 5D of the Agvet Code.

INSTRUCTIONS FOR PERSONS WHO POSSESS, HAVE CUSTODY OR USE OF THE CANCELLED PRODUCT

A person who possesses, has custody of or uses the cancelled product referred to in the above table 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 product in accordance with those instructions.

POSSESSION OR CUSTODY

A person may possess the cancelled product referred to in the above table in accordance with its label instructions until 31 January 2021.

USE, SUPPLY OR OTHERWISE DEAL WITH

A person may use the cancelled product referred to in the above table according to its label instructions, including any conditions relating to shelf life or expiry date, until 31 January 2021.

A person may supply, or cause to be supplied, at wholesale or retail level the cancelled product referred to in the above table, until 31 January 2021.

A person may not manufacture or import the cancelled product referred to in the above table from the date of cancellation.

WARNING—CONTRAVENTIONS

After 31 January 2021 it will be an offence against the Agvet Code to supply the cancelled product, or to have possession or custody of the cancelled products with the intention to supply.

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled products listed in the table above 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.

Notice of end of registration

In accordance with section 47C of the Agricultural and Veterinary Chemical Code scheduled to the *Agricultural and Veterinary Chemical Code Act 1994* (the Agvet Code), the product registrations and associated label approvals in the table below have ended without being renewed.

Product registration number(s)	Label approval number(s)	Product name	Holder
40742	40742/60777 40742/0309 40742/1103 40742/0998	Poppit Sanosil Pool & Spa Sanitiser	Waterco Limited
47963	47963/1098	Ozone Accelerator Pool & Spa Sanitiser	Isaac Technology Pty Ltd
48356	48356/RV0518A	Htl Bio-Blu Swimming Pool & Spa Water Treatment & Sanitiser	The Good Splash Co Pty Ltd
49284	49284/120565 49284/RV0518B	King Neptune's Ozone Clear Pool Sanitiser	Isaac Technology Pty Ltd
65124	65124/50210	Spa Fresh Spa Sanitiser, Conditioner, Clarifier & Bactericide	Spa Industries Global Pty Ltd
68642	68642/58813	Zodiac Spa Sanifresh	Fluidra Group Australia Pty Ltd
86184	86184/114920	Zodiac Bio Blu Spa Sanitiser	The Good Splash Co Pty Ltd
86344	86344/115525	Spa Fresh Peroxsil395 Chlorine Free Sanitiser	Waterco Limited

DATE REGISTRATION HAS ENDED

The product registrations ended on 1 July 2020.

INSTRUCTIONS FOR PERSONS WHO POSSESS, HAVE CUSTODY OR USE OF THE CANCELLED PRODUCT

A person who possesses, has custody of or uses the product referred to in the above table in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 47D of the Agvet Code to possess, have custody of or use the product in accordance with those instructions.

The permit issued under s 47D of the Agvet Code will cease to apply on 31 January 2021.

POSSESSION OR CUSTODY

A person may possess the products referred to in the above table in accordance with its label instructions until 31 January 2021.

USE, SUPPLY OR OTHERWISE DEAL WITH

A person may use the products referred to in the above table according to its label instructions, including any conditions relating to shelf life or expiry date, until 31 January 2021.

A person may supply, or cause to be supplied, at wholesale or retail level the products referred to in the above table, until 31 January 2021.

A person may not manufacture or import the products referred to in the above table from the date the registration has ended.

WARNING—CONTRAVENTIONS

After the date the permit has ended it will be an offence against the Agvet Code to have possession or custody of the products with the intention to supply, or to supply the product.

It is an offence to possess, have custody of, use, or otherwise deal with the products listed in the table above in a manner that contravenes the above instructions.

APVMA CONTACT

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

Finance Team
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300

Email: finance@apvma.gov.au.

Final regulatory decisions for certain products containing chlorpyrifos as an active constituent

STATEMENT OF REASONS

1. The Australian Pesticides and Veterinary Medicines Authority (**APVMA**) has made the following decisions in respect of registration and approvals under section 41 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code)*, to:

1.1 CANCEL under section 41(1) of the Agvet Code the product registrations set out in Table 1 which contain chlorpyrifos; and

1.2 CANCEL under section 41(1) of the Agvet Code the label approvals set out in Table 1 for products which contain chlorpyrifos; and

1.3 CANCEL under section 41(1) of the Agvet Code the prior label approvals set out in Table 2 for products which contain chlorpyrifos.

Table 1: The cancelled product registrations and label approvals for unvaried combination chlorpyrifos products

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
49315	Richgro Garden Products Lawn Beetle And Grub Killer	A. Richards Pty Ltd	49315/0206
68279	Agro-Essence Chlorpyrifos 500 Insecticide	Agro-Alliance (Australia) Pty Ltd	68279/105168, 68279/57925
42039	David Grays PCO Chlorpyrifos 500	David Gray & Co Pty Ltd	42039/0501
86544	Foison Chlorpyrifos 500 EE Insecticide	Eureka! Agresearch Pty Ltd	86544/116014
70062	Macphersons Chlorpyrifos 500 Insecticide	Eurochem Pty Ltd	70062/62409
86544	Foison Chlorpyrifos 500 EC Insecticide	Foison Scitech Co., Limited	86544/116014
55208	Halley Chlorpyrifos 500 Insecticide	Halley International Enterprise (Australia) Pty Ltd	55208/0203, 55208/0702, 55208/0202
67170	Novaguard Chlorpyrifos 500 Insecticide	Novaguard Pty Ltd	67170/55388
69990	Agvantage Chlorpyrifos 500 EC Insecticide	Nutrien Ag Solutions Limited	N/A
52596	Macro Protect Chlorpyrifos 500 Insecticide And Termiticide	Nutrien Ag Solutions Limited	N/A
80093	Oztec Chlorpyrifos 500EC Insecticide	Oztec Rural Pty Ltd	80093/100196

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
45227	Surefire Antout Granular Insecticide	Pct Holdings Pty Ltd	45227/115365, 45227/0501
85424	Profeng Chlorpyrifos 500 EC Insecticide	Profeng Australia Pty Ltd	85424/113255
85005	Raystar Chlorpyrifos 500 EC Insecticide	Raystar Cropprotection Pty Ltd	85005/112016
68729	Contraforce Termiticide & Insecticide	Sherwood Chemicals Australasia Pty Ltd	68729/58966
84836	Submarino Chlorpyrifos 500 Insecticide	Submarino Pty Ltd	84836/111529
54957	Wsd Chlorpyrifos 500 EC Insecticide	Wsd Agribusiness Pty Ltd	54957/0502

Table 2: The cancelled prior approved label(s) for varied combination chlorpyrifos products

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
49869	4farmers Chlorpyrifos 500 Insecticide	4 Farmers Australia Pty Ltd	49869/56833, 49869/0402
68574	Accensi Micro-Lo Pre-Construction/Post-Construction Termiticide And Insecticide	Accensi Pty Ltd	68574/109102, 68574/58615
68575	Accensi Pre-Construction/Post-Construction Termiticide And Insecticide	Accensi Pty Ltd	68575/58616
69776	Accensi Chlorpyrifos 500 Insecticide	Accensi Pty Ltd	69776/61713
61071	Strike-Out 500 Wp Insecticide	Adama Australia Pty Ltd	61071/63186, 61071/0710, 61071/0609, 61071/0906
85326	Agprotect Chlorpyrifos 500 EC Insecticide	Agprotect Australasia Pty Ltd	85326/112937
63145	Aw Cuft 500 Insecticide And Termiticide	Agri West Pty Ltd	63145/58996, 63145/0908
49666	Barmac Chlorpyrifos G Granular Insecticide	Amgrow Pty Ltd	49666/0402

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
86612	Arysta Lifescience Chlorpyrifos 500 EC Insecticide	Arysta Lifescience Australia Pty Ltd	86612/116202
81735	ACP Chlorpyrifos 500 Insecticide	Australis Crop Protection Pty Ltd	81735/103921
68745	AC Chop 500 Insecticide and Termiticide	Axichem Pty Ltd	68745/59000
55897	Conquest Chlorpyrifos 500 Insecticide	Conquest Crop Protection Pty Ltd	55897/0408, 55897/0702
69048	Smart Chlorpyrifos 500 Insecticide	Crop Smart Pty Ltd	69048/59718
42284	David Grays Chlorpyrifos 500	David Gray & Co Pty Ltd	42284/0901
51211	Lorsban 750 WG Insecticide	Dow Agrosiences Australia Limited	51211/0306, 51211/0501, 51211/0401
67984	Ezycrop Chlorpyrifos 500 Insecticide	Ezycrop Pty Ltd	67984/57224
64319	Farmalinx Chlorpos 500 EC Insecticide	Farmalinx Pty Ltd	64319/59285, 64319/0809
53428	Generifos 500EC Insecticide	Grow Choice Pty Ltd	53428/59489, 53428/0202
60611	Huilong Chlorpyrifos 500 EC Insecticide	Huilong Agrochemicals Australia Pty Ltd	60611/107504, 60611/53005, 60611/0806
51190	Imtrade Chlorpyrifos 500 Insecticide	Imtrade Australia Pty Ltd	51190/106298, 51190/0809, 51190/0502
32902	Nufarm Chlorpyrifos 500 EC Insecticide	Nufarm Australia Limited	32902/0809, 32902/1208, 32902/1207, 32902/0305, 32902/0104, 32902/0903, 32902/0303, 32902/0902, 32902/0801
39885	Nufarm Chlorpyrifos Pco Insecticide	Nufarm Australia Limited	39885/0801
60188	Genfarm Chlorpyrifos 500 Insecticide	Nutrien Ag Solutions Limited	60188/52767, 60188/0209, 60188/1106, 60188/0905

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
55755	Surefire Fortune 500 Multi-Purpose Insecticide And Termiticide	Pct Holdings Pty Ltd	55755/108773, 55755/0502
51875	Pidgeon's Pest Controller 500 Termiticide And Insecticide	Pooma Fertilizers Pty Ltd	51875/1206, 51875/0406, 51875/0402, 51875/1100
67451	Sabakem Chlorpyrifos 500EC Insecticide	Sabakem Pty Ltd	67451/113873, 67451/105206, 67451/56062
65556	Rainbow Chlorpyrifos 500 Insecticide	Shandong Rainbow International Co Ltd	65556/51274
83310	Sinon Chlorpyrifos 500 EC Insecticide	Sinon Australia Pty Ltd	83310/107951
86189	Sinon Chlorpyrifos 500 Insecticide	Sinon Australia Pty Ltd	86189/114945
67887	Spalding Chlorpyrifos 500 Insecticide	Spalding Holdings Pty Ltd	67887/57029
65160	Apparent Dingo 500 Insecticide	Titan Ag Pty Ltd	65160/59930, 65160/50307
68467	Chlorban 500 EC Insecticide	Upl Australia Pty Ltd	68467/101329, 68467/101482, 68467/61695, 68467/58407

2. The reasons for these decisions are set out below.

LEGISLATIVE FRAMEWORK

3. The following sections of the Agvet Code and Agricultural and Veterinary Chemicals Regulations 1995 (**Agvet Code Regs**) are relevant to the final decisions:

Section	Provision
4	Definition of <i>agricultural chemical product</i>
5A	Definition of <i>meets the safety criteria</i>
5B	Definition of <i>meets the efficacy criteria</i>
5C	Definition of <i>meets the trade criteria</i>
5D	Definition of <i>meets the labelling criteria</i>

Section	Provision
34P	The APVMA must not suspend or cancel an approval or registration unless it has given the holder a written notice that it intends to do so, and has had regard to any submissions made by the person to whom the written notice is given
35	The APVMA must not suspend or cancel an approval or registration unless it has given written notice of the intended action to each coordinator designated for a jurisdiction
41	The APVMA may suspend or cancel the approval of an active constituent for a proposed or existing chemical product, or the registration of a chemical product, if it appears to the APVMA that the product may not meet the safety criteria, the trade criteria or the efficacy criteria. The APVMA may suspend or cancel the approval of a label for containers for a chemical product if it appears to the APVMA that the label may not meet the labelling criteria or may not comply with any requirement prescribed by the regulations

4. Relevant extracts of these provisions are found at **Appendix A**.

EVIDENCE OR OTHER MATERIAL ON WHICH ANY FINDINGS OF FACT ARE BASED

5. The following were considered and relied upon for the final decisions:

- 5.1 The relevant provisions of the Agvet Code as set out above;
 - 5.2 The relevant provisions of any regulations, standards and determinations as set out above;
 - 5.3 The relevant particulars of the products in Table 1, in particular the APVMA product registration number, the distinguishing name of the chemical product, registration holder and label approval number(s) for products;
 - 5.4 The report titled Reconsideration of chlorpyrifos: Toxicology update, 2019;
 - 5.5 The report titled Reconsideration of chlorpyrifos: Residential exposure and public space use exposure assessment and risk characterisation update, 2019;
 - 5.6 The report titled Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses, 2019
 - 5.7 The APVMA's policy on worker health and safety risk assessments;¹
 - 5.8 Information given to the APVMA in response to 78 notices given under section 32(1) of the Agvet Code during the reconsideration of the active constituent chlorpyrifos;
 - 5.9 Submissions made to the APVMA in response to an invitation given under section 32(2A)(b) of the Agvet Code during the reconsideration of the active constituent chlorpyrifos;
 - 5.10 Information given to the APVMA in response to two notices given under section 33 of the Agvet Code during the reconsideration of the active constituent chlorpyrifos; and
 - 5.11 The APVMA's final regulatory decision for the registrations of chlorpyrifos home garden and domestic pest control products, as outlined in the Special Gazette of 25 September 2019.²
6. No submissions were received in response to notices given to jurisdiction chemical coordinators or to holders and nominated agents, in accordance with s 35 and s 34P of the Code, respectively.

¹ apvma.gov.au/node/31421

² apvma.gov.au/node/54976

MATERIAL FINDINGS OF FACT

7. Based on the evidence and other material set out above, including the APVMA's final regulatory decision for the registrations of chlorpyrifos home garden and domestic pest control products, the APVMA makes the following findings of fact which are material to the final decision:
- 7.1 chlorpyrifos is hazardous to mammals (including human beings)—that is, it has the *potential* to cause harm;
 - 7.2 the types of adverse effects from exposure to chlorpyrifos are dependent on the level of exposure, with more severe adverse effects occurring as the level of exposure increases;
 - 7.3 exposure to chlorpyrifos at levels that result in detectable inhibition of blood cholinesterases is a serious neurodevelopmental and neuro-behavioural developmental health hazard for humans;
 - 7.4 the acceptable daily intake (ADI) for chlorpyrifos is 0.001 mg/kg bw/day (1 µ/kg bw/day);
 - 7.5 the acute reference dose for chlorpyrifos is 0.03 mg/kg bw;
 - 7.6 chlorpyrifos exposure reasonably expected in connection with non-professional residential use of the products will likely exceed the acute reference dose;
 - 7.7 post-application re-entry intervals and personal protective equipment (apart from gloves) do not represent realistic risk mitigation strategies for non-professional users in a residential setting;
 - 7.8 the use of the products in a residential setting is likely to have an effect that is harmful to human beings;
 - 7.9 the use of the products by non-professionals in a residential setting poses an undue hazard to the safety of people exposed to said products during their handling;
 - 7.10 the chronic avian dietary no observed effect level for chlorpyrifos is 25 mg/kg;
 - 7.11 the acute avian oral lethal dose (LD₅₀) is 28.9 mg/kg bw;
 - 7.12 the use of the products in a residential setting, including application to turf at rates that exceed 850 g ac/ha poses an unacceptable risk to birds;
 - 7.13 granular chlorpyrifos products used in a residential setting are prone to being applied at application rates in excess of 850 g ac/ha; and
 - 7.14 the use of granular chlorpyrifos products in a residential setting is likely to have an unintended effect that is harmful to animals.
8. The APVMA is not satisfied that:
- 8.1 the products in Table 1 meet the safety criteria set out in section 5A(1) of the Agvet Code; and
 - 8.2 the labels set out in Table 1 and Table 2 meet the labelling criteria set out in section 5D(1) of the Agvet Code.

DOES NOT MEET THE SAFETY CRITERIA

9. Section 5A(1) of the Agvet Code provides that a chemical product meets the safety criteria if use of the product, in accordance with any instructions approved or to be approved by the APVMA:
- 9.1 is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (s 5A(1)(a)); and
 - 9.2 is not, or would not be, likely to have an effect that is harmful to human beings (s 5A(1)(b)); and
 - 9.3 is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (s 5A(1)(c)).

10. Section 5A(3) of the Agvet Code outlines the matters the APVMA must/may have regard to in determining whether a product meets the safety criteria. These include:

10.1 how the product is formulated (s 5A(3)(a)(iii));

10.2 the composition and form of the constituents of the product (s 5A(3)(a)(iv));

10.3 any conditions to which the registration would be subject (s 5A(3)(a)(v);

10.4 any relevant particulars that are, or would be entered into the Register (s 5A(3)(a)(vi));

10.5 whether the product conforms to a standard made under section 6E (s 5A(3)(a)(via) to the extent that the standard relates to matters covered by section 5A (1);

10.6 any specific matters prescribed by the Agvet Code Regulations (s 5A(3)(a)(vii)), which includes the method of analysis of chemical composition and form of the constituents (r8AB(1)(a));

10.7 the stability of the product (s 5A(3)(b)(iv));

10.8 the specifications for containers of the product (s 5A(3)(b)(v); and

10.9 other chemistry and manufacture specific matters as the APVMA thinks is relevant (s 5A(3)(b)(vi).

11. The APVMA is not satisfied that the products in Table 1 meet the safety criteria. Specifically, the APVMA is not satisfied that the products in Table 1 are not:

11.1 an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residue, for the purposes of section 5A(1)(a) of the Agvet Code;

11.2 likely to have an effect that is harmful to human beings, for the purposes of section 5A(1)(b) of the Agvet Code; and

11.3 or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment for the purposes of paragraph 5A(1)(c) of the Agvet Code.

DOES NOT MEET THE LABELLING CRITERIA

12. Section 5D(1) of the Agvet Code provides that a label for containers for a chemical product *meets the labelling criteria* if the label contains adequate instructions relating to the matters set out in s5D(1) that are appropriate.

13. Section 5D(2) of the Agvet Code outlines the matters the APVMA must have regard to in determining whether a label meets the labelling criteria. These include:

13.1 any conditions to which the label approval is or would be subject (s 5D(2)(a));

13.2 any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label (s 5D(2)(b));

13.3 whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1) (s 5D(2)(c)).

14. The APVMA is not satisfied that the labels in Table 1 and Table 2 meet the labelling criteria. Specifically, the APVMA is not satisfied:

14.1 For the purposes of paragraph 5D(1)(a) of the Agvet Code regarding the circumstances in which the products should be used:

14.1.1 The labels for the products in Table 1 and Table 2 have certain uses or circumstances in domestic or residential areas, container plants, public spaces to which children have access, potted ornamentals and other potted plants, duboisia (in domestic and public space uses), macrocarpa hedges (in domestic and public space uses), uses on turf and/or lawns to which children have access and mosquito adult/larvae control in vegetation, that are

concluded in the Reconsideration of chlorpyrifos: Residential exposure and public space use exposure assessment and risk characterisation update, 2019 to pose unacceptable risks to humans; and

- 14.1.2 The labels for the products in Table 1 and Table 2 have certain uses or circumstances in domestic areas, public places and turf, that have use rates above 850 g ac/ha, that are concluded in the Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) to pose unacceptable risks to animals, especially birds;
- 14.2 For the purposes of paragraph 5D(1)(b) of the Agvet Code regarding how the products should be used, the labels for the products in Table 1 and Table 2 contain certain uses in domestic, public places and turf above 850 g ac/ha that are concluded in the Reconsideration of chlorpyrifos: Supplementary environment assessment report Part —Home garden, domestic and certain non-agricultural uses (2019) to pose unacceptable risks to animals, especially birds;
- 14.3 For the purposes of paragraph 5D(1)(f) of the Agvet Code regarding the re-entry period after the use of the products, the labels for the products in Table 1 and Table 2 do not have adequate instructions for re-entry after the products are used in domestic or residential areas, container plants, public spaces to which children have access, potted ornamentals and other potted plants, duboisia (in domestic and public space uses), macrocarpa hedges (in domestic and public space uses), uses on turf and/or lawns to which children have access and mosquito adult/larvae control in vegetation, and therefore pose uncontrolled risks to humans, mainly children, on re-entry period into treated areas after the use of the products.

CONCLUSION

15. On the basis of the evidence set out above, the APVMA has determined that:

15.1 the products listed in Table 1 do not meet the safety criteria set out in section 5A(1) of the Agvet Code; and

15.2 the labels listed in Table 1 and Table 2 do not meet the labelling criteria set out in section 5A(1) of the Agvet Code.

16. Accordingly, the APVMA has decided to:

- a) CANCEL under section 41(1) of the Agvet Code the product registrations set out in Table 1 which contain chlorpyrifos; and
- b) CANCEL under section 41(1) of the Agvet Code the label approvals set out in Table 1 for products which contain chlorpyrifos; and
- c) CANCEL under section 41(1) of the Agvet Code the prior label approvals set out in Table 2 for products which contain chlorpyrifos.

APPENDIX A: LEGISLATIVE FRAMEWORK

Agricultural and Veterinary Chemicals Code Scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth)

Section 4 Definition of agricultural chemical product

1. This section defines what is meant by an agricultural chemical product for the purposes of this Code.
2. Subject to subsections (3) and (4), an agricultural chemical product is a substance or mixture of substances that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:
 - a) destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or a thing; or
 - b) destroying a plant; or
 - c) modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or
 - d) modifying an effect of another agricultural chemical product; or
 - e) attracting a pest for the purpose of destroying it.
3. An agricultural chemical product includes a substance or mixture of substances declared by the regulations to be an agricultural chemical product.
4. An agricultural chemical product does not include:
 - a) a veterinary chemical product; or
 - b) a substance or mixture of substances declared by the regulations not to be an agricultural chemical product.

Section 5A Definition of *meets the safety criteria*

1. An active constituent or chemical product meets the safety criteria if use of the constituent or product, in accordance with any instructions approved, or to be approved, by the APVMA for the constituent or product or contained in an established standard:
 - a) is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
 - b) is not, or would not be, likely to have an effect that is harmful to human beings; and
 - c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment.
2. For the purposes of being satisfied as to whether an active constituent meets the safety criteria, the APVMA:
 - a) must have regard to the following:
 - (i) the toxicity of the constituent and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;
 - (ii) the method by which the constituent is, or is proposed to be, manufactured;
 - (iii) the extent to which the constituent will contain impurities;
 - (iv) whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis;

- (v) any conditions to which its approval is, or would be, subject;
 - (vi) any relevant particulars that are, or would be, entered in the Record for the constituent;
 - (vii) whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection (1);
 - (viii) any matters prescribed by the regulations; and
- b) may have regard to such other matters as it thinks relevant.
3. For the purposes of being satisfied as to whether a chemical product meets the safety criteria, the APVMA:
- a) must have regard to the following:
 - (i) the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;
 - (ii) the relevant poison classification of the product under the law in force in this jurisdiction;
 - (iii) how the product is formulated;
 - (iv) the composition and form of the constituents of the product;
 - (v) any conditions to which its registration is, or would be, subject;
 - (vi) any relevant particulars that are, or would be, entered in the Register for the product;
 - (vii) whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
 - (viii) any matters prescribed by the regulations; and
 - b) may have regard to one or more of the following:
 - (i) the acceptable daily intake of each constituent contained in the product;
 - (ii) any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under subsection 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under subsection 82(4) of that Act;
 - (iii) whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves;
 - (iv) the stability of the product;
 - (v) the specifications for containers for the product;
 - (vi) such other matters as it thinks relevant.

Section 5D Definition of meets the labelling criteria

1. A label for containers for a chemical product **meets the labelling criteria** if the label contains adequate instructions relating to such of the following as are appropriate:
 - a) the circumstances in which the product should be used;
 - b) how the product should be used;
 - c) the times when the product should be used;
 - d) the frequency of the use of the product;
 - e) the withholding period after the use of the product;
 - f) the re-entry period after the use of the product;
 - g) the disposal of the product when it is no longer required;
 - h) the disposal of containers of the product;
 - i) the safe handling of the product and first aid in the event of an accident caused by the handling of the product;
 - j) any matters prescribed by the regulations.
2. For the purposes of being satisfied as to whether a label meets the labelling criteria, the APVMA must have regard to the following:
 - a) any conditions to which its approval is, or would be, subject;
 - b) any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label;
 - c) whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).

Section 34P Notice of final suspension or cancellation to be given to holder

1. The APVMA must not suspend or cancel an approval or registration unless it has given the holder a written notice that:
 - a) states that the APVMA proposes to suspend or cancel the approval, or suspend or cancel the registration, as the case may be; and
 - b) sets out the reasons for the proposed suspension or cancellation; and
 - c) invites the holder to make, within a reasonable period specified in the notice, submissions to the APVMA in relation to the proposed suspension or cancellation.
2. The APVMA must not make a decision relating to the proposed suspension or cancellation, as the case may be, until it has had regard to any submission made by the person in response to an invitation under paragraph (1)(c).
3. A written notice under subsection (1) must specify the period of the suspension.
4. Subsection (1) does not apply to a suspension or cancellation under section 34AA, 35A, 39 or 42.

Section 35 Notice of proposed suspension or cancellation to be given to co-ordinators

1. Subject to subsection (2), the APVMA must not suspend or cancel an approval or registration unless:
 - a) it has given notice of the proposed suspension or cancellation to each co-ordinator designated for a jurisdiction; and

- b) a period of 10 working days, or any other period that the APVMA thinks adequate in a particular case, has elapsed since the notice was given.
- 2. Subsection (1) does not apply to a suspension or cancellation under section 35A.

Section 41 Suspension or cancellation of approval or registration for non-compliance with criteria for approval or registration or prescribed requirements

1. The APVMA may suspend or cancel the approval of an active constituent for a proposed or existing chemical product, or the registration of a chemical product, if it appears to the APVMA:
 - a) for an active constituent—that the constituent may not meet the safety criteria; or
 - b) for a chemical product—that the product may not meet the safety criteria, the trade criteria or the efficacy criteria; or
 - c) that the constituent or product may not comply with any requirement prescribed by the regulations.
2. The APVMA may suspend or cancel the approval of a label for containers for a chemical product if it appears to the APVMA that the label may not meet the labelling criteria or may not comply with any requirement prescribed by the regulations.

AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995

Regulation 8AB Safety criteria—chemical products

1. For subparagraph 5A(3)(a)(vii) of the Code, the following are prescribed matters for a chemical product:
 - a) for all chemical products—the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product;
 - b) for a product manufactured in Australia—whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code;
 - c) for a product manufactured outside Australia—whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code;
 - d) for a molluscicide in the form of a bait and of which the active constituent is metaldehyde:
 - (i) whether the product contains sufficient green pigment or dye to colour the bait a distinctive green colour; and
 - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
 - e) for a molluscicide in the form of a bait and of which the active constituent is methiocarb:
 - (i) whether the product contains sufficient blue pigment or dye to colour the bait a distinctive blue colour; and
 - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
 - f) for an agricultural chemical product to be applied to seeds to be stored before planting or sowing—whether the product contains sufficient pigment or dye to colour the seed to enable the seed to be readily distinguished from seed to which the product has not been applied.
2. However, paragraphs (1)(b) and (c) do not apply if the product is prescribed under subregulation 59(1) for the purposes of section 120A of the Code

Regulation 8AE Labelling criteria

1. For paragraph 5D(1)(j) of the Code, the following are prescribed matters:
 - a) for a chemical product that is a veterinary chemical product—the duration of any treatment using the product;
 - b) the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia;
 - c) the appropriate signal words (if any) required by the current Poisons Standard;
 - d) for a chemical product that is a date-controlled chemical product—the storage of containers for the product;
 - e) any other matter determined by the APVMA CEO under subregulation (2).
2. For paragraph 6(2)(c) of the Act, the APVMA CEO may determine matters in relation to which a label must contain adequate instructions.

Notice of cancellation of the registration of certain chlorpyrifos products and associated labels

In accordance with section 41(1)(b) and 41(2) of the Agricultural and Veterinary Chemical Code scheduled to the *Agricultural and Veterinary Chemical Code Act 1994* (the Agvet Code), the Australian Pesticides and Veterinary Medicines Authority (APVMA) has cancelled the product registrations and label approvals in the tables below.

Table 1: Cancelled product registrations and label approvals

Product registration number(s)	Label approval number(s)	Product name	Holder	Date of cancellation
42039	42039/0501	David Grays Pco Chlorpyrifos 500	David Gray & Co Pty Ltd	24 July 2020
45227	45227/115365 45227/0501	Surefire Antout Granular Insecticide	Pct Holdings Pty Ltd	24 July 2020
49315	49315/0206	Richgro Garden Products Lawn Beetle And Grub Killer	A. Richards Pty Ltd	24 July 2020
52596	No approved label—previously voluntarily cancelled under s42 (29 Jul 19)	Macro Protect Chlorpyrifos 500 Insecticide And Termiticide	Nutrien Ag Solutions Limited	24 July 2020
54957	54957/0502	Wsd Chlorpyrifos 500 EC Insecticide	Wsd Agribusiness Pty Ltd	24 July 2020
55208	55208/0203 55208/0702 55208/0202	Halley Chlorpyrifos 500 Insecticide	Halley International Enterprise (Australia) Pty Ltd	24 July 2020
67170	67170/55388	Novaguard Chlorpyrifos 500 Insecticide	Novaguard Pty Ltd	24 July 2020
68279	68279/105168 68279/57925	Agro-Essence Chlorpyrifos 500 Insecticide	Agro-Alliance (Australia) Pty Ltd	24 July 2020
68729	68729/58966	Contraforce Termiticide & Insecticide	Sherwood Chemicals Australasia Pty Ltd	24 July 2020
69990	No approved label—previously voluntarily cancelled under s42 (29-Jul-19)	Agvantage Chlorpyrifos 500 EC Insecticide	Nutrien Ag Solutions Limited	24 July 2020
70062	70062/62409	Macphersons Chlorpyrifos 500 Insecticide	Eurochem Pty Ltd	24 July 2020

Product registration number(s)	Label approval number(s)	Product name	Holder	Date of cancellation
80093	80093/100196	Oztec Chlorpyrifos 500EC Insecticide	Oztec Rural Pty Ltd	24 July 2020
84836	84836/111529	Submarino Chlorpyrifos 500 Insecticide	Submarino Pty Ltd	24 July 2020
85005	85005/112016	Raystar Chlorpyrifos 500 EC Insecticide	Raystar Cropprotection Pty Ltd	24 July 2020
85424	85424/113255	Profeng Chlorpyrifos 500 EC Insecticide	Profeng Australia Pty Ltd	24 July 2020
86544	86544/116014	Foison Chlorpyrifos 500 EC Insecticide	Eureka! Agresearch Pty Ltd	24 July 2020
86544	86544/116014	Foison Chlorpyrifos 500 EC Insecticide	Foison Scitech Co., Limited	24 July 2020

Table 2: Cancelled label approval numbers

Product registration number(s)	Label approval number(s)	Product name	Holder	Date of cancellation
32902	32902/0809 32902/1208 32902/1207 32902/0305 32902/0104 32902/0903 32902/0303 32902/0902 32902/0801	Nufarm Chlorpyrifos 500 EC Insecticide	Nufarm Australia Limited	24 July 2020
39885	39885/0801	Nufarm Chlorpyrifos Pco Insecticide	Nufarm Australia Limited	24 July 2020
42284	42284/0901	David Grays Chlorpyrifos 500	David Gray & Co Pty Ltd	24 July 2020
49666	49666/0402	Barmac Chlorpyrifos G Granular Insecticide	Amgrow Pty Ltd	24 July 2020
49869	49869/56833 49869/0402	4farmers Chlorpyrifos 500 Insecticide	4 Farmers Australia Pty Ltd	24 July 2020
51190	51190/106298 51190/0809 51190/0502	Imtrade Chlorpyrifos 500 Insecticide	Imtrade Australia Pty Ltd	24 July 2020

Product registration number(s)	Label approval number(s)	Product name	Holder	Date of cancellation
51211	51211/0306 51211/0501 51211/0401	Lorsban 750 WG Insecticide	Dow Agrosiences Australia Limited	24 July 2020
51875	51875/1206 51875/0406 51875/0402 51875/1100	Pidgeon's Pest Controller 500 Termiticide And Insecticide	Pooma Fertilizers Pty Ltd	24 July 2020
53428	53428/59489 53428/0202	Generifos 500EC Insecticide	Grow Choice Pty Ltd	24 July 2020
55755	55755/108773 55755/0502	Surefire Fortune 500 Multi-Purpose Insecticide And Termiticide	Pct Holdings Pty Ltd	24 July 2020
55897	55897/0408 55897/0702	Conquest Chlorpyrifos 500 Insecticide	Conquest Crop Protection Pty Ltd	24 July 2020
60188	60188/52767 60188/0209 60188/1106 60188/0905	Genfarm Chlorpyrifos 500 Insecticide	Nutrien Ag Solutions Limited	24 July 2020
60611	60611/107504 60611/53005 60611/0806	Huilong Chlorpyrifos 500 EC Insecticide	Huilong Agrochemicals Australia Pty Ltd	24 July 2020
61071	61071/63186 61071/0710 61071/0609 61071/0906	Strike-Out 500 Wp Insecticide	Adama Australia Pty Ltd	24 July 2020
63145	63145/58996 63145/0908	Aw Cuft 500 Insecticide and Termiticide	Agri West Pty Ltd	24 July 2020
64319	64319/59285 64319/0809	Farmalinx Chlorpos 500 EC Insecticide	Farmalinx Pty Ltd	24 July 2020
65160	65160/59930 65160/50307	Apparent Dingo 500 Insecticide	Titan Ag Pty Ltd	24 July 2020
65556	65556/51274	Rainbow Chlorpyrifos 500 Insecticide	Shandong Rainbow International Co Ltd	24 July 2020
67451	67451/113873 67451/105206 67451/56062	Sabakem Chlorpyrifos 500EC Insecticide	Sabakem Pty Ltd	24 July 2020
67887	67887/57029	Spalding Chlorpyrifos 500 Insecticide	Spalding Holdings Pty Ltd	24 July 2020

Product registration number(s)	Label approval number(s)	Product name	Holder	Date of cancellation
67984	67984/57224	Ezycrop Chlorpyrifos 500 Insecticide	Ezycrop Pty Ltd	24 July 2020
68467	68467/101329 68467/101482 68467/61695 68467/58407	Chlorban 500 EC Insecticide	Upl Australia Pty Ltd	24 July 2020
68574	68574/109102 68574/58615	Accensi Micro-Lo Pre-Construction/Post-Construction Termiticide And Insecticide	Accensi Pty Ltd	24 July 2020
68575	68575/58616	Accensi Pre-Construction/Post-Construction Termiticide And Insecticide	Accensi Pty Ltd	24 July 2020
68745	68745/59000	Ac Chop 500 Insecticide And Termiticide	Axichem Pty Ltd	24 July 2020
69048	69048/59718	Smart Chlorpyrifos 500 Insecticide	Crop Smart Pty Ltd	24 July 2020
69776	69776/61713	Accensi Chlorpyrifos 500 Insecticide	Accensi Pty Ltd	24 July 2020
81735	81735/103921	ACP Chlorpyrifos 500 Insecticide	Australis Crop Protection Pty Ltd	24 July 2020
83310	83310/107951	Sinon Chlorpyrifos 500 EC Insecticide	Sinon Australia Pty Ltd	24 July 2020
85326	85326/112937	Agprotect Chlorpyrifos 500 EC Insecticide	Agprotect Australasia Pty Ltd	24 July 2020
86189	86189/114945	Sinon Chlorpyrifos 500 Insecticide	Sinon Australia Pty Ltd	24 July 2020
86612	86612/116202	Arysta Lifescience Chlorpyrifos 500 EC Insecticide	Arysta Lifescience Australia Pty Ltd	24 July 2020

BRIEF REASONS FOR DECISIONS

Pursuant to section 41(1) of the Agvet Code the APVMA is not satisfied that the Products listed in Table 1 meet the safety criteria set out in section 5A of the Agvet Code.

Pursuant to section 41(2) the APVMA is also not satisfied that the labels listed in Tables 1 and 2 meet the labelling criteria set out in section 5D of the Agvet Code.

INSTRUCTIONS FOR PERSONS WHO POSSESS, HAVE CUSTODY OR USE OF THE CANCELLED PRODUCT

A person who possesses, has custody of or uses the cancelled product referred to in the above table 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 product in accordance with those instructions.

POSSESSION OR CUSTODY

A person may possess the cancelled product referred to in the above table 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 product referred to in the above table according to its label instructions except for the prohibited uses, including any conditions relating to shelf life or expiry date, for 12 months from the date of cancellation.

PROHIBITED USES

The cancelled labels may include instructions for use in situations listed below. The use of those products in these situations is no longer approved and the following restraints apply:

DO NOT USE IN THE FOLLOWING CIRCUMSTANCES

- In domestic areas or public places
- In vegetation for mosquito adult/larvae control
- On container plants, including potted ornamentals and other potted plants
- On duboisia or macrocarpa hedges (in domestic and public space uses)
- On turf (in domestic and public space uses, or to which the general public has access)

All remaining uses can continue according to directions and instructions on the cancelled label.

A person may supply, or cause to be supplied, at wholesale or retail level the cancelled product bearing a cancelled label referred to in the above tables, for 12 months from the date of cancellation.

A person may not manufacture or import the cancelled product referred to in the above tables from the date of cancellation.

WARNING—CONTRAVENTIONS

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

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled products listed in the table above in a manner that contravenes the above instructions.

APVMA CONTACT

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

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Australian Pesticides and Veterinary Medicines Authority
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