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Gazette

Agricultural and veterinary chemicals

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

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General information

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

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

Distribution and subscription

The APVMA Gazette is published in electronic format only and is available from the APVMA website.

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Agricultural chemical products and approved labels

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

Table 1: Agricultural products based on existing active constituents

Application no.	131706
Product name	Titan Pelargonic 525 Herbicide
Active constituent/s	525 g/L nonanoic acid
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Summary of use	For the suppression of established weeds and perennial species and for control of moss and algae according to the directions for use
Date of registration	11 October 2021
Product registration no.	91305
Label approval no.	91305/131706

Application no.	126235
Product name	Orma Delta Insecticide
Active constituent/s	25 g/L deltamethrin
Applicant name	Orma S.r.l.
Applicant CAN	N/A
Summary of use	For the control of a range of insect pests in various situations
Date of registration	12 October 2021
Product registration no.	89851
Label approval no.	89851/126235

Application no.	130773
Product name	Titan Atrazine 600 SC Herbicide
Active constituent/s	600 g/L atrazine
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Summary of use	For the control of weeds and grasses in TT-canola, lupins, maize, sorghum, sugarcane and other crops
Date of registration	12 October 2021
Product registration no.	91025
Label approval no.	91025/130773

Application no.	131860
Product name	Relyon Fludioxonil 230 SC Fungicide
Active constituent/s	230 g/L fludioxonil
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Summary of use	For the control of certain post-harvest diseases in citrus, pome fruit, stone fruit, kiwi fruit, mangoes and pomegranates
Date of registration	12 October 2021
Product registration no.	91328
Label approval no.	91328/131860

Application no.	126338
Product name	Farmalinx Sayonara 10 GR Herbicide
Active constituent/s	10 g/kg prodiamine
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Summary of use	For the pre-emergent control of weeds in established turf
Date of registration	13 October 2021
Product registration no.	89917
Label approval no.	89917/126338

Application no.	131938
Product name	AgMerch Chlorpyrifos 500 Insecticide
Active constituent/s	500 g/L chlorpyrifos
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	For the control of a wide range of insect pests on fruit, vegetables, oilseeds, cotton, cereals, pasture, commercial turf and other situations as specified in the directions for use
Date of registration	13 October 2021
Product registration no.	91352
Label approval no.	91352/131938

Application no.	126514
Product name	Imtrade Kersel 850 WG Insecticide
Active constituent/s	850 g/kg spirotetramat
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Summary of variation	For the control of various insect pests in certain fruit and vegetable crops
Date of variation	15 October 2021
Product registration no.	89958
Label approval no.	89958/126514

Application no.	129485
Product name	David Grays Fipronil 100SC Termiticide and Insecticide
Active constituent	100 g/L fipronil
Applicant name	David Gray & Co Pty Ltd
Applicant ACN	008 671 127
Summary of use	For the protection of structures from subterranean termite damage and for the control of subterranean termites and ants around domestic and commercial structures
Date of registration	15 October 2021
Product registration no.	90608
Label approval no.	90608/129485

Application no.	129617
Product name	Imtrade D-Ploy Plus Grain Protectant
Active constituents	250 g/L chlorpyrifos-methyl, 200 g/L piperonyl butoxide, 25 g/L deltamethrin
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Summary of use	For the treatment of cereal grain to prevent infestation of stored grain pests
Date of registration	15 October 2021
Product registration no.	90623
Label approval no.	90623/129617

Application no.	127835
Product name	AVA Pro-Teb Fungicide
Active constituent/s	210 g/L prothioconazole, 210 g/L tebuconazole
Applicant name	American Vanguard Australia Pty Ltd
Applicant ACN	629 600 906
Summary of use	For the control of various diseases in wheat, barley, oats, triticale, canola and pyrethrum
Date of registration	19 October 2021
Product registration no.	90170
Label approval no.	90170/127835

Application no.	131941
Product name	AgMerch Oxyfluorfen 240 Herbicide
Active constituent/s	240 g/L oxyfluorfen
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	For the selective control of certain broadleaf and grass weeds as per directions for use table
Date of registration	20 October 2021
Product registration no.	91354
Label approval no.	91354/131941

Application no.	132074
Product name	F.S.A. Clopyralid 600 Herbicide
Active constituent/s	600 g/L clopyralid present as the acid and triisopropanolamine salt
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Summary of use	For the control of a wide range of broadleaf weeds in wheat, barley, triticale, oats, pastures, canola, fallow land, forests and industrial situations as specified in the directions for use
Date of registration	21 October 2021
Product registration no.	91387
Label approval no.	91387/132074

Application no.	132083
Product name	F.S.A. Diflufenican 500 SC Herbicide
Active constituent/s	500 g/L diflufenican
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Summary of use	For the control of certain weeds in clover-based pasture field peas, lentils, lupins and oilseed poppy as specified in the directions for use table
Date of registration	21 October 2021
Product registration no.	91390
Label approval no.	91390/132083

Application no.	131952
Product name	4Farmers Zinc Phosphide Mouse Bait
Active constituent/s	25 g/kg zinc phosphide
Applicant name	4 Farmers Australia Pty Ltd
Applicant ACN	160 092 428
Summary of use	For the control of heavy infestation of mice
Date of registration	22 October 2021
Product registration no.	91357
Label approval no.	91357/131952

Table 2: Listed registrations

Application no.	132383
Product name	Pool Protector Stabilised Chlorine
Active constituent/s	560 g/kg available chlorine (Cl) present as sodium dichloroisocyanurate
Applicant name	Pool Ranger Pty Ltd
Applicant ACN	078 758 040
Summary of use	For the control of bacteria, viruses and protozoa in swimming pools and spas
Date of registration	15 October 2021
Product registration no.	91489
Label approval no.	91489/132383

Application no.	132379
Product name	Maytronics Ecoclear S Sanitiser for Pool Water
Active constituent/s	560 g/kg available chlorine (Cl) present as sodium dichloroisocyanurate
Applicant name	Pool Ranger Pty Ltd
Applicant ACN	078 758 040
Summary of use	For the control of bacteria, viruses and protozoa in swimming pools and spas
Date of registration	20 October 2021
Product registration no.	91487
Label approval no.	91487/132379

Table 3: Variations of registration

Application no.	133068
Product name	Omite 570EW Liquid Miticide
Active constituent/s	570 g/L propargite
Applicant name	Arysta Lifescience Australia Pty Ltd
Applicant ACN	005 225 507
Summary of variation	To update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook
Date of variation	29 September 2021
Product registration no.	63387
Label approval no.	63387/133068

Application no.	133117
Product name	Nufarm Kamba 750 Selective Herbicide
Active constituent/s	750 g/L dicamba as the dimethylamine and monomethylamine salt
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Summary of variation	To vary the distinguishing product name and the name that appears on the label from 'Kamba 750 Selective Herbicide' to 'Nufarm Kamba 750 Selective Herbicide'
Date of variation	5 October 2021
Product registration no.	69302
Label approval no.	69302/133117

Application no.	133118
Product name	Promote Opti Growth Regulator
Active constituent/s	1000 g/L ethephon
Applicant name	ADAMA Australia Pty Ltd
Applicant CAN	050 328 973
Summary of variation	To vary the distinguishing product name and the name that appears on the label from 'Promote 1000 Growth Regulator' to 'Promote Opti Growth Regulator'
Date of variation	5 October 2021
Product registration no.	88033
Label approval no.	88033/133118

Application no.	133201
Product name	Farmalinx FLX700 Aquatic Penetrating Surfactant
Active constituent/s	350 g/L soyal phospholipids, 350 g/L propionic acid
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Summary of variation	To vary the distinguishing product name and the name that appears on the label from 'Farmalinx Aquasurf Penetrating Surfactant' to 'Farmalinx FLX700 Aquatic Penetrating Surfactant'
Date of variation	12 October 2021
Product registration no.	89880
Label approval no.	89880/133201

Application no.	131819
Product name	EuroChem RED COLOURING AGENT Plant Growth Regulator
Active constituent/s	100 g/kg S-abscisic acid
Applicant name	TGAC Australia Pty. Ltd.
Applicant ACN	134 570 700
Summary of variation	To add a new additional pack size
Date of variation	12 October 2021
Product registration no.	87349
Label approval no.	87349/131819

Application no.	131983
Product name	4Farmers Procymidone 500 FS Seed Dressing
Active constituent/s	500 g/L procymidone
Applicant name	4 Farmers Australia Pty Ltd
Applicant ACN	160 092 428
Summary of variation	To amend the product name
Date of variation	12 October 2021
Product registration no.	67183
Label approval no.	67183/131983

Application no.	133211
Product name	Titan Confide 200 SC Insecticide
Active constituent/s	200 g/L imidacloprid
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Summary of variation	To vary the distinguishing product name and the name that appears on the label from 'Titan Imidacloprid 200 Insecticide' to 'Titan Confide 200 SC Insecticide'
Date of variation	13 October 2021
Product registration no.	63238
Label approval no.	63238/133211

Application no.	131848
Product name	TRIF 480 Herbicide
Active constituent/s	480 g/L trifluralin
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Summary of variation	To change the name of the product from 'Nufarm Triflur 480 Selective Herbicide' to 'TRIF 480 Herbicide'
Date of variation	13 October 2021
Product registration no.	61991
Label approval no.	61991/131848

Application no.	132858
Product name	ADAMA 2,4-D LV Ester 680 Herbicide
Active constituent/s	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Summary of variation	To approve variations to the existing product registration and label in line with the 2,4-D reconsideration final regulatory decision
Date of variation	13 October 2021
Product registration no.	61895
Label approval no.	61895/132858

Application no.	133212
Product name	Titan Confide 350 SC Insecticide
Active constituent/s	350 g/L imidacloprid
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Summary of variation	To vary the distinguishing product name and the name that appears on the label from 'Titan Imidacloprid 350 SC Insecticide' to 'Titan Confide 350 SC Insecticide'
Date of variation	13 October 2021
Product registration no.	86992
Label approval no.	86992/133212

Application no.	133242
Product name	Relyon Prosulfocarb 800 EC Herbicide
Active constituent/s	800 g/L prosulfocarb
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 'Persista 800EC Herbicide' to 'Relyon Prosulfocarb 800 EC Herbicide' and to update the safety directions appearing on a label to reflect the current FAISD Handbook
Date of variation	14 October 2021
Product registration no.	83418
Label approval no.	83418/133242

Application no.	129414
Product name	MIRAVIS ADEPIDYN Technology Fungicide
Active constituent/s	200 g/L pydiflumetofen
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Summary of variation	To add aerial application in potatoes and to update the product name
Date of variation	15 October 2021
Product registration no.	82484
Label approval no.	82484/129414

Application no.	131061
Product name	Nufarm Grunt 750WDG Herbicide
Active constituent	750 g/kg hexazinone
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Summary of variation	To extend use in <i>Pinus pinaster</i> in all states and make other various minor label amendments
Date of variation	15 October 2021
Product registration no.	62549
Label approval no.	62549/131061

Application no.	132018
Product name	Titan Prosulfocarb 800 EC Herbicide
Active constituent	800 g/L prosulfocarb
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Summary of variation	To amend the statement of claims and directions for use to include a use in barley against annual ryegrass
Date of variation	15 October 2021
Product registration no.	84685
Label approval no.	84685/132018

Application no.	132021
Product name	Macspred Hexmac 750SG Herbicide
Active constituent/s	750 g/kg hexazinone
Applicant name	Macspred Pty. Ltd.
Applicant ACN	011 029 495
Summary of variation	To vary the use situations and critical comments in the directions for use, and to update the first aid instructions and safety directions in line with the FAISD Handbook
Date of variation	15 October 2021
Product registration no.	61923
Label approval no.	61923/132021

Application no.	130770
Product name	Surefire Zinam 500 SC Fungicide
Active constituent/s	500 g/L fluazinam
Applicant name	PCT Holdings Pty Ltd
Applicant ACN	099 023 962
Summary of variation	To extend use to potato, apple and grape vine crops and update label as per the Ag Labelling Code
Date of variation	18 October 2021
Product registration no.	85676
Label approval no.	85676/130770

Application no.	131813
Product name	Kelpie Amine 625 Herbicide
Active constituent/s	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name	Sinochem International Australia Pty Ltd
Applicant ACN	160 164 616
Summary of variation	To amend the product label in line with the 2,4-D reconsideration final regulatory decision and add the uses in wheat, barley, oil tea tree, hardwood and softwood plantations, fallow and other various situations
Date of variation	18 October 2021
Product registration no.	70018
Label approval no.	70018/131813

Application no.	129249
Product name	Virkon Aquatic Broad Spectrum Virucidal Bactericidal Fungicidal Disinfectant
Active constituent/s	497 g/kg potassium peroxymonosulfate, 15 g/kg sodium chloride
Applicant name	Alltech Lienert Australia Pty. Ltd.
Applicant ACN	008 293 007
Summary of variation	For use in shrimp and prawn farms
Date of variation	19 October 2021
Product registration no.	68503
Label approval no.	68503/129249

Application no.	131944
Product name	Silawrap Max Gibberellic Acid Growth Regulant
Active constituent/s	100 g/L gibberellic acid
Applicant name	Australian Adjuvants Pty Ltd
Applicant ACN	614 361 705
Summary of variation	To add use in pastures
Date of variation	19 October 2021
Product registration no.	46740
Label approval no.	46740/131944

Application no.	132896
Product name	Enforcer 75-D Herbicide
Active constituent/s	300 g/L 2,4-D present as the triisopropanolamine salt, 75 g/L picloram present as the triisopropanolamine salt
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Summary of variation	To amend the product label in line with the 2,4-D reconsideration final regulatory decision and add the use of agricultural non-crop areas, commercial and industrial areas, pastures, rights of way under the permit to label project
Date of variation	19 October 2021
Product registration no.	64206
Label approval no.	64206/132896

Application no.	131931
Product name	Imtrade Linuron 800 WG Herbicide
Active constituent/s	800 g/kg linuron
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Summary of variation	For the control of various pests and diseases in pyrethrum and tea tree oil and grass and broadleaf weeds in parsnips, celery, jojoba, leeks, celeriac, shallots and spring onions
Date of variation	20 October 2021
Product registration no.	81574
Label approval no.	81574/131931

Table 4: Label approval

Application no.	132249
Product name	OFF! Skintastic Familycare Insect Repellent Spray
Active constituent/s	92.8 g/L picaridin
Applicant name	S.C. Johnson & Son Pty Ltd
Applicant ACN	000 021 009
Summary of variation	To approve a new label for the product 'OFF! Skintastic Familycare Insect Repellent Spray' with the label name 'OFF! Kids DEET Free Up To 4 Hours Protection Great For Kids 12 Months + non greasy - gentle on skin - softly scented insect repellent spray'
Date of variation	13 October 2021
Product registration no.	51713
Label approval no.	51713/132249

Application no.	132271
Product name	Fastrac Pro Place Pacs Rodenticide
Active constituent	0.1 g/kg bromethalin contains denatonium benzoate
Applicant name	Bell Laboratories, Inc.
Applicant ACN	N/A
Summary of variation	To approve a new label for the product, 'Fastrac Pro Place Pacs Rodenticide' with the label name 'Tomcat with Bromethalin Place Pacs Rodenticide'
Date of variation	15 October 2021
Product registration no.	88455
Label approval no.	88455/132271

Veterinary chemical products and approved labels

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

Table 5: Veterinary products based on existing active constituents

Application no.	131918
Product name	Sidewinder LA Long Acting Injection For Sheep
Active constituent/s	20 g/L moxidectin
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Summary of use	Registration of a 20 g/L formulation of moxidectin for the treatment and control of roundworms, nasal bot and itch mite in sheep. For protection against severe challenge by Haemonchus contortus (Barber's pole worm) for up to 4 months
Date of registration	13 October 2021
Product registration no.	91347
Label approval no.	91347/131918

Application no.	122395
Product name	24.7 Smartrace Adult Sheep Oral Boluses
Active constituent/s	Each 48 g bolus contains: 762 mg iodine as calcium iodate, 146 mg cobalt as basic cobalt (ii) carbonate and 66 mg selenium as sodium selenate
Applicant name	Agrimin Ltd
Applicant ACN	01363538
Summary of use	Registration of a 762 mg iodine as calcium iodide, 145 mg cobalt as basic cobalt (II) carbonate and 66 mg selenium as sodium selenate oral bolus product for supplementation of the trace elements iodine, cobalt and selenium in adult sheep
Date of registration	22 October 2021
Product registration no.	88817
Label approval no.	88817/122395

Table 6: Variations of registration

Application no.	133101
Product name	YP Ceftiofur-Ketoprofen Injectable
Active constituent/s	150 mg/mL ketoprofen, 50 mg/mL ceftiofur as hydrochloride
Applicant name	South Yarra Pharma Pty Ltd
Applicant ACN	629 173 351
Summary of variation	Variation to the particulars of registration and label approval to vary the distinguishing product name and the name that appears on the label from 'Ceftiofur – Ketoprofen Injectable' to 'YP Ceftiofur-Ketoprofen Injectable'
Date of variation	30 September 2021
Product registration no.	90614
Label approval no.	90614/133101

Application no.	132044
Product name	Cydectin Platinum Dual Active LV Pour-On for Cattle
Active constituent/s	200 g/L levamisole, 10 g/L moxidectin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Summary of variation	Variation to the particulars of registration and label approval to update the instructions of use under precautions, side effects and dosage and administration sections
Date of variation	20 October 2021
Product registration no.	88072
Label approval no.	88072/132044

Application no.	130709
Product name	Thyroxine Oral Replacement Of Thyroid Hormone For Dogs And Cats
Active constituent/s	0.4 mg per tablet thyroxine sodium
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Summary of variation	Variation to the particulars of registration and label approval to amend the precautions, side effects, general directions, safety directions and disposal statements on the approved label
Date of variation	20 October 2021
Product registration no.	48560
Label approval no.	48560/130709

Table 7: Label approval

Application no.	131930
Product name	Ilium Medetomidine Injection
Active constituent/s	1 mg/mL medetomidine hydrochloride
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Summary of variation	Variation to the conditions of label approval to update precautions and side effects statements
Date of variation	13 October 2021
Product registration no.	64251
Label approval no.	64251/131930

Application no.	129837
Product name	Apex Meloxicam Oral Suspension for Cats
Active constituent/s	0.5 mg/mL meloxicam
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Summary of variation	Variation to the conditions of label approval by reducing the storage conditions from 30°C (room temperature) to 25°C (air conditioning) for both the 3mL and 15mL pack sizes and updating to the current Vet Labelling Code
Date of variation	15 October 2021
Product registration no.	83287
Label approval no.	83287/129837

Approved active constituents

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

Table 8: Active constituent

Application no.	130338
Active constituent/s	Alpha-cypermethrin
Applicant name	Krishi Rasayan Exports Pvt Ltd
Applicant ACN	N/A
Summary of use	For use in agricultural chemical products
Date of approval	11 October 2021
Approval no.	90886

Application no.	131520			
Active constituent/s	Spectinomycin sulfate			
Applicant name	Zoetis Australia Pty Ltd			
Applicant ACN	156 476 425			
Summary of use	For use in veterinary chemical products			
Date of approval	13 October 2021			
Approval no.	91257			

Application no.	131815			
Active constituent/s	Oleic acid			
Applicant name	Ceva Animal Health Pty Ltd			
Applicant ACN	002 692 426			
Summary of use	For use in veterinary chemical products			
Date of approval	13 October 2021			
Approval no.	91314			

Application no.	130345			
Active constituent/s	Prosulfocarb			
Applicant name	Krishi Rasayan Exports Pvt Ltd			
Applicant ACN	N/A			
Summary of use	For use in agricultural chemical products			
Date of approval	13 October 2021			
Approval no	90889			

Application no.	131817			
Active constituent/s	Palmitic acid			
Applicant name	Ceva Animal Health Pty Ltd			
Applicant ACN	002 692 426			
Summary of use	y of use For use in veterinary chemical products			
Date of approval	13 October 2021			
Approval no.	91316			

Application no.	131840			
Active constituent/s	Estradiol benzoate			
Applicant name	Zoetis Australia Pty Ltd			
Applicant ACN	156 476 425			
Summary of use	For use in veterinary chemical products			
Date of approval	13 October 2021			
Approval no.	91319			

Application no.	131818			
Active constituent/s	Azelaic acid			
Applicant name	eva Animal Health Pty Ltd			
Applicant ACN	002 692 426			
Summary of use	For use in veterinary chemical products			
Date of approval	15 October 2021			
Approval no.	91317			

Table 9: Variations of active constituent

Application no.	132230		
Active constituent/s	Meloxicam		
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd		
Applicant ACN	071 187 285		
Summary of variation Variation of relevant particulars or conditions of an approved active constituent			
Date of variation	20 October 2021		
Approval no.	55805		

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 website.

New licenses

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

Table 10: New licenses issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Silliker Australia Pty Ltd	6077	006 462 335	Unit C2 Regents Park Estate 391 Park Road Regents Park NSW 2143	Category 6: non-sterile dosage forms	Analysis and testing (microbiological).	12 January 2021
Phebra Pty Ltd	1097	059 357 890	17–19 Orion Road Lane Cove West NSW 2066	Category 1: sterile products for injection and sterile liquid products Category 2: liquids	Quality assurance (QA) of raw materials, formulation including blending, filling, aseptic filling, packaging, labelling, secondary packaging / labelling, sterilisation (filtration, heat), analysis and testing (physical, microbiological, endotoxin, and sterility), storage, and release for supply.	19 January 2021
Baron Rubber Proprietary Limited	6222	005 178 549	11 Northcorp Bvd Broadmeadows VIC 3047	Category 6: rubber	Quality assurance (QA) of raw materials, formulation including blending (Rubber compounding), rubber insert moulding, analysis and testing (physical), storage, packaging, labelling.	26 February 2021
Teradoran Pty Ltd t/a Activ Pharmaceuti cals Pty Ltd	2236	081 432 411	2 Blackmore Road Smeaton Grange NSW 2567	Category 2: creams/lotions, ointments, gels, pastes, sprays and liquids Category 4: liquids	Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, labelling, analysis and testing (physical and	9 March 2021

^{*}Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements Category 6: Single-step manufacturer

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
					chemical), storage and release for supply.	
BJP Laboratories Pty Ltd	4112	132 975 412	2 Alloy Street Yatala QLD 4207	Category 4: powder, tablet, liquid, & capsule: hard shell	Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, packaging, labelling, repackaging, relabelling, sachet packaging, tablet coating, capsule filling from bulk, analysis and testing (physical), and release for supply.	12 March 2021
Mera Chemicals Pty. Ltd.	2269	077 088 236	34 Law Court Sunshine West VIC 3020	Category 2: liquid topical	Quality assurance (QA) of raw materials, formulation including blending, filling (bulk filling only), analysis and testing (physical and chemical), storage, packaging, labelling, release for supply.	15 March 2021
Phibro Animal Health Pty Ltd	6228	093 869 991	6 Distribution Drive Orchard Hills NSW 2748	Category 6: all dosage forms	Quality assurance (QA) of raw materials, labelling, relabelling, storage and release for supply.	16 March 2021
Treidlia Biovet Pty Ltd	1096	150 496 138	Unit 76, Powers Business Park 45 Powers Road Seven Hills NSW 2147	Category 1: immunobiologicals	Quality assurance (QA) of raw materials, bacterial fermentation, fungal fermentation, wart tissue extraction, pilot scale affinity chromatography, formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat, chemical and filtration), microbiological reduction treatment (heat, filtration, and chemical), analysis and testing (physical, chemical, microbiological, serological, sterility testing, vaccine safety testing, and protein	29 March 2021

^{*}Category 1: Immunobiologicals and sterile veterinary preparations
Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements
Category 3: Ectoparasiticides
Category 4: Premixes and supplements
Category 6: Single-step manufacturer

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
					biochemistry), storage and release for supply.	
Aristopet Pty Ltd	2211	145 418 882	118 Links Avenue South Eagle Farm QLD 4009	Category 2: tablets, creams, lotions, ointments, pastes, gels, powders, sprays, liquids and suspensions Category 3: liquids, sprays, powders, and tablets (soluble for aquarium)	Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, tableting, packaging, labelling, secondary packaging, secondary labelling, relabelling, blister packaging, analysis and testing (physical), storage and release for supply.	8 April 2021
Nutrien Ag Solutions Limited	6230	008 743 217	Building 1, 1 Fox Road Acacia Ridge QLD 4110	Category 6: all dosage forms	Secondary packaging, secondary labelling, storage, and release for supply.	8 April 2021
Spectrum Sales Australia Pty Ltd	2272	624 186 965	1/2 Aurnga Drive Beresfield NSW 2322	Category 2: liquids, powders, gels and pastes Category 4: pastes and powders	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, repackaging, relabelling, storage and release for supply.	22 April 2021
Abbey Laboratories Pty Ltd	6223	156 000 430	16 Voyager Circuit Glendenning NSW 2761	Category 6: all dosage forms	Release for supply.	18 June 2021
Delta Laboratories Pty Limited	1056	050 324 742	8 Warringah Close Somersby NSW 2250	Category 1: sterile products for injection Category 2: creams/ lotions, ointments, pastes, sprays, liquids and gels	Quality assurance (QA) of raw materials, formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat and filtration), analysis and testing (physical, chemical and microbiological), storage and release for supply.	18 June 2021
QPharma Pty Ltd	2211	145 418 882	118 Links Avenue South Eagle Farm	Category 2: tablets, creams, lotions, ointments, pastes, gels, powders, sprays,	Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling,	23 June 2021

*Category 1: Immunobiologicals and sterile veterinary preparations
Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements
Category 3: Ectoparasiticides
Category 4: Premixes and supplements
Category 6: Single-step manufacturer

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
			QLD 4009	liquids and suspensions Category 3: liquids, sprays, powders, and tablets (soluble for aquarium)	granulation, filling, tableting, packaging, labelling, secondary packaging, secondary labelling, relabelling, blister packaging, analysis and testing (physical), storage and release for supply.	
Micronisers Pty Ltd	6011	006 825 538	6-8 England Street Dandenong VIC 3175	Category 6: powders	Wet milling, dry milling.	31 August 2021
DHL Supply Chain (Australia) Pty Limited	6071	071 798 617	16 Picrite Close Greystanes NSW 2145	Category 6: secondary packaging, secondary/ supplementary labelling, storage and release for supply	Secondary packaging, secondary/supplement ary labelling, storage and release for supply.	31 August 2021
RTH Scientific Services Pty Ltd	6236	112 358 915	Unit 7, 5 Belconnen Crescent Brendale QLD 4500	Category 6: all dosage forms	Analysis and testing (chemical and physical).	1 September 2021
Probiotec Pharma Pty Ltd	2268	076 755 354	83 Cherry Lane Laverton North VIC 3026	Category 2: capsules – hard shell, tablets, liquids (oral and topical), creams/lotions, ointment, gels, pastes, powders, granules, sprays, suspensions Category 3: powders, pastes Category : premix (liquid and powder), supplements (liquid and powder)	Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, packaging (including sachet and blister packaging) labelling, tableting, tablet coating, capsule filling from bulk, analysis and testing (physical and chemical), storage and release for supply.	21 September 2021
Homart Pharmaceuti cals Pty Ltd	4115	057 411 640	59 Kirby Street Rydalmere NSW 2116	Category 4: premixes and supplements	Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, tableting, tablet coating, capsule filling from bulk, filling, packaging, sachet packaging, labelling, analysis and testing (physical), storage, and release for supply.	8 October 2021
Agricure Pty Limited	2161	000 178 790	19 Gantry Place Braemar	Category 2: creams/ lotions, ointments, pastes, powders,	Quality assurance (QA) of raw materials, formulation including	22 October 2021

*Category 1: Immunobiologicals and sterile veterinary preparations
Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements
Category 3: Ectoparasiticides
Category 4: Premixes and supplements
Category 6: Single-step manufacturer

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
			NSW 2575	sprays, liquids and pellets. Category 4: premixes and supplements.	blending, dry milling, pelleting, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply.	

Licence cancellations

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

Table 11: Licenses cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Eurofin Chemical Analysis Pty Ltd	6177	114 804 572	110 Merrindale Drive Croydon VIC 3136	12 March 2021
Phibro Animal Health Pty Ltd	6209	093 869 991	1/7–10 Denoci Close Wetherill Park NSW 2164	5 May 2021
Baron Rubber Proprietary Limited	6096	005 178 549	3 Sheppard Street North Coburg VIC 3058	11 June 2021
Sphere Healthcare Pty Ltd	2187	054 309 705	10-12 Church Road Moorebank NSW 2170	23 July 2021
QEA Australia Pty Ltd	6116	114 603 968	Unit 4, 127 Magowar Road Girraween NSW 2145	5 August 2021

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

^{*}Category 1: Immunobiologicals and sterile veterinary preparations Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements Category 6: Single-step manufacturer

Notice of cancellation at the request of the holder

At the request of the holder, in accordance with section 42(1) of the *Agricultural and Veterinary Chemicals Code Act* 1994 (Agvet Code), the APVMA has cancelled the approvals and/or registrations set out in Table 12:

Table 12: Active constituent approval/product registration/label approval cancelled at the request of the holder

Approval or registration number	Name	Type of approval or registration	Holder	Reason for cancellation (if relevant pursuant to s 45A(3))	Date of cancellation
87680/118963 87680/123937	Apparent Alternative Herbicide	Label approval	Titan Ag Pty Ltd	At the request of the holder	11 August 2021
68118/121803 68118/120615 68118/118651 68118/118523 68118/111541 68118/110733 68118/57540	Slasher Organic Weedkiller	Label approval	Duluxgroup (Australia) Pty Ltd	At the request of the holder	25 August 2021
88850 /122677	Beloukha Herbicide	Label approval	Belchim Crop Protection NV	At the request of the holder	25 August 2021
87994/119985	Brunnings NA Weedkiller 525g/L	Label approval	Brunnings Garden Products Pty Ltd	At the request of the holder	27 August 2021
56791/0904 56791/0208 56791/50187 56791/50851 56791/58330 56791/103572	Paramite Selective Miticide	Label approval	Sumitomo Chemical Australia Pty Limited	At the request of the holder	30 August 2021
88791/122304	Brunnings NA Weed Kill Ready To Use	Label approval	Brunnings Garden Products Pty Ltd	At the request of the holder	7 September 2021
52416	Oxyflurofen	Active constituent	Nutrichem Company Limited	At the request of the holder	23 September 2021
80885	Tebuthiuron	Active constituent	Nutrichem Company Limited	At the request of the holder	23 September 2021
51413/0703 51413/0802 51413/0808 51413/1098 51413/1106	Vitaflo C Seed Treatment	Label approval	Arysta Lifescience Australia Pty Ltd	At the request of the holder	28 September 2021
64604/106008	Exodus Long Acting Injection For Sheep	Label approval	Boehringer Ingelheim Animal Health Australia Pty. Ltd.	At the request of the holder	19 October 2021

In accordance with section 45A(1)(b) of the Agvet Code, the APVMA publishes this notice of the cancellation, including the following instructions which set out how a person can deal with the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 12.

Instructions

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

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A person who possesses, has custody of or uses the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 12 in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 45B(3) of the Agvet Code to possess, have custody of or use the cancelled active constituent, cancelled product or product bearing a cancelled label, in accordance with those instructions.

Possession or custody

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

Use, supply or otherwise deal with

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

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

Contraventions

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

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled active constituents, cancelled products or products bearing the cancelled label listed in Table 12 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

More information

The APVMA publishes a list of <u>voluntary cancellations at the request of the holder</u> on its website, and provides a <u>subscription option</u> to be notified by email when the list is update.

Notice under section 32(1) of the Agvet Code: Reconsideration of anticoagulant rodenticide approvals and registrations

- The Australian Pesticides and Veterinary Medicines Authority (APVMA) gives notice that the APVMA is reconsidering active constituent approvals, product registrations and associated label approvals of anticoagulant rodenticides for: first generation anticoagulant rodenticides (warfarin, coumatetralyl, diphacinone) and second generation anticoagulant rodenticides (brodifacoum, bromadiolone, difenacoum, difethialone, and flocoumafen), under section 31(1) of the Agricultural and Veterinary Chemical Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code).
- 2) The reconsideration includes the active constituent approvals, product registrations and label approvals shown in Attachment A.

Matters the APVMA is proposing to reconsider in relation to anticoagulant rodenticides

- 3) The APVMA is reconsidering anticoagulant rodenticide approvals and registrations because of concerns about potential for unacceptable risks in the following areas:
 - a. environmental safety, including primary and secondary poisoning of non-target domestic animals and wildlife;
 - b. human health, including worker exposure and public health; and,
 - c. residues, including livestock and edible wildlife exposure, consumer safety, and trade.
- 4) The APVMA will review the following aspects of active constituent approvals, product registrations and label approvals for the specified anticoagulant rodenticides:
 - a. Chemistry
 - i. The establishment of appropriate standards for manufacturing concentrates;
 - b. Toxicology
 - i. The safe level of exposure of humans via the oral, dermal and inhalational routes
 - c. Worker and public exposure
 - i. Risks arising from exposure during handling and applications;
 - ii. Re-entry exposure risks including exposure in domestic situations;
 - d. Residues
 - i. Residues in foods through primary and secondary exposure; and
 - e. Environment
 - i. Off target poisoning
 - ii. Secondary poisoning
- The APVMA is also considering whether product labels carry adequate instructions and warning statements.

Reasons for those matters being dealt with in the reconsideration

6) The matters that are dealt with in the reconsideration include component chemistry, environment, residues, toxicology and occupational health and safety assessments.

- 7) The basis for the reconsideration is whether the APVMA is satisfied that:
 - a. the active constituents continue to meet the safety criteria as set out in section 5A of the Agvet Code; and
 - b. the products continue to meet the safety criteria as set out in section 5A of the Agvet Code; and
 - c. the products continue to meet the trade criteria as set out in section 5C of the Agyet Code; and
 - d. the labels continue to meet the labelling criteria as set out in section 5D of the Agvet Code; and
 - e. the active constituent, product or label complies with any requirement prescribed by the Agricultural and Veterinary Chemicals Code Regulations 1995.

Reconsideration Work Plan

8) A Work Plan for the reconsideration has been prepared in accordance with section 31(2) of the Agvet Code and can be found in Attachment B.

Data requirements

9) The general data guidelines for each of the relevant risk areas are provided on the APVMA website as detailed in Table 13 below. The APVMA has identified the specific aspects of these data that are required to inform the assessments to be undertaken in paragraph 4 above. Additional information may be requested during the reconsideration pursuant to section 33 of the Agyet Code.

Table 13: APVMA data guidelines

Risk area	Data guideline
Chemistry	apvma.gov.au/node/1051
Toxicology	apvma.gov.au/node/1036 apvma.gov.au/node/1038
Work health and safety	apvma.gov.au/node/1027
Residues	apvma.gov.au/node/1037 apvma.gov.au/node/1017
Environment	apvma.gov.au/node/805

Making a submission

10) The APVMA invites submissions on the matters being reconsidered and the reasons for the reconsideration.

Preparing your comments for submission

- 11) When preparing your submission, the APVMA prefers you to:
 - a. clearly identify the issue and clearly state your point of view
 - b. give reasons for your comments, supporting them with relevant scientific information and indicating the source of the information you have used.
- 12) Electronic submissions are preferred; all electronic submissions to the APVMA will be acknowledged via email. When making a submission please include:

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

Please note: Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential.

Please lodge your submission with a <u>public submission coversheet</u> which provides options for how your submission will be published.

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

Note that all submissions received are subject to legislative requirements, including the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code. In providing your submission to the APVMA, you agree to the APVMA publicly disclosing your submission in whole or summary form. The APVMA confirm that if your submission includes confidential commercial information or protected information, such information shall be subject to the relevant provisions of the Agvet Code including relevant limitations on use and disclosure by the APVMA.

- 13) The closing date for submissions is 2 February 2021.
- 14) Submissions can be sent to:

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
SYDNEY NSW 2001

Telephone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au

15) If you require further information, please contact the Chemical Review Team.

Attachment A: Active constituent approval(s), product registration(s) and/or label approval(s) placed under reconsideration

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Active constituent	44211	Coumatetralyl	Coumatetralyl	N/A
Active constituent	54214	Coumatetralyl	Coumatetralyl	N/A
Active constituent	64241	Coumatetralyl	Coumatetralyl	N/A
Active constituent	54768	Diphacinone	Diphacinone	N/A
Active constituent	46121	Warfarin	Warfarin	N/A
Active constituent	44191	Brodifacoum	Brodifacoum Manufacturing Concentrate	N/A
Active constituent	44192	Brodifacoum	Brodifacoum	N/A
Active constituent	44522	Brodifacoum	Brodifacoum	N/A
Active constituent	48319	Brodifacoum	Brodifacoum Manufacturing Concentrate	N/A
Active constituent	48386	Brodifacoum	Brodifacoum Manufacturing Concentrate	N/A
Active constituent	54774	Brodifacoum	Brodifacoum	N/A
Active constituent	56139	Brodifacoum	Brodifacoum	N/A
Active constituent	62292	Brodifacoum	Brodifacoum	N/A
Active constituent	62619	Brodifacoum	Brodifacoum	N/A
Active constituent	67386	Brodifacoum	Brodifacoum	N/A
Active constituent	85489	Brodifacoum	Brodifacoum	N/A
Active constituent	44475	Bromadiolone	Bromadiolone	N/A
Active constituent	47758	Bromadiolone	Bromadiolone Manufacturing Concentrate	N/A
Active constituent	47789	Bromadiolone	Bromadiolone Manufacturing Concentrate	N/A
Active constituent	47790	Bromadiolone	Bromadiolone Manufacturing Concentrate	N/A
Active constituent	49195	Bromadiolone	Bromadiolone	N/A
Active constituent	51576	Bromadiolone	Bromadiolone	N/A

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Active constituent	59135	Bromadiolone	Bromadiolone	N/A
Active constituent	67898	Bromadiolone	Bromadiolone	N/A
Active constituent	58752	Difenacoum	Difenacoum	N/A
Active constituent	63286	Difenacoum	Difenacoum	N/A
Active constituent	67881	Difenacoum	Difenacoum	N/A
Active constituent	45234	Difethialone	Difethialone	N/A
Active constituent	44267	Flocoumafen	Flocoumafen	N/A
Active constituent	49436	Flocoumafen	Flocoumafen	N/A
Active constituent	65328	Flocoumafen	Flocoumafen	N/A
Product	42040	Coumatetralyl	Readi Rac Rat & Mouse Killer	42040/0702
Product	49256	Coumatetralyl	Ratex Mouse and Rat Bait	49256/01, 49256/0101, 49256/0206, 49256/0402, 49256/52077
Product	51508	Coumatetralyl	Racumin Rat and Mouse Paste	51508/0300, 51508/0500, 51508/0704, 51508/1005
Product	52098	Coumatetralyl	Racumin Rat and Mouse Blocks	52098/0704, 52098/1005, 52098/1099, 52098/62430
Product	52182	Coumatetralyl	Racumin 8 Rat and Mouse Rodenticide	52182/0704, 52182/1099
Product	59284	Coumatetralyl	Bayer Racumin Rat & Mouse Killer	59284/0505, 59284/109277
Product	82217	Coumatetralyl	Surefire Couma All Weather Blocks Rodenticide	82217/105225
Product	86417	Coumatetralyl	Racumin TP Rat and Mouse Rodenticide	86417/115726
Product	54756	Diphacinone	Ramik Green Bait Bits Rodenticide	54756/0106, 54756/0606, 54756/109643
Product	89433	Diphacinone	Ramik Bars Rodenticide	89433/124858
Product	33942	Warfarin	David Grays Rat 'N' Mouse Killer	33942/0802

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	33945	Warfarin	Rci Ratblitz Bait	33945/0899
Product	42368	Warfarin	Rat Kill	42368/45031
Product	60285	Warfarin	Double Strength Ratsak Kills Rats & Mice	60285/0609, 60285/0905
Product	33896	Brodifacoum	Talon Rat & Mouse Killer Pellets	33896/0108, 33896/02, 33896/0302, 33896/0399, 33896/0500, 33896/0600, 33896/105633, 33896/1198, 33896/55730
Product	48332	Brodifacoum	Oztec Ratal Rodenticide Pellets	48332/01
Product	48502	Brodifacoum	Mortein Rat Kill Professional Household Protection	48502/01, 48502/0101, 48502/0301, 48502/0304, 48502/0398, 48502/0509, 48502/0702, 48502/0807, 48502/1101, 48502/58161
Product	48793	Brodifacoum	Farmoz Rodex B Rodenticide Pellets	48793/01, 48793/0205, 48793/104438
Product	49867	Brodifacoum	Ditrac All Weather Blox Rodenticide	49867/0207, 49867/0997, 49867/113105, 49867/125129
Product	49868	Brodifacoum	Ditrac Rodenticide	49868/0108, 49868/0997, 49868/113073
Product	50363	Brodifacoum	Farmoz Rodex B Rat Blocks	50363/0198, 50363/104439, 50363/107134, 50363/110244, 50363/1105
Product	50697	Brodifacoum	Tomcat II All Weather Blox Rodenticide	50697/0207, 50697/0898, 50697/1102, 50697/125125
Product	51181	Brodifacoum	Pestmaster Mouse & Rat Bait	51181/0301, 51181/0699, 51181/0999, 51181/1098

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	51280	Brodifacoum	Tomcat II Rodenticide	51280/0407, 51280/0499, 51280/1006
Product	52675	Brodifacoum	Talon Rat & Mouse Killer All Weather Wax Blocks	52675/0109, 52675/0202, 52675/0500, 52675/0510, 52675/105632
Product	54661	Brodifacoum	Mortein Rat Kill Professional	54661/0304, 54661/0507, 54661/0509, 54661/1001, 54661/1206, 54661/58160
Product	54836	Brodifacoum	Fast Action Ratsak Bait Station Kills Rats and Mice	54836/1101, 54836/0207, 54836/0309, 54836/108614
Product	54839	Brodifacoum	Rentokil Brodifacoum Paste	54839/0205
Product	56632	Brodifacoum	Fast Action Ratsak Throwpacks Kills Rats & Mice	56632/0309, 56632/1102, 56632/51139, 56632/62792
Product	57805	Brodifacoum	Raticide Mouse and Rat Bait	57805/54399
Product	58301	Brodifacoum	Talon Rat & Mouse Killer Ezy Throw Pellets	58301/0204, 58301/1004, 58301/105634, 58301/59466
Product	58338	Brodifacoum	Talon Rat & Mouse Killer Pellet Trays	58338/0204, 58338/1007, 58338/105637
Product	58339	Brodifacoum	Talon Rat & Mouse Killer Wax Blocks	58339/1207, 58339/0304, 58339/0408, 58339/105629
Product	58661	Brodifacoum	Mortein Kills Rats & Mice And The Fleas They Carry Dual Action Bait	58661/0208, 58661/0309, 58661/0606, 58661/119901
Product	59323	Brodifacoum	Talon XT Pro Rodenticide Wax Blocks	59323/0510, 59323/0607, 59323/0805, 59323/1008
Product	59875	Brodifacoum	All Weather PCT First Formula Blocks Rodenticide	59875/0607, 59875/0705

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	59876	Brodifacoum	Surefire All Weather Blocks Rodenticide	59876/0605, 59876/0607, 59876/1107
Product	62635	Brodifacoum	Talon Mouse Bait Station	62635/1107
Product	63624	Brodifacoum	X-Verminator Single Feed Lethal Dose Rodent Blocks	63624/1009, 63624/116937
Product	63625	Brodifacoum	X-Verminator Single Feed, Lethal Dose Rodent Pellets	63625/1009, 63625/116935
Product	63867	Brodifacoum	Surefire Pellets Rodenticide	63867/0309
Product	63885	Brodifacoum	Mortein Kills Rats & Mice and the Fleas They Carry Dual Action Throwpack	63885/0409, 63885/119902
Product	65423	Brodifacoum	4Farmers Rat and Mouse Bait Pellets	65423/50888
Product	65597	Brodifacoum	Imtrade Top Cat Rodenticide Wax Blocks	65597/51397, 65597/104361
Product	66235	Brodifacoum	Rodenthor Block Rodenticide	66235/56295
Product	66331	Brodifacoum	Rodenthor Soft Bait Rodenticide	66331/55716
Product	67610	Brodifacoum	Ratsak Professional Pellets	67610/56453
Product	67611	Brodifacoum	Ratsak Professional All Weather Wax Blocks	67611/56454
Product	67652	Brodifacoum	Fast Action Ratsak Waxblocks	67652/56541, 67652/60303
Product	68021	Brodifacoum	Brigand Rodenticide Paste	68021/57286
Product	68025	Brodifacoum	Brigand Rodenticide Blocks	68025/57306
Product	68028	Brodifacoum	Brigand Rodenticide Pellets	68028/57312
Product	68122	Brodifacoum	Pestmaster Rat & Mouse Killer Wax Blocks	68122/57559
Product	69017	Brodifacoum	Fast Action Ratsak Reusable Mouse Bait Station With Wax Blocks	69017/129476, 69017/59659
Product	69119	Brodifacoum	Fast Action Ratsak Reusable Rodent Bait Station With Wax Blocks	69119/60011

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	69158	Brodifacoum	Fast Action Ratsak Disposable Mouse Bait Station With Wax Block	69158/60095
Product	69209	Brodifacoum	Ratshot Rapidkill Rodenticide Blocks	69209/105162, 69209/60250
Product	69210	Brodifacoum	Ratshot Final Kill Paste Rodenticide	69210/60254
Product	69490	Brodifacoum	Mortein Mice Kill Professional	69490/60927
Product	69643	Brodifacoum	Ratal B Rat Blocks	69643/61308
Product	69867	Brodifacoum	Klerat XT Pro Rodenticide Wax Blocks	69867/61920
Product	69942	Brodifacoum	Farmalinx RoDi Wax Blocks	69942/62105
Product	80029	Brodifacoum	Ratshot One Shot Rodenticide Pellets	80029/100069
Product	80059	Brodifacoum	Farmalinx RoDi Pellets	80059/100142
Product	81663	Brodifacoum	The Big Cheese Ultra Power Fast Action Bait Blocks	81663/103579
Product	81664	Brodifacoum	The Big Cheese Ultra Power Rat Kill Bait Station	81664/103580
Product	81665	Brodifacoum	The Big Cheese Ultra Power Mouse Kill Bait Station	81665/103581
Product	81666	Brodifacoum	The Big Cheese Ultra Power Fast Action Bait Packs	81666/103583
Product	82233	Brodifacoum	Time's Up Fast Action Baited Mouse Station	82233/105245
Product	82234	Brodifacoum	The Big Cheese Ultra Power Fast Action Disposable Mouse Kill Bait Station	82234/105246, 82234/106354
Product	83673	Brodifacoum	Fast Action Ratsak Multi Pack	83673/108828, 83673/109941
Product	84215	Brodifacoum	Freezone Ratshot G Quickshot Rodenticide	84215/109902
Product	85522	Brodifacoum	Time's Up Fast Action Throw Pack	85522/113504
Product	85523	Brodifacoum	Time's Up Fast Action Block Bait	85523/113506

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	86214	Brodifacoum	The Big Cheese Ultra Power Fast Action Block Bait Rodenticide	86214/115020
Product	87657	Brodifacoum	Bainbridge Bait Blocks Rodenticide	87657/118892
Product	87659	Brodifacoum	Bainbridge Bait Pellets Rodenticide	87659/118895
Product	87706	Brodifacoum	Rodenthor Gel Rodenticide	87706/119034
Product	88636	Brodifacoum	Titan Rat & Mouse Killer Wax Blocks	88636/121880
Product	88649	Brodifacoum	Titan Mouse & Rat Bait	88649/121900
Product	88845	Brodifacoum	The Big Cheese Ultra Power Block Bait Rodenticide	88845/122664, 88845/131958
Product	88846	Brodifacoum	The Big Cheese Ultra Power All Weather Block Bait	88846/122665, 88846/131959
Product	88847	Brodifacoum	The Big Cheese Ultra Power Rat and Mouse Kill Throw Packs	88847/122666, 88847/131976
Product	89039	Brodifacoum	Solo 25 Blox Rodenticide	89039/123473
Product	89557	Brodifacoum	Raticate All-Weather Block - Brodifacoum	89557/125253
Product	91553	Brodifacoum	Titan Onza Red Rodenticide Paste	91553/132635
Product	91554	Brodifacoum	Titan Onza Red Rodenticide Blocks	91554/132644
Product	33908	Bromadiolone	Bromakil Block Bait For Rats and Mice	33908/01, 33908/0403, 33908/56728, 33908/107570
Product	33911	Bromadiolone	Bromakil Pellet Bait For Rats and Mice	33911/01, 33911/0202, 33911/0402, 33911/0901, 33911/54503, 33911/56726, 33911/107568
Product	39461	Bromadiolone	Rentokil Bromard	39461/0309, 39461/0800, 39461/1197, 39461/52730, 39461/106838, 39461/113385

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	47484	Bromadiolone	Bromakil Super Rat Drink	47484/01, 47484/0901, 47484/107572
Product	48145	Bromadiolone	Bromakil Grain Bait for Rats and Mice	48145/01, 48145/1201, 48145/54504, 48145/56729, 48145/107571
Product	48372	Bromadiolone	Contrac Blox	48372/01, 48372/0108, 48372/0508, 48372/113009, 48372/122805, 48372/125107
Product	48373	Bromadiolone	Contrac Rat and Mouse Bait	48373/01, 48373/0108, 48373/63376, 48373/113008
Product	48374	Bromadiolone	Contrac Rodenticide	48374/01, 48374/113074, 48374/123187
Product	49776	Bromadiolone	Tomcat All-Weather Blox	49776/01, 49776/0107, 49776/0207, 49776/0908, 49776/1105, 49776/1206, 49776/58197, 49776/125300
Product	49782	Bromadiolone	Tomcat Rat and Mouse Bait	49782/01, 49782/0206, 49782/0407, 49782/0710, 49782/1105
Product	51245	Bromadiolone	Mouseoff Bromadiolone Rodent Bait	51245/0499, 51245/0603, 51245/0604, 51245/0701, 51245/0800, 51245/0999, 51245/106952
Product	61668	Bromadiolone	Bromakil Kills Rats and Mice!	61668/0407, 61668/107586
Product	62180	Bromadiolone	Maki Block Weather - Proof Rodenticide	62180/1207
Product	64849	Bromadiolone	Surefire Broma Blocks Rodenticide	64849/0410
Product	64850	Bromadiolone	Surefire Broma Pellets Rodenticide	64850/0210
Product	64931	Bromadiolone	Rodemise Bromadiolone Rodent Block	64931/49617, 64931/101539,

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
				64931/102579, 64931/104910
Product	65675	Bromadiolone	Imtrade Alley Cat Rodenticide Wax Blocks	65675/102999, 65675/51544
Product	67142	Bromadiolone	Surefire Broma Grain Bait Rodenticide	67142/55303
Product	67578	Bromadiolone	Rodemise Super Bromadiolone Rodent Block	67578/56393, 67578/101717
Product	69641	Bromadiolone	Rat Stop Grain Bait	69641/61306
Product	80379	Bromadiolone	Generation Green Rodenticide Pellet	80379/100723
Product	80388	Bromadiolone	Bromakil Power Block For Rats and Mice	80388/100735, 80388/130542
Product	81205	Bromadiolone	Tomcat Bait Packs	81205/102547
Product	81206	Bromadiolone	Tomcat All-Weather Rat & Mouse Block Baits	81206/102549
Product	86179	Bromadiolone	Resolv Soft Bait Rodenticide	86179/114907
Product	86331	Bromadiolone	Contrac Soft Bait	86331/115500, 86331/120488, 86331/120939
Product	69994	Bromadiolone, Difenacoum	Muskil Dual Active Rodenticide Blocks With Fluo-NP Technology	69994/62249, 69994/113128, 69994/123005, 69994/131184
Product	82450	Bromadiolone, Difenacoum	Muskil Soft Bait With Two Actives For Faster Kill Of Rats & Mice	82450/105783, 82450/113141, 82450/123000
Product	84831	Bromadiolone, Difenacoum	Ratsak Rapid Strike Dual Active Waxblocks	84831/111524, 84831/113394
Product	84832	Bromadiolone, Difenacoum	Ratsak Rapid Strike Advanced Dual Active Soft Bait	84832/111525, 84832/113395
Product	61842	Difenacoum	Sorexa Pro Rodenticide Blocks	61842/0407, 61842/1108
Product	61847	Difenacoum	Sorexa Pro Rodenticide Pellets	61847/0407, 61847/1108
Product	61848	Difenacoum	Sorexa Pro Rodenticide Gel	61848/0407, 61848/51053

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	61910	Difenacoum	Sorexa Pro Rodenticide Paste	61910/0407, 61910/1108
Product	65339	Difenacoum	Roban Rodenticide Blocks	65339/50720, 65339/57935
Product	65358	Difenacoum	Roban Rodenticide Paste	65358/50750
Product	65528	Difenacoum	Roban Rodenticide Pellets	65528/51125
Product	65672	Difenacoum	Rodemise Difenacoum Rodent Bait Blocks	65672/51541
Product	66399	Difenacoum	Roban Rodenticide Placepacks	66399/53566
Product	66562	Difenacoum	The Big Cheese All-Weather Block Bait Rodenticide	66562/53873, 66562/56513, 66562/101128
Product	66563	Difenacoum	The Big Cheese Rat And Mouse Killer Ready To Use Bait Packs	66563/53874, 66563/56512, 66563/61473
Product	66587	Difenacoum	Cougar Rodenticide Paste Sachets	66587/53944
Product	66588	Difenacoum	Cougar Rodenticide Wax Blocks	66588/53945
Product	67484	Difenacoum	Roban Rat and Mouse Killer Paste	67484/56164
Product	67644	Difenacoum	Time's Up Rat & Mouse Killer Ready To Use Bait Packs	67644/56525
Product	67647	Difenacoum	Time's Up All-Weather Block Bait Rodenticide	67647/56528, 67647/111089
Product	67681	Difenacoum	Time's Up Baited Mouse Kill Station	67681/56618
Product	68759	Difenacoum	Ratshot Rodenticide Paste	68759/59027
Product	68760	Difenacoum	Ratshot Reusable Baited Rat Kill Station	68760/59028
Product	68762	Difenacoum	Ratshot Rodenticide Blocks	68762/59030, 68762/105164
Product	68763	Difenacoum	Ratshot Rat and Mouse Killer Paste	68763/59031
Product	68962	Difenacoum	Effect Rodent Soft Bait	68962/59504

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product
Product	69347	Difenacoum	Roban Rodenticide Grain Bait	69347/60553
Product	69911	Difenacoum	Surefire Difenate All Weather Blocks Rodenticide	69911/62048
Product	80124	Difenacoum	All Weather PCT Pro Formula Blocks Rodenticide	80124/100264
Product	80667	Difenacoum	Ratshot-G Rodenticide Grain Bait	80667/101364
Product	81106	Difenacoum	Ratsak Wax Blocks	81106/102329
Product	81513	Difenacoum	Effect Rodent Wax Block Baits	81513/103270
Product	83231	Difenacoum	Victor Rodenticide Grain Bait	83231/107788
Product	83232	Difenacoum	Victor Rodenticide Blocks	83232/107789
Product	83308	Difenacoum	Ratsak Rat And Mouse Killer Soft Bait	83308/107949
Product	85512	Difenacoum	Amgrow Patrol All Weather Blocks Rodenticide	85512/113486
Product	85513	Difenacoum	Amgrow Patrol Rat & Mouse Soft Bait Rodenticide	85513/113487, 85513/115837
Product	87869	Difenacoum	The Big Cheese Home Choice All Weather Block Bait	87869/119608, 87869/123663, 87869/127037
Product	87870	Difenacoum	The Big Cheese Home Choice Rat & Mouse Kill Throw Packs	87870/119609, 87870/123664
Product	89203	Difenacoum	The Big Cheese Home Choice Rat & Mouse Killer Ready To Use Bait Station	89203/123969
Product	89204	Difenacoum	The Big Cheese Home Choice Mouse Killer Bait Station	89204/123972
Product	89206	Difenacoum	The Big Cheese Home Choice Rat Killer Bait Station	89206/123976
Product	89510	Difenacoum	Surefire Difenate Paste Bait Rodenticide	89510/125105
Product	89556	Difenacoum	Raticate All-Weather Block - Difenacoum	89556/125251

Туре	Approval or registration number	Active constituent	Name	Label approval number(s) associated with the product	
Product	91552	Difenacoum	Titan Onza Blue Rodenticide Grain Bait	91552/132630	
Product	91555	Difenacoum	Titan Onza Blue Rodenticide Paste	91555/132645	
Product	91556	Difenacoum	Titan Onza Blue Rodenticide Blocks	91556/132647	
Product	62178	Difethialone	Generation Blue Max Block Single-Feed Rodenticide	62178/1009	
Product	62694	Difethialone	Generation Block Single- Feed Rodenticide	62694/1209, 62694/53580, 62694/104029	
Product	66889	Difethialone	Generation Firststrike Single-Feed Rodenticide	66889/54630	
Product	69086	Difethialone	Rodilon Pro Rodenticide	69086/59936	
Product	80381	Difethialone	Generation Blue Rodenticide Block	80381/100726	
Product	80382	Difethialone	Generation Blue Rodenticide Pellet	80382/100727	
Product	80386	Difethialone	Generation Blue Rodenticide Soft Bait	80386/100731	
Product	47768	Flocoumafen	Storm Wax Block Rodenticide	47768/01, 47768/0609	
Product	54191	Flocoumafen	Storm Secure Wax Block Rodenticide	54191/0501, 54191/0508, 54191/0609, 54191/0704, 54191/1102, 54191/129919	
Product	80663	Flocoumafen	Storm Soft Bait Rodenticide	80663/101357, 80663/129939	
Product	90839	Flocoumafen	Stratagem Soft Bait Rodenticide	90839/130175	
Product	90840	Flocoumafen	Stratagem Wax Block Rodenticide	90840/130176	

Attachment B: Work plan for the reconsideration of anticoagulant rodenticides

CHEMICAL	First and second generation anticoagulant rodenticides		
ASSESSMENTS	Chemistry [2.2], Toxicology [3.2], Environment [7.1], Occupational Health and Safety [6.1],		
	Residues and Trade [5.2], Finalisation [11.1]		
ASSESSMENT PERIOD	42 months, see Attachment C		
TIMEFRAME	START: February 2022	Finish: July 2025	
WORK PLAN DATES	The timeframe for the review commences at the end of the period specified in the s 32 notice.		

Sta	<u>ige</u>	<u>Details</u>	<u>Timeline</u>	
1.	Nomination	Nominated for review following identification of new worker exposure, public health risks (2015).	n and environmental safety	
2.	Prioritisation	Prioritised based on consideration of key criteria, including worker exposure, public health, environmental safety, and the potential for residues in food (2021).		
3.	Scoping and work plan	Scope: chemistry, toxicology, worker and public exposure, environment, residues, label instructions (2021).	trade and adequacy of	
4.	Notice of reconsideration	S 32(1) notices sent to holders upon commencement of the review on 2 Novembe Notice of reconsideration – Published in Gazette on 2 November2021.	r 2021.	
		START DATE (clock starts)	February 2022	
5.	Assessment	<u>Component assessment reports to be completed</u> Chemistry, toxicology, worker and public exposure, environment residues and trade.	Expected 2024	
6.	Draft regulatory measure	<u>Draft regulatory measures to be completed</u> Proposed regulatory decisions.	Expected 2024	
7.	Consultation	Consultation to be undertaken A 3-month public consultation period will follow the publication of the proposed regulatory decisions report. Any further data or information submitted during consultation will be taken into consideration before the final regulatory decision is made.	Expected 2024	
8.	Regulatory decision	The legislated timeframe for the final regulatory decision is 42 months, although it may be completed sooner. Regulatory decisions to be made The APVMA will determine whether to: Vary, suspend or cancel actives, products or labels (s34AB) Affirm actives, products or labels (s34AC)	Expected 2024	
		END DATE (final regulatory decision)	July 2025	
9.	Implementation	The APVMA will publish details of any applicable phase out periods if any approva of products or label approvals are cancelled. The maximum phase out period specified in the legislation is 12-months.	als of actives, registration	

Attachment C

	AGRICULTURAL AND VETERINARY CHEMICALS CODE REGUL	ATIONS 1995 – regulation78	3	
	PERIOD WITHIN WHICH APVMA IS TO CONCLUDE RE			
$\Delta = the$	A + B + 2E + 3C + J + D + X e longest of the following periods (in months) relevant to the scope	of the reconsideration		
Item	Module level or type	Period for completion	Scope	
3.1	Toxicology – Level 1	13		
3.2	Toxicology – Level 2	9	•	
3.3	Toxicology – Level 3	5		
4.1	Toxicology (requiring poison schedule classification)	13		
7.1	Environment – Level 1	13	•	
7.2	Environment – Level 2	7		
7.3	Environment – Level 3	4		
D = 41-	TOTAL TIME FOR A	13	13	
	e longest of the following periods (in months) relevant to the scop		Saana	
<i>Item</i> 2.1	Module level or type Chemistry – Level 1	Period for completion 13	Scope	
2.1	Chemistry – Level 1 Chemistry – Level 2	9		
2.2	Chemistry – Level 2 Chemistry – Level 3	6		
2.3 5.1	Residues – Level 1	13		
5.2	Residues – Level 2	8		
5.4	Residues – Level 4	4	_	
6.1	Occupational Health and Safety – Level 1	13	•	
6.2	Occupational Health and Safety – Level 2	7		
6.3	Occupational Health and Safety – Level 3	4		
9	Non-food trade	6		
10.1	Special data – Level 1	13		
10.2	Special data – Level 2	7		
10.3	Special data – Level 3	7		
	TOTAL TIME FOR B	13	13	
	2E = the longest of the following periods (in months) relevant to the scope of the reconsideration			
Item	Module level or type	Period for completion	Scope	
8.1	Efficacy and safety – Level 1	6		
8.2	Efficacy and safety – Level 2	4		
8.3	Efficacy and safety – Level 3	3		
3C = tl	TOTAL TIME FOR E ne longest of the following periods (in months) relevant to the sco	$2 \times 0 = 0$		
Item	Module level or type	Period for completion	Scope	
11.1	Finalisation – type 1	3	•	
11.2	Finalisation – type 2	2		
11.3	Finalisation – type 3	2		
	TOTAL TIME FOR C	3 x 3 = 9		
J = wh	ichever is relevant			
	Consultation with jurisdictional coordinator	3	•	
	In any other case	0		
D	TOTAL TIME FOR D TOTAL TIME FOR D	3		
	ichever is relevant	4		
7	Appointment of an arbitrator under s.64	3		
	In any other case	0	•	
	TOTAL TIME FOR X	0		
	TOTAL TIMEFRAME	42 months		