

## Commonwealth of Australia

## **Gazette**

## Agricultural and veterinary chemicals

No. APVMA 18, Tuesday 7 September 2021

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## **Australian Government**

# 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 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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#### **Privacy**

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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.	127982
Product name	Nufarm Digger EW Fungicide
Active constituent/s	125 g/L difenoconazole
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Summary of use	For use in grapes, potatoes and tomatoes for the control of a range of diseases
Date of registration	16 August 2021
Product registration no.	90198
Label approval no.	90198/127982

Application no.	130957
Product name	Etong Glyphosate 450 SL Herbicide
Active constituent/s	450 g/L glyphosate present as the isopropylamine salt
Applicant name	Shanghai E-Tong Chemical Co Ltd
Applicant ACN	N/A
Summary of use	For non-selective control of most perennial and annual weeds in conservation tillage situations
Date of registration	17 August 2021
Product registration no.	91105
Label approval no.	91105/130957

Application no.	130927
Product name	Sanonda Paraquat 250 Herbicide
Active constituent/s	250 g/L paraquat present as paraquat dichloride
Applicant name	Sanonda (Australia) Pty Ltd
Applicant ACN	059 813 973
Summary of use	For the control of a wide range of grasses and broadleaf weeds
Date of registration	18 August 2021
Product registration no.	91098
Label approval no.	91098/130927

Application no.	131059
Product name	APS Glyphosate 540 K Herbicide
Active constituent/s	540 g/L glyphosate present as the potassium salt
Applicant name	Agricultural Product Services Pty Ltd
Applicant ACN	092 350 279
Summary of use	For the control of many annual and perennial weeds
Date of registration	23 August 2021
Product registration no.	91146
Label approval no.	91146/131059

Application no.	131046
Product name	Sabakem Triasulfuron 750 WG
Active constituent/s	750 g/kg triasulfuron
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Summary of use	For pre-plant control of annual ryegrass, paradoxa grass and certain broadleaf weeds in wheat; and for post-emergent control of wild radish in wheat, oats and barley
Date of registration	24 August 2021
Product registration no.	91140
Label approval no.	91140/131046

Application no.	131053
Product name	Sabakem MCPA 750 Herbicide
Active constituent/s	750 g/L MCPA present as the dimethylamine salt
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Summary of use	For the selective control of broadleaf weeds in cereals, linseed, pastures, rice, sugar cane and turf
Date of registration	24 August 2021
Product registration no.	91143
Label approval no.	91143/131053

Application no.	131160
Product name	AC Repeal 900 SL Growth Regulator
Active constituent/s	900 g/L ethephon
Applicant name	Axichem Pty Ltd
Applicant ACN	131 628 594
Summary of use	For anti-lodging in barley or crop thinning, loosening or ripening in various crops and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton
Date of registration	24 August 2021
Product registration no.	91190
Label approval no.	91190/131160

Application no.	131058
Product name	Sanonda Clethodim 360EC Herbicide
Active constituent/s	360 g/L clethodim
Applicant name	Sanonda (Australia) Pty Ltd
Applicant ACN	059 813 973
Summary of use	For the control of certain grass weeds in beetroot, cabbage, canola, celery, cotton, forestry, lettuce, non-bearing fruit trees, onions, ornamentals, peanuts, pulses, potatoes, soybeans, and pasture legume seed crops and pastures
Date of registration	25 August 2021
Product registration no.	91145
Label approval no.	91145/131058

Application no.	131117
Product name	AgMerch Terbuthylazine 875 WG Herbicide
Active constituent/s	875 g/kg terbuthylazine
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	For the control of weeds in chickpeas, faba beans, fallows, field peas, lentils, lupins, sorghum and triazine tolerant canola
Date of registration	25 August 2021
Product registration no.	91177
Label approval no.	91177/131117

Application no.	131076
Product name	F.S.A. Delkura 480 SC Herbicide
Active constituent/s	480 g/L pyroxasulfone
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Summary of use	For the control of annual ryegrass, barley grass, annual Phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops
Date of registration	27 August 2021
Product registration no.	91154
Label approval no.	91154/131076

Application no.	131016
Product name	AgMerch Paraquat 135 & Diquat 115 Herbicide
Active constituent/s	135 g/L paraquat present as paraquat dichloride, 115 g/L diquat present as diquat dibromide
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	For the control of a wide range of grasses and broadleaf weeds
Date of registration	2 September 2021
Product registration no.	91135
Label approval no.	91135/131016

**Table 2: Variations of registration** 

Application no.	132208
Product name	Apparent Clobbertime 400 Herbicide
Active constituent/s	400 g/L carfentrazone-ethyl
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Apparent Clobber 400 Herbicide' to 'Apparent Clobbertime 400 Herbicide'
Date of registration	4 August 2021
Product registration no.	86549
Label approval no.	86549/132208

Application no.	132213
Product name	Relyon Paclobutrazol 250 Plant Growth Regulator
Active constituent/s	250 g/L paclobutrazol
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Offset 250 Plant Growth Regulator' to 'Relyon Paclobutrazol 250 Plant Growth Regulator' and to update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook
Date of registration	4 August 2021
Product registration no.	84665
Label approval no.	84665/132213

Application no.	132386
Product name	AgMerch Phosphorous Acid 600 Systemic Fungicide
Active constituent/s	600 g/L phosphorous (phosphonic) acid present as mono (and) di potassium phosphite
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'MLChem Phosphorous Acid 600 Systemic Fungicide' to 'AgMerch Phosphorous Acid 600 Systemic Fungicide'
Date of registration	16 August 2021
Product registration no.	90987
Label approval no.	90987/132386

Application no.	132388
Product name	AgMerch Gibberellic Acid 200 WG Growth Regulator
Active constituent/s	200 g/kg gibberellic acid
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'MLChem Gibberellic Acid 200 WG Growth Regulator'
Date of registration	16 August 2021
Product registration no.	90941
Label approval no.	90941/132388

Application no.	128031
Product name	Brevis Fruit Thinner
Active constituent/s	150 g/kg metamitron
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Summary of use	To add use in pears and increase the maximum seasonal rate for apples
Date of registration	17 August 2021
Product registration no.	84928
Label approval no.	84928/128031

Application no.	129256
Product name	Balance 750 WG Herbicide
Active constituent/s	750 g/kg isoxaflutole
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Summary of use	To add use in pineapples
Date of registration	17 August 2021
Product registration no.	49456
Label approval no.	49456/129256

Application no.	132390
Product name	AgMerch Sulphur 800 WG Fungicide & Miticide
Active constituent/s	800 g/kg sulphur (S) present as Wettable Sulphur
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'MLChem Sulphur 800 WG Fungicide & Miticide' to 'AgMerch Sulphur 800 WG Fungicide & Miticide'
Date of registration	17 August 2021
Product registration no.	90996
Label approval no.	90996/132390

Application no.	132391
Product name	AgMerch Chlorothalonil 720 Fungicide
Active constituent/s	720 g/L chlorothalonil
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Submarino Chlorothalonil 720 Fungicide' to 'AgMerch Chlorothalonil 720 Fungicide'
Date of registration	17 August 2021
Product registration no.	84450
Label approval no.	84450/132391

Application no.	132395
Product name	AgMerch Propiconazole 250 EC Fungicide
Active constituent/s	250 g/L propiconazole
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Submarino Propiconazole 250 EC Fungicide' to 'AgMerch Propiconazole 250 EC Fungicide'
Date of registration	17 August 2021
Product registration no.	84844
Label approval no.	84844/132395

Application no.	132397
Product name	AgMerch Glufosinate 200 Herbicide
Active constituent/s	200 g/L glufosinate-ammonium
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'MLChem Glufosinate 200 Herbicide' to 'AgMerch Glufosinate 200 Herbicide'
Date of registration	17 August 2021
Product registration no.	91136
Label approval no.	91136/132397

Application no.	132398
Product name	AgMerch Tebuconazole 430 SC Fungicide
Active constituent/s	430 g/L tebuconazole
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Submarino Tebuconazole 430 SC Fungicide' to 'AgMerch Tebuconazole 430 SC Fungicide'
Date of registration	17 August 2021
Product registration no.	84845
Label approval no.	84845/132398

Application no.	132399
Product name	AgMerch Metribuzin 750 WG Herbicide
Active constituent/s	750 g/kg metribuzin
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Submarino Metribuzin 750 WG Herbicide' to 'AgMerch Metribuzin 750 WG Herbicide'
Date of registration	17 August 2021
Product registration no.	90316
Label approval no.	90316/132399

Application no.	132400
Product name	AgMerch Atrazine 900 WG Herbicide
Active constituent/s	900 g/kg atrazine
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Submarino Atrazine 900 WG Herbicide' to 'AgMerch Atrazine 900 WG Herbicide'
Date of registration	17 August 2021
Product registration no.	84777
Label approval no.	84777/132400

Application no.	130029
Product name	Nufarm Weedmaster DST Dual Salt Technology Herbicide
Active constituent/s	470 g/L glyphosate present as the potassium & mono-ammonium salt
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Summary of use	To vary product registration and label approval to update the label format and inherit protected use patterns from reference products
Date of registration	18 August 2021
Product registration no.	62723
Label approval no.	62723/130029

Application no.	130956
Product name	Etong Propyzamide 900 WG Herbicide
Active constituent/s	900 g/kg propyzamide
Applicant name	Shanghai E-Tong Chemical Co Ltd
Applicant ACN	N/A
Summary of use	For selective control of certain grasses and broad leaf weeds in lettuce, sports turf, home lawns and legume seed crops and pastures
Date of registration	18 August 2021
Product registration no.	91104
Label approval no.	91104/130956

Application no.	130907
Product name	Genfarm Metham Sodium Soil Fumigant
Active constituent/s	423 g/L metham present as sodium salt
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Summary of use	To add uses for control of germinating weed seeds and soil borne pathogens in blueberries and <i>rubus spp</i> . berries
Date of registration	19 August 2021
Product registration no.	66978
Label approval no.	66978/130907

Application no.	132447
Product name	Surefire MetaMorph 500 SC Fungicide
Active constituent/s	500 g/L dimethomorph
Applicant name	PCT Holdings Pty Ltd
Applicant ACN	099 023 962
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Surefire Dimethomorph 500 SC Fungicide' to 'Surefire MetaMorph 500 SC Fungicide'
Date of registration	23 August 2021
Product registration no.	88374
Label approval no.	88374/132447

Application no.	131111
Product name	Slasher Organic Weedkiller
Active constituent/s	525 g/L nonanoic acid
Applicant name	Duluxgroup (Australia) Pty Ltd
Applicant ACN	000 049 427
Summary of use	To update the product claims, directions for use, safety directions and first aid instructions for label 'Yates Weeds Gone Rapid Action Weedkiller Concentrate'
Date of registration	25 August 2021
Product registration no.	68118
Label approval no.	68118/131111

Application no.	131155
Product name	Surefire Viento 240 SC Insecticide
Active constituent/s	240 g/L spirotetramat
Applicant name	PCT Holdings Pty Ltd
Applicant ACN	099 023 962
Summary of use	To extend the use to bulb vegetables and wine grapes
Date of registration	25 August 2021
Product registration no.	89337
Label approval no.	89337/131155

Application no.	131062
Product name	EuroChem Abamectin 18EC Insecticide
Active constituent/s	18 g/L abamectin
Applicant name	EuroChem Pty Ltd
Applicant ACN	622 603 507
Summary of use	To add uses in a wide range of crops and ornamentals as per the directions for use
Date of registration	26 August 2021
Product registration no.	89149
Label approval no.	89149/131062

Application no.	131182
Product name	Accensi Amine 625 Selective Herbicide
Active constituent/s	625 g/L 2,4-D present as the dimethyl amine salt
Applicant name	Accensi Pty Ltd
Applicant ACN	079 875 184
Summary of use	To amend the product label and registration in line with the 2,4-D reconsideration final regulatory decision and add uses in fallow, hardwood and softwood plantations, agricultural non-crop areas, commercial and industrial areas, pastures, rights of way and oil tea tree
Date of registration	26 August 2021
Product registration no.	55427
Label approval no.	55427/131182

Application no.	131408
Product name	Accensi 2,4-D Amine 700 Dual Selective Herbicide
Active constituent/s	700 g/L 2,4-D present as the dimethylamine and diethanolamine salt
Applicant name	Accensi Pty Ltd
Applicant ACN	079 875 184
Summary of use	To amend the product label in line with the 2,4-D reconsideration final regulatory decision and add uses in oil tea tree
Date of registration	27 August 2021
Product registration no.	70408
Label approval no.	70408/131408

#### 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 3: Veterinary products based on existing active constituents

Application no.	130955
Product name	TalentCare Doramectin Pour On Endectocide
Active constituent/s	5 mg/mL doramectin
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Summary of use	For the treatment and control of doramectin sensitive internal and external parasites of cattle
Date of registration	23 August 2021
Product registration no.	91103
Label approval no.	91103/130955

Application no.	130991
Product name	Rametin Oral Sheep Drench
Active constituent/s	800 g/kg napthalophos (anticholinesterase compound)
Applicant name	Pharm Smart Australia Pty Ltd
Applicant ACN	635 495 135
Summary of use	For the control of organophosphate susceptible strains of gastrointestinal mature and immature roundworms in sheep and lambs
Date of registration	24 August 2021
Product registration no.	91124
Label approval no.	91124/130991

**Table 4: Variations of registration** 

Application no.	132252
Product name	Aristopet Animal Health Complete Flea and Lice for Cats and Kittens
Active constituent/s	120 g/L (S)-methoprene, 100 g/L fipronil
Applicant name	QPharma Pty Ltd
Applicant ACN	145 418 882
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Aristopet Complete Flea and Lice for Cats and Kittens' to 'Aristopet Animal Health Complete Flea and Lice for Cats and Kittens'
Date of registration	5 August 2021
Product registration no.	90930
Label approval no.	90930/132252

Application no.	132306
Product name	Aristopet Animal Health Complete Flea and Tick for Small Dogs up to 10 kg
Active constituent/s	100 g/L fipronil, 90 g/L (S)-methoprene
Applicant name	QPharma Pty Ltd
Applicant ACN	145 418 882
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Aristopet Complete Flea and Tick for Small Dogs' to 'Aristopet Animal Health Complete Flea and Tick for Small Dogs up to 10 kg'
Date of registration	10 August 2021
Product registration no.	90931
Label approval no.	90931/132306

Application no.	132309
Product name	Aristopet Animal Health Complete Flea and Tick for Medium Dogs 10 – 20kg
Active constituent/s	100 g/L fipronil, 90 g/L (S)-methoprene
Applicant name	QPharma Pty Ltd
Applicant ACN	145 418 882
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Aristopet Complete Flea and Tick for Medium Dogs' to 'Aristopet Animal Health Complete Flea and Tick for Medium Dogs 10 – 20kg'
Date of registration	10 August 2021
Product registration no.	90932
Label approval no.	90932/132309

Application no.	132311
Product name	Aristopet Animal Health Complete Flea and Tick for Large Dogs 20-40kg
Active constituent/s	100 g/L fipronil, 90 g/L (S)-methoprene
Applicant name	QPharma Pty Ltd
Applicant ACN	145 418 882
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Aristopet Complete Flea and Tick for Large Dogs' to 'Aristopet Animal Health Complete Flea and Tick for Large Dogs 20 – 40kg'
Date of registration	10 August 2021
Product registration no.	90933
Label approval no.	90933/132311

Application no.	132310
Product name	Aristopet Animal Health Complete Flea and Tick for Extra Large Dogs 40–60kg
Active constituent/s	100 g/L fipronil; 90 g/L (S)-methoprene
Applicant name	QPharma Pty Ltd
Applicant ACN	145 418 882
Summary of use	To vary the distinguishing product name and the name that appears on the label from 'Aristopet Complete Flea and Tick for Extra Large Dogs' to 'Aristopet Animal Health Complete Flea and Tick for Extra Large Dogs 40 – 60kg'
Date of registration	10 August 2021
Product registration no.	90934
Label approval no.	90934/132310

Application no.	129251
Product name	Tolfedine CS Injection
Active constituent/s	40 mg/mL tolfenamic acid
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Summary of use	To vary the chemical product and label particulars to update the in-use shelf life
Date of registration	23 August 2021
Product registration no.	52850
Label approval no.	52850/129251

Application no.	131082
Product name	Bravecto 1-Month 560 Mg Fluralaner Chewable Tablets For Very Large Dogs
Active constituent/s	54.6 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the product name and vary label claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	87859
Label approval no.	87859/131082

Application no.	131105
Product name	Bravecto 1 – Month 400 Mg Fluralaner Chewable Tablets For Large Dogs
Active constituent/s	54.6 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the product name and vary label claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	87860
Label approval no.	87860/131105

Application no.	131107
Product name	Bravecto 1 – Month 200 Mg Fluralaner Chewable Tablets For Medium Dogs
Active constituent/s	54.6 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the product name and vary label claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	87861
Label approval no.	87861/131107

Application no.	131110
Product name	Bravecto 1 – Month 100 Mg Fluralaner Chewable Tablets For Small Dogs
Active constituent/s	54.6 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the product name and vary label claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	87862
Label approval no.	87862/131110

Application no.	131113
Product name	Bravecto 1 – Month 45 Mg Fluralaner Chewable Tablets for Very Small Dogs
Active constituent/s	54.6 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the product name and vary label claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	87863
Label approval no.	87863/131113

Application no.	130967
Product name	Zolexx Paste For Horses
Active constituent/s	370 mg/g omeprazole
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Summary of use	To add a pack size as well as to amend the dosage and administration section of the label
Date of registration	24 August 2021
Product registration no.	63080
Label approval no.	63080/130967

Application no.	130524
Product name	Ultravac 5 in 1 Vaccine
Active constituent/s	CI. perfringens type D $\geq$ 5 IU/mL, CI. tetani $\geq$ 2.5 IU/mL, CI. novyi type B $\geq$ 3.5 IU/mL, CI. septicum $\geq$ 2.5 IU/mL (as ultrafiltered toxoids), CI chauvoei (meets Ph.Eur.) as formol culture
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Summary of use	To update the label constituent statement to Ph.Eur
Date of registration	25 August 2021
Product registration no.	51279
Label approval no.	51279/130524

Application no.	129814
Product name	Bovatec 20CC Lasalocid Sodium Premix
Active constituent/s	200 g/kg lasalocid sodium
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Summary of use	To add additional claims for use in lactating dairy cattle as an aid in the control of ketosis and clinical mastitis and as an aid in reducing bloat in pasture fed cattle
Date of registration	27 August 2021
Product registration no.	60761
Label approval no.	60761/129814

#### Table 5: Variation of label approval

Application no.	130988
Product name	Bravecto 1400 Mg Fluralaner Chewable Tablets for Very Large Dogs
Active constituent/s	136.4 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	68873
Label approval no.	68873/130988

Application no.	131042
Product name	Bravecto 1000 Mg Fluralaner Chewable Tablets for Large Dogs
Active constituent/s	136.4 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	68870
Label approval no.	68870/131042

Application no.	131047
Product name	Bravecto 500 Mg Fluralaner Chewable Tablets for Medium Dogs
Active constituent/s	136.4 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	68871
Label approval no.	68871/131047

Application no.	131057
Product name	Bravecto 250 Mg Fluralaner Chewable Tablets for Small Dogs
Active constituent/s	136.4 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	68872
Label approval no.	68872/131057

Application no.	131074
Product name	Bravecto 112.5 Mg Fluralaner Chewable Tablets for Very Small Dogs
Active constituent/s	136.4 g/kg fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Summary of use	To vary the claim to include a clarification statement on paralysis tick efficacy
Date of registration	23 August 2021
Product registration no.	68867
Label approval no.	68867/131074

#### Approved active constituents

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

**Table 6: Active constituent** 

Application no.	129201
Active constituent/s	Thiamethoxam
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Summary of use	For use in agricultural chemical products
Date of approval	16 August 2021
Approval no.	90519

Application no.	130711
Active constituent/s	Thiabendazole
Applicant name	Decco US Post-Harvest Inc
Applicant ACN	N/A
Summary of use	For use in agricultural chemical products
Date of approval	25 August 2021
Approval no.	91003

Application no.	129865
Active constituent/s	Fluazuron
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Summary of use	For use in veterinary chemical products
Date of approval	25 August 2021
Approval no.	90715

Application no.	130792
Active constituent/s	Tilmicosin phosphate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Summary of use	For use in veterinary chemical products
Date of approval	25 August 2021
Approval no.	91032

#### **Table 7: Variations of active constituent**

Application no.	129659
Active constituent/s	Ammonium chloride
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Summary of use	Variation of relevant particulars or conditions of an approved active constituent
Date of approval	20 August 2021
Approval no.	88404

Application no.	131072
Active constituent/s	Flonicamid
Applicant name	Ishihara Sangyo Kaisha Ltd
Applicant ACN	N/A
Summary of use	Variation of relevant particulars or conditions of an approved active constituent
Date of approval	25 August 2021
Approval no.	65027

Application no.	130990
Active constituent/s	Furosemide
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Summary of use	Variation of relevant particulars or conditions of an approved active constituent
Date of approval	25 August 2021
Approval no.	85900

#### Amendments to the APVMA MRL Standard

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

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

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

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument* (No. 7) 2021.

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

The MRL Standard is accessible via the Federal Register of Legislation website.

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

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

In the previous notice on page 18 of APVMA Gazette No. 18, the APVMA gazetted amendments which it has approved to vary maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out in the APVMA's MRL Standard.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (Agricultural and Veterinary Chemicals Code *(MRL Standard)* Amendment Instrument 2021 (No. 7)) to MRLs into Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

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

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

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

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

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

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

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

#### 7 September 2021

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

#### To commence: on gazettal of variation

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

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

#### Agvet chemical: Proquinazid

Permitted residue - commodities of plant origin:

Proquinazid

Permitted residue – commodities of animal origin: Sum of proquinazid and 3-(6-iodo-4-oxo-3-propyl-3H-quinazolin-2-yloxy)propionic acid, expressed as proquinazid

Tomato 0.3

#### Agvet chemical: Trifloxystrobin

Permitted residue: Sum of trifloxystrobin and its acid metabolite ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl)-ethylideneaminooxymethyl] phenyl] acetic acid), expressed as trifloxystrobin equivalents

Beans [except broad bean; soya 0.06 bean]

Raspberries, red, black 3

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

#### Agvet chemical: Fluopyram

Permitted residue – commodities of plant origin: Fluopyram

Permitted residue – commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram

Cane berries [except raspberries, 3 red, black]

Agvet chemical: Flupyradifurone	
Permitted residue: Flupyradifurone	
Avocado	0.7
Common bean (pods and/or immature seeds)	2
Edible offal (mammalian)	0.5
Eggs	*0.01
Fruiting vegetables, cucurbits	0.5
Mango	0.7
Meat (mammalian)	0.1
Milks	0.07
Papaya (pawpaw)	0.5
Poultry meat	*0.01
Poultry, edible offal of	*0.01
Sweet potato	0.07

#### Agvet chemical: Imidacloprid

Permitted residue: Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid

Avocado	0.2
Mango	0.2
Papaya (pawpaw)	0.2

#### Agvet chemical: Proquinazid

Permitted residue – commodities of plant origin: Proquinazid

Permitted residue – commodities of animal origin: Sum of proquinazid and 3-(6-iodo-4-oxo-3-propyl-3H-quinazolin-2-yloxy)propionic acid, expressed as proquinazid

Fruiting vegetables, other than 0.3 cucurbits [except peppers, sweet]

#### Agvet chemical: Trifloxystrobin

Permitted residue: Sum of trifloxystrobin and its acid metabolite ((E,E)-methoxyimino-[2-[1-(3trifluoromethylphenyl)-ethylideneaminooxymethyl] phenyl] acetic acid), expressed as trifloxystrobin equivalents

0.06
3
0.4

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

Agvet chemical: Etoxazole	
Permitted residue: Etoxazole	
Avocado	T0.1

#### Agvet chemical: Fluopyram

Permitted residue - commodities of plant origin: Fluopyram

Permitted residue - commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram

2 Strawberry

Agvet chemical: Flupyradifurone	
Permitted residue: Flupyradifurone	
All other foods except animal food commodities	0.2
Potato	0.07

#### Agvet chemical: Imidacloprid

Permitted residue: Sum of imidacloprid and metabolites containing the 6chloropyridinylmethylene moiety, expressed as

imidacloprid

Common bean (pods and/or

2 immature seeds)

#### Agvet chemical: Mefentrifluconazole

Permitted residue: Mefentrifluconazole

Tree nuts 0.2

#### Invitation for submissions

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

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

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

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

#### Deadline for public submissions

Submissions must be received by 5 October 2021 (28 days from date Gazette published). Submissions received after this deadline will only be considered by prior arrangement or if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the <u>public</u> consultation coversheet).

Please lodge your submission using the <u>public consultation 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.

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

**Phone:** +61 2 6770 2300

Email: enquiries@apvma.gov.au

#### **Privacy**

For information on how the APVMA manages personal information when you make a submission, see our Privacy Policy.

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

The APVMA has previously gazetted particular amendments which it had made to the APVMA MRL Standard and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Schedule 20 – Maximum residue limits of the Australia New Zealand Food Standards Code. This notice pertains to proposals (No. 4) gazetted on 4 May 2021 (No. APVMA 9) and (No. 5) gazetted on 1 June 2021 (No. APVMA 11).

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

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Schedule 20. A copy of the Amendment Instrument (No. APVMA 5, 2021) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the <u>Federal Register of Legislation</u>.

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

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

Sanitary and Phytosanitary notifications to the World Trade Organization (WTO) was also made in relation to the variations to MRLs in Schedule 20 and a comment was received in response to that notice which has been addressed.

A copy of these variations have been given to FSANZ.

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

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

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

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#### **Australian Government**

### Australian Pesticides and Veterinary Medicines Authority

# Australia New Zealand Food Standards Code — Schedule 20 — Maximum residue limits Variation Instrument No. APVMA 5, 2021

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

Sheila Logan

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

Dated this First day of September 2021

#### Part 1 Preliminary

#### 1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code* — *Schedule 20* — *Maximum residue limits Variation Instrument No. APVMA 5, 2021* (Amendment Instrument).

#### 2 Commencement

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

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

#### 3 Object

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

#### 4 Interpretation

In this instrument: —

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

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

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

#### 5 Variations to Schedule 20

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

#### **Schedule**

#### Variations to Schedule 20 – Maximum residue limits

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

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

T0.5

#### Agvet chemical: Flonicamid

Permitted residue: Flonicamid [N -(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [N - (4-trifluoromethylnicotinoyl)glycine]

Agvet chemical: Pyriproxyfen	
Permitted residue: Pyriproxyfen	
Beans [except broad bean; soya bean]	T0.5

#### Agvet chemical: Saflufenacil

Yard-long bean (pods)

Permitted residue – commodities of plant origin: Sum of saflufenacil, N'-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl-N-isopropyl sulfamide and N-[4-chloro-2-fluoro-5-([(isopropylamino)sulfonyl]amino) carbonyl)phenyl]urea, expressed as saflufenacil equivalents

Permitted residue – commodities of animal origin: Saflufenacil

Oilseed \*0.03

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

Agvet chemical: Cyantraniliprole	
Permitted residue: Cyantraniliprole	
Celery	T7
Agvet chemical: Dimethoate	
Permitted residue: Sum of dimethoate and omethoate, expressed as dimethoate	
see also Omethoate	
Olives for oil production	Т3

vai	iations to scriet
Agvet chemical: Flonicamid	
Permitted residue: Flonicamid [N -(cyar (trifluoromethyl)-3-pyridinecarboxamide metabolites TFNA [4-trifluoromethylnicotramide (4-trifluoromethylnicotinamide (4-trifluoromethylnicotinoyl)glycine]	] and its otinic acid],
Fruiting vegetables, other than cucurbit	s T0.5
Rape seed (canola)	0.5
Agvet chemical: Fluxapyroxad	
Permitted residue: Fluxapyroxad	
Oats	T0.2
Agvet chemical: Isopyrazam	
Permitted residue: Isopyrazam	
All other foods except animal food commodities	0.01
Almonds	*0.01
Agvet chemical: Isoxaflutole	
Permitted residue: Sum of isoxaflutole a cyclopropylcarbonyl-3-(2-methylsulfony trifluoromethylphenyl)-3-oxopropaneniti as isoxaflutole	1-4-
All other foods except animal food commodities	0.02
Pineapple	*0.02
Agvet chemical: Mefentrifluconazole	1
Permitted residue: Mefentrifluconazole	
Barley	T0.2
Oats	T0.2
Rape seed [canola]	T0.05

Agvet chemical: Mesotrione	
Permitted residue: Mesotrione	
All other foods except animal food commodities	0.01
Linseed	T*0.01
Sweet corn (corn-on-the-cob)	T*0.01

T0.03

Wheat

Agvet chemical: Methomyl	
Permitted residue: Methomyl	
Pitaya (dragon fruit)	T0.2
Agvet chemical: Metribuzin	
Permitted residue: Metribuzin	
Pineapple	*0.01
Agvet chemical: Omethoate	
Permitted residue: Omethoate	
see also Dimethoate	
Olives for oil production	T2
Olive oil, refined	T0.2
Agvet chemical: Pyriproxyfen	
Permitted residue: Pyriproxyfen	
Beans with pods	T0.3

#### Agvet chemical: Saflufenacil

Permitted residue – commodities of plant origin: Sum of saflufenacil, N'-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl-N-isopropyl sulfamide and N-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino} carbonyl)phenyl]urea, expressed as saflufenacil equivalents

Permitted residue – commodities of animal origin: Saflufenacil

Linseed T0.5

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

Agvet chemical: Azoxystrobin	
Permitted residue: Azoxystrobin	
Beetroot	T*0.005
Agvet chemical: Bromoxynil	
Permitted residue: Bromoxynil	
Onion, bulb	*0.01

#### Agvet chemical: Carbendazim

Permitted residue: Sum of carbendazim and 2aminobenzimidazole, expressed as carbendazim

Mushrooms T1

#### Agvet chemical: Dimethoate

Permitted residue: Sum of dimethoate and omethoate, expressed as dimethoate

see also Omethoate

Olive oil, refined T0.3

#### Agvet chemical: Imazapyr

Permitted residue: Imazapyr

Broad bean (dry) 0.07

#### Agvet chemical: Mefentrifluconazole

Permitted residue: Mefentrifluconazole

Edible offal (mammalian) T0.3

Meat (mammalian) (in the fat) T0.2

#### Agvet chemical: Saflufenacil

Permitted residue – commodities of plant origin: Sum of saflufenacil, N'-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl-N-isopropyl sulfamide and N-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino} carbonyl)phenyl]urea, expressed as saflufenacil equivalents

Permitted residue – commodities of animal origin: Saflufenacil

Oilseed [except cotton seed; \*0.03 linseed; rapeseed; sunflower seed]

#### Agvet chemical: Spiroxamine

Permitted residue – commodities of plant origin: Spiroxamine

Permitted residue – commodities of animal origin: Spiroxamine carboxylic acid, expressed as spiroxamine

Barley	0.03
Podded pea (young pods) (snow and	T0.6
sugar snap)	

## Proposed establishment of active constituent standard as a legislative instrument under section 6E of the Agvet Code

The APVMA proposes to convert the current informal standards established mainly for active constituents in agricultural chemical products and published on its <u>website</u> into a formal standard (legislative instrument) established under section 6E of the Agvet Code.

Under regulation 8AF of the Agricultural and Veterinary Chemicals Code Regulations (the Agvet Code Regulations), the APVMA must publish a notice of its intention to establish a standard under section 6E in the APVMA gazette and on the website. The draft standard must also be published on the website, and a period not less than 28 days must be allowed for comment on the proposed standard.

A copy of the <u>draft section 6E standard</u> is available on the APVMA website. The <u>consultation notice</u> has been published on the APVMA website on 7 September 2021.

Regulation 42(3) of the Agvet Code Regulations specifies the standard prescribed for a chemical product or a constituent within that product, for the purposes of section 87 of the Agvet Code (which relates to compliance of a product or constituent with standards, and includes penalties for non-compliance) as being the standard published in any of a 'cascade' of publications, with a publication higher in the cascade taking precedence over one lower down. The publications are, in order, an standard specified in an Order made under section 7 of the Agvet Code Act (of which there are none currently), a standard made under section 6E of the Agvet Code (as is proposed), a standard published for a listed chemical product, a monograph in the British, European or US Pharmacopoeia, or a specification by published by FAO and/or WHO.

Establishment of the active constituent standards as a standard under section 6E would mean that the APVMA standards, over which APVMA has full control, would take precedence over a potentially inappropriate and irrelevant standard from another publication.

All standards currently listed on the website are proposed for inclusion in the new section 6E standard, together with approximately 20 standards for recently approved actives which have been consulted on via a gazette notice, but are not yet published on the website. Minor errors were also corrected when found. Beyond this, it should be noted that no changes to the standards currently published on the website, in terms of changes to minimum purities, or changes to identities or levels for impurities, are proposed in conjunction with the establishment of a standard under section 6E.

This standard would operate in conjunction with the current requirements and processes for approval of active constituents, and there are no proposed changes to those processes. In particular, this standard operates in conjunction with and does not replace the conditions of approval of active constituents prescribed under regulation 17C(1) of the Agvet Code Regulations. For example, where a source of active is approved with a higher minimum purity than the minimum specified by the standard, the conditions of approval will still prescribe the higher minimum purity approved for that particular source.

Should the standard be created as a legislative instrument, it would be updated regularly to include new active constituents, and to make any changes necessary to existing standards, such as in conjunction with a chemical review. All such changes would be consulted on as required by regulation 8AF.

Further information on the proposed standard can be obtained from the contact details given below.

In accordance with regulation 8AF of the Agvet Code Regulations, the APVMA therefore invites any person to make written submissions on the proposed standard.

Submissions must be received by APVMA by 5 October 2021 and be directed to the contact listed below.

Please note that submissions will be published on the APVMA's website unless you have asked for the submission to remain confidential (see public submission coversheet).

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.

Please send your written submission and coversheet by email or by post to:

Email: enquiries@apvma.gov.au

#### Post:

Director Chemistry and Manufacture Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

#### Privacy:

For information on how the APVMA manages personal information when make a submission, see our privacy policy.

Links to the relevant legislative references are provided below:

Agricultural and Veterinary Chemicals Code Act 1994

Agricultural and Veterinary Chemicals Code Regulations 1995