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of Australia**

Gazette

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**AGRICULTURAL AND
VETERINARY CHEMICALS**



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

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

DISTRIBUTION AND SUBSCRIPTION

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Agricultural Chemical Products and Approved Labels

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

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

| | |
|---------------------------------------|--|
| Application no.: | 107693 |
| Product name: | Beanzone 480 Herbicide |
| Active constituent/s: | 480 g/L bentazone (present as sodium salt) |
| Applicant name: | Grow Choice Australia Pty Limited |
| Applicant ACN: | 069 839 961 |
| Summary of use | For selective post-emergence control of certain broadleaf weeds in green (dwarf french) beans, navy (haricot) beans, peanuts, red kidney beans, red mexican beans and soybeans |
| Date of registration/approval: | 29 November 2016 |
| Product registration no.: | 83184 |
| Label approval no.: | 83184/107693 |

| | |
|---------------------------------------|--|
| Application no.: | 105223 |
| Product name: | Brunnings Weed Kill for Lawns Spot Spray |
| Active constituent/s: | 1.5 g/L MCPA, 0.3 g/L dicamba (both present as dimethylamine salt) |
| Applicant name: | Brunnings Garden Products Pty Ltd |
| Applicant ACN: | 050 655 760 |
| Summary of use | For the control of a range of weeds in lawns (except buffalo) |
| Date of registration/approval: | 13 January 2017 |
| Product registration no.: | 82215 |
| Label approval no.: | 82215/105223 |

| | |
|---------------------------------------|--|
| Application no.: | 103456 |
| Product name: | Brocan Herbicide |
| Active constituent/s: | 250 g/L bromoxynil present as the octanoate, 25 g/L diflufenican |
| Applicant name: | Shandong Rainbow International Co., Ltd. |
| Applicant ACN: | N/A |
| Summary of use | For the control of certain broadleaf weeds in winter cereals and pasture |
| Date of registration/approval: | 17 January 2017 |
| Product registration no.: | 81611 |
| Label approval no.: | 81611/103456 |

| | |
|---------------------------------------|--|
| Application no.: | 102878 |
| Product name: | Genfarm Methomyl 225 L Insecticide |
| Active constituent/s: | 225 g/L methomyl (an anti-cholinesterase compound) |
| Applicant name: | Landmark Operations Limited |
| Applicant ACN: | 008 743 217 |
| Summary of use | For the control of insect pests in various crops |
| Date of registration/approval: | 17 January 2017 |
| Product registration no.: | 81354 |
| Label approval no.: | 81354/102878 |

| | |
|---------------------------------------|--|
| Application no.: | 106652 |
| Product name: | MACSPRED Haloxyfop 520 Herbicide |
| Active constituent/s: | 520 g/L haloxyfop present as the haloxyfop-P-methyl ester |
| Applicant name: | Macspred Pty Ltd |
| Applicant ACN: | 011 029 495 |
| Summary of use | For the post-emergent control of a wide range of annual and perennial grass weeds in grain, legume and oilseed crops, lucerne, medic and clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops |
| Date of registration/approval: | 20 January 2017 |
| Product registration no.: | 82753 |
| Label approval no.: | 82753/106652 |
| Application no.: | 108140 |
| Product name: | Nadal 2,4-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: | Rotam Agrochemical Co., Ltd |
| Applicant ACN: | N/A |
| Summary of use | For the control of a wide range of annual and perennial broadleaf weeds |
| Date of registration/approval: | 25 January 2017 |
| Product registration no.: | 83371 |
| Label approval no.: | 83371/108140 |
| Application no.: | 107931 |
| Product name: | Ozcrop 2,4-DB 500 SC Herbicide |
| Active constituent/s: | 500 g/L 2,4-DB (present as the dimethylamine salt) |
| Applicant name: | Ozcrop Pty. Ltd. |
| Applicant ACN: | 160 656 431 |
| Summary of use | For the control of broadleaf weeds in seedling and established lucerne, medic and clover pasture, peanuts and cereal crops undersown with lucerne, medic or clover |
| Date of registration: | 25 January 2017 |
| Product registration no.: | 83302 |
| Label approval no.: | 83302/107931 |
| Application no.: | 105577 |
| Product name: | Kenso Agcare Rebellion Gold Herbicide |
| Active constituent/s: | 800 g/L prosulfocarb, 120 g/L s-metolachlor |
| Applicant name: | Kenso Corporation (M) SDN. BHD. |
| Applicant ACN: | N/A |
| Summary of use | For control of annual ryegrass and other grass and broadleaf weeds in barley and wheat |
| Date of registration/approval: | 27 January 2017 |
| Product registration no.: | 82365 |
| Label approval no.: | 82365/105577 |

| | |
|---------------------------------------|--|
| Application no.: | 107201 |
| Product name: | Relyon Bolt 200EC Herbicide |
| Active constituent/s: | 200 g/L bromoxynil present as the n-octanoyl ester |
| Applicant name: | Ruralco Holdings Limited |
| Applicant ACN: | 009 660 879 |
| Summary of use | For the control of weeds in wheat, oats, barley, cereal rye and triticale (alone or undersown) linseed, clover and lucerne pastures, turf, fallow, non-crop, roadsides and rights-of-way |
| Date of registration/approval: | 30 January 2017 |
| Product registration no.: | 82951 |
| Label approval no.: | 82951/107201 |
| Application no.: | 102266 |
| Product name: | Sero-X Insecticide |
| Active constituent/s: | 400 g/L clitoria ternatea extract |
| Applicant name: | Innovate Ag Pty Limited |
| Applicant ACN: | 099 056 952 |
| Summary of use | For control or suppression of green mirid, silver leaf whitefly (biotype b) and heliothis in cotton |
| Date of registration/approval: | 30 January 2017 |
| Product registration no.: | 81070 |
| Label approval no.: | 81070/102266 |
| Application no.: | 105775 |
| Product name: | Countdown Herbicide |
| Active constituent/s: | 800 g/L prosulfocarb |
| Applicant name: | Adama Australia Pty Limited |
| Applicant ACN: | 050 328 973 |
| Summary of use | For the control/suppression of annual ryegrass and other grass and broadleaf weeds in barley and wheat |
| Date of registration/approval: | 31 January 2017 |
| Product registration no.: | 82446 |
| Label approval no.: | 82446/105775 |
| Application no.: | 107843 |
| Product name: | Spalding Chlorothalonil 720 SC Fungicide |
| Active constituent/s: | 720 g/L chlorothalonil |
| Applicant name: | Spalding Holdings Pty Ltd |
| Applicant ACN: | 010 155 852 |
| Summary of use | For the control of fungal diseases on almonds, bananas, cucurbits, grapes, ornamentals, peanuts, stone fruit, tobacco and vegetables |
| Date of registration/approval: | 31 January 2017 |
| Product registration no.: | 83251 |
| Label approval no.: | 83251/107843 |

2. VARIATIONS OF REGISTRATION

| | |
|----------------------------------|--|
| Application no: | 108615 |
| Product name: | Kenso Agcare Ken-Up 500 Flexi Herbicide |
| Active constituent/s: | 500 g/L glyphosate present as the isopropylamine salt |
| Applicant name: | Kenso Corporation (M) Sdn. Bhd. |
| Applicant ACN: | N/A |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'KENSO AGCARE KEN-UP 500 CT HERBICIDE' to 'KENSO AGCARE KEN-UP 500 FLEXI HERBICIDE' |
| Date of variation: | 17 November 2016 |
| Product registration no.: | 68140 |
| Label approval no.: | 68140/108615 |
| Application no: | 108752 |
| Product name: | Hortico Insect Killer Citrus & Flowers |
| Active constituent/s: | 150 g/kg petroleum oil |
| Applicant name: | Duluxgroup (Australia) Pty Ltd |
| Applicant ACN: | 000 049 427 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'HORTICO INSECT KILLER FRUIT & CITRUS' to 'HORTICO INSECT KILLER CITRUS & FLOWERS' |
| Date of variation: | 28 November 2016 |
| Product registration no.: | 67031 |
| Label approval no.: | 67031/108752 |
| Application no: | 108790 |
| Product name: | Apparent Popstar Plant Growth Regulator |
| Active constituent/s: | 200 g/kg gibberellic acid |
| Applicant name: | Apparent Pty Ltd |
| Applicant ACN: | 143 724 136 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'APPARENT GIBBERELIC ACID PLANT GROWTH REGULATOR' to 'APPARENT POPSTAR PLANT GROWTH REGULATOR' |
| Date of variation: | 2 December 2016 |
| Product registration no.: | 81255 |
| Label approval no.: | 81255/108790 |
| Application no: | 108822 |
| Product name: | Armoury Herbicide |
| Active constituent/s: | 150 g/L imazapyr present as the potassium salt, 150 g/L glyphosate present as the potassium salt |
| Applicant name: | Crop Culture Pty Ltd |
| Applicant ACN: | 142 860 473 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'CROP CULTURE ARMOURY HERBICIDE' to 'ARMOURY HERBICIDE' |
| Date of variation: | 6 December 2016 |
| Product registration no.: | 67206 |
| Label approval no.: | 67206/108822 |

| | |
|----------------------------------|--|
| Application no: | 108889 |
| Product name: | Macro Protect Flutriafol 250 Fungicide |
| Active constituent/s: | 250 g/L flutriafol |
| Applicant name: | Macrofertil Australia Pty Ltd |
| Applicant ACN: | 166 370 976 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'RAVENSDOWN FLUTRIAFOL IN-FURROW & FOLIAR FUNGICIDE' to 'MACRO PROTECT FLUTRIAFOL 250 FUNGICIDE' |
| Date of variation: | 12 December 2016 |
| Product registration no.: | 58520 |
| Label approval no.: | 58520/108889 |
| Application no: | 108327 |
| Product name: | Intersmooth 7460HS SPC Antifouling |
| Active constituent/s: | 794 g/L copper present as cuprous oxide, 84 g/L copper pyrithione |
| Applicant name: | AKZO Nobel Pty Limited |
| Applicant ACN: | 000 119 424 |
| Summary of variation: | To approve a new label for the product 'INTERSMOOTH 7460HS SPC ANTIFOULING' with the label name 'INTERSMOOTH 7370HS SPC ANTIFOULING' |
| Date of variation: | 31 January 2017 |
| Product registration no.: | 65261 |
| Label approval no.: | 65261/108327 |

Veterinary Chemical Products and Approved Labels

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

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

| | |
|---------------------------------------|---|
| Application no.: | 105807 |
| Product name: | Bovimec Pour-On for Beef and Dairy Cattle |
| Active constituent/s: | 5 g/L ivermectin |
| Applicant name: | Abbey Laboratories Pty Ltd |
| Applicant ACN: | 156 000 430 |
| Summary of use | For use in the treatment and control of ivermectin-sensitive internal and external parasites of beef and dairy cattle |
| Date of registration/approval: | 20 January 2017 |
| Product registration no.: | 82468 |
| Label approval no.: | 82468/105807 |

| | |
|---------------------------------------|---|
| Application no.: | 105862 |
| Product name: | Bovimisolet Pour-On Wormer for Cattle |
| Active constituent/s: | 125 g/L levamisole |
| Applicant name: | Abbey Laboratories Pty Ltd |
| Applicant ACN: | 156 000 430 |
| Summary of use | For use in the treatment of mature and immature roundworms and lungworm in cattle |
| Date of registration/approval: | 30 January 2017 |
| Product registration no.: | 82481 |
| Label approval no.: | 82481/105862 |

2. VARIATIONS OF REGISTRATION

| | |
|----------------------------------|---|
| Application no.: | 108506 |
| Product name: | Improvac For Male Pigs |
| Active constituent/s: | 300 µg/2 mL GnRF-protein conjugate |
| Applicant name: | Zoetis Australia Pty Ltd |
| Applicant ACN: | 156 476 425 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'IMPROVEST FOR MALE PIGS' to 'IMPROVAC FOR MALE PIGS' |
| Date of variation: | 4 November 2016 |
| Product registration no.: | 70058 |
| Label approval no.: | 70058/108506 |

| | |
|----------------------------------|---|
| Application no: | 108539 |
| Product name: | Websters 5 In 1 Vaccine |
| Active constituent/s: | Contains toxoid and cell concentrates prepared from formalin killed clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL) and Cl. chauvoei (EP 0361). contains 0.13 g/L thiomersal |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'WEBSTERS LOW VOLUME 5 IN 1 VACCINE FOR CATTLE AND SHEEP' to 'WEBSTERS 5 IN 1 VACCINE' |
| Date of variation: | 11 November 2016 |
| Product registration no.: | 51333 |
| Label approval no.: | 51333/108539 |
| Application no: | 108542 |
| Product name: | Websters 6 In 1 Vaccine |
| Active constituent/s: | Contains toxoid and cell concentrates prepared from formalin killed corynebacterium pseudotuberculosis (ovis) (1.0 U/mL), clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL) and Cl. chauvoei (EP 0361) |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'WEBSTERS LOW VOLUME 6 IN 1 VACCINE (INCLUDING CHEESY GLAND) FOR SHEEP' to 'WEBSTERS 6 IN 1 VACCINE' |
| Date of variation: | 11 November 2016 |
| Product registration no.: | 51336 |
| Label approval no.: | 51336/108542 |
| Application no: | 108547 |
| Product name: | Websters 5 In 1 B12 Vaccine |
| Active constituent/s: | Contains toxoid and cell concentrates prepared from formalin killed clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL), Cl. chauvoei (EP 0361) and vitamin B12 (hydroxocobalamin acetate) 1 mg/mL |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'WEBSTERS 5 IN 1 VACCINE WITH VITAMIN B12 FOR CATTLE AND SHEEP' to 'WEBSTERS 5 IN 1 B12 VACCINE' |
| Date of variation: | 11 November 2016 |
| Product registration no.: | 50632 |
| Label approval no.: | 50632/108547 |

| | |
|----------------------------------|---|
| Application no: | 108546 |
| Product name: | Websters 3 In 1 B12 & Se Vaccine |
| Active constituent/s: | Contains aluminium adjuvanted toxoid and cellular antigen from Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Clostridium tetani 2.5 IU/mL, Vitamin B12 (hydroxocobalamin acetate) 2 mg/mL and Selenium (as sodium selenate) 1 mg/mL |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'WEBSTERS LOW VOLUME 3 IN 1 VACCINE WITH SELENIUM AND VITAMIN B12 (INCLUDING CHEESY GLAND) FOR LAMBS' to 'WEBSTERS 3 IN 1 B12 & SE VACCINE' |
| Date of variation: | 11 November 2016 |
| Product registration no.: | 54575 |
| Label approval no.: | 54575/108546 |

| | |
|----------------------------------|---|
| Application no: | 108545 |
| Product name: | Websters 3 In 1 Se Vaccine |
| Active constituent/s: | Contains aluminium adjuvanted toxoid and cellular antigen from corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, clostridium perfringens type D 5.0 IU/mL, clostridium tetani 2.5 IU/mL and selenium (as sodium selenate) 1 mg/mL |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'WEBSTERS LOW VOLUME 3 IN 1 VACCINE WITH SELENIUM (INCLUDING CHEESY GLAND) FOR LAMBS' to 'WEBSTERS 3 IN 1 SE VACCINE' |
| Date of variation: | 11 November 2016 |
| Product registration no.: | 51335 |
| Label approval no.: | 51335/108545 |

| | |
|----------------------------------|---|
| Application no: | 108544 |
| Product name: | Websters 6 In 1 Se Vaccine |
| Active constituent/s: | Contains aluminium adjuvanted toxoid and cellular antigen from corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, clostridium perfringens type D 5.0 IU/mL, Cl. novyi type B 3.5 IU/mL, Cl. tetani 2.5 IU/mL, Cl. septicum 2.5 IU/mL, Cl. chauvoei EP 0361 and selenium (as sodium selenate) 1 mg/mL |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from 'WEBSTERS LOW VOLUME 6 IN 1 VACCINE WITH SELENIUM (INCLUDING CHEESY GLAND) FOR LAMBS' to 'WEBSTERS 6 IN 1 SE VACCINE' |
| Date of variation: | 11 November 2016 |
| Product registration no.: | 51337 |
| Label approval no.: | 51337/108544 |

Approved Active Constituents—Agricultural

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

1. ACTIVE CONSITUTENT

| | |
|------------------------------|---|
| Application no.: | 106813 |
| Active constituent/s: | Benzofenap |
| Applicant name: | Oat Agrio Co., Ltd |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 23 January 2017 |
| Approval no.: | 82800 |
| Application no.: | 106814 |
| Active constituent/s: | Benzofenap |
| Applicant name: | Oat Agrio Co., Ltd |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 23 January 2017 |
| Approval no.: | 82801 |
| Application no.: | 105732 |
| Active constituent/s: | Glufosinate-ammonium |
| Applicant name: | Inner Mongolia Join Dream Fine Chemicals Co., Ltd |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 24 January 2017 |
| Approval no.: | 82437 |
| Application no.: | 105690 |
| Active constituent/s: | Pyraclostrobin |
| Applicant name: | Kenso Corporation (M) Sdn. Bhd. |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 24 January 2017 |
| Approval no.: | 82415 |
| Application no.: | 106729 |
| Active constituent/s: | Fluroxypyr-meptyl |
| Applicant name: | Foison Scitech Co., Limited |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 25 January 2017 |
| Approval no.: | 82777 |

| | |
|------------------------------|---|
| Application no.: | 101362 |
| Active constituent/s: | Metazachlor |
| Applicant name: | BASF Australia Ltd |
| Applicant ACN: | 008 437 867 |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 31 January 2017 |
| Approval no.: | 80665 |

Approved Active Constituents—Veterinary

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, s14A, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

1. ACTIVE CONSITUTENT

| | |
|------------------------------|---|
| Application no.: | 107881 |
| Active constituent/s: | Gonadotrophin-Serum |
| Applicant name: | Vetoquinol Australia Pty Ltd |
| Applicant ACN: | 006 949 480 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83279 |
| Application no.: | 108780 |
| Active constituent/s: | Cetrimide |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83646 |
| Application no.: | 108695 |
| Active constituent/s: | Oxantel Embonate |
| Applicant name: | Zoetis Australia Pty Ltd |
| Applicant ACN: | 156 476 425 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83609 |
| Application no.: | 108692 |
| Active constituent/s: | Flunixin Meglumine |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products. |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83606 |
| Application no.: | 108677 |
| Active constituent/s: | Cephalonium |
| Applicant name: | Norbrook Laboratories Australia Pty Limited |
| Applicant ACN: | 080 972 596 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83596 |

| | |
|------------------------------|---|
| Application no.: | 108676 |
| Active constituent/s: | Pyrantel Embonate |
| Applicant name: | Zoetis Australia Pty Ltd |
| Applicant ACN: | 156 476 425 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83595 |

| | |
|------------------------------|---|
| Application no.: | 108663 |
| Active constituent/s: | Sodium Hyaluronate |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83586 |

| | |
|------------------------------|---|
| Application no.: | 108684 |
| Active constituent/s: | Vitamine B12 Acetate |
| Applicant name: | Merial Australia Pty Ltd |
| Applicant ACN: | 071 187 285 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83600 |

| | |
|------------------------------|---|
| Application no.: | 108366 |
| Active constituent/s: | Zinc Bacitracin Feed Grade Concentrate |
| Applicant name: | Zamira Life Sciences Pty Ltd |
| Applicant ACN: | 130 641 502 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83475 |

| | |
|------------------------------|--|
| Application no.: | 108535 |
| Active constituent/s: | Pergolide Mesylate |
| Applicant name: | Boehringer Ingelheim Pty Limited, Vetmedica Division |
| Applicant ACN: | 000 452 308 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 9 January 2017 |
| Approval no.: | 83518 |

| | |
|------------------------------|---|
| Application no.: | 108622 |
| Active constituent/s: | Neomycin Sulfate |
| Applicant name: | Apex Laboratories Pty Ltd |
| Applicant ACN: | 614 716 700 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 13 January 2016 |
| Approval no.: | 83563 |

| | |
|------------------------------|---|
| Application no.: | 108661 |
| Active constituent/s: | Pentosan Polysulfate Sodium |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 13 January 2016 |
| Approval no.: | 83584 |

| | |
|------------------------------|---|
| Application no.: | 108660 |
| Active constituent/s: | Detomidine Hydrochloride |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 13 January 2016 |
| Approval no.: | 83583 |

| | |
|------------------------------|---|
| Application no.: | 108659 |
| Active constituent/s: | Copper Carbonate |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 13 January 2016 |
| Approval no.: | 83582 |

| | |
|------------------------------|---|
| Application no.: | 108657 |
| Active constituent/s: | Manganese Carbonate |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 13 January 2016 |
| Approval no.: | 83580 |

| | |
|------------------------------|---|
| Application no.: | 108654 |
| Active constituent/s: | EDTA (Acid) |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 13 January 2016 |
| Approval no.: | 83576 |

| | |
|------------------------------|---|
| Application no.: | 108604 |
| Active constituent/s: | Insulin, Porcine |
| Applicant name: | Intervet Australia Pty Limited |
| Applicant ACN: | 008 467 034 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 16 January 2017 |
| Approval no.: | 83555 |

| | |
|------------------------------|---|
| Application no.: | 108680 |
| Active constituent/s: | Albendazole |
| Applicant name: | Jurox Pty Limited |
| Applicant ACN: | 000 932 230 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 16 January 2017 |
| Approval no.: | 83598 |

| | |
|------------------------------|---|
| Application no.: | 108860 |
| Active constituent/s: | Potassium Gluconate |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 17 January 2017 |
| Approval no.: | 83700 |

| | |
|------------------------------|---|
| Application no.: | 108863 |
| Active constituent/s: | Phenylbutazone |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 17 January 2017 |
| Approval no.: | 83703 |

| | |
|------------------------------|---|
| Application no.: | 109157 |
| 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: | 24 January 2017 |
| Approval no.: | 83877 |

| | |
|------------------------------|--|
| Application no.: | 108950 |
| Active constituent/s: | Flugestone Acetate |
| Applicant name: | Intervet Australia Pty Limited |
| Applicant ACN: | 008 467 034 |
| Summary of use: | For use in veterinary chemical products. |
| Date of approval: | 30 January 2017 |
| Approval no.: | 83770 |

| | |
|------------------------------|---|
| Application no.: | 108602 |
| Active constituent/s: | Altrenogest |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 30 January 2017 |
| Approval no.: | 83553 |

| | |
|------------------------------|---|
| Application no.: | 108552 |
| Active constituent/s: | Omeprazole |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 31 January 2017 |
| Approval no.: | 83526 |

| | |
|------------------------------|---|
| Application no.: | 108777 |
| Active constituent/s: | Levamisole Hydrochloride |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 31 January 2017 |
| Approval no.: | 83643 |

| | |
|------------------------------|---|
| Application no.: | 109019 |
| Active constituent/s: | Carprofen |
| Applicant name: | Jurox Pty Limited |
| Applicant ACN: | 000 932 230 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83815 |

| | |
|------------------------------|---|
| Application no.: | 108603 |
| Active constituent/s: | Trimethoprim |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83554 |

| | |
|------------------------------|---|
| Application no.: | 108738 |
| Active constituent/s: | Clenbuterol Hydrochloride |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83623 |

| | |
|------------------------------|---|
| Application no.: | 108649 |
| Active constituent/s: | Ractopamine Hydrochloride |
| Applicant name: | Zoetis Australia Pty Ltd |
| Applicant ACN: | 156 476 425 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83573 |

| | |
|------------------------------|---|
| Application no.: | 108768 |
| Active constituent/s: | Chlortetracycline |
| Applicant name: | Dox-AI Australia Pty Ltd |
| Applicant ACN: | 079 454 265 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83638 |

| | |
|------------------------------|---|
| Application no.: | 108782 |
| Active constituent/s: | Diethylcarbamazine Citrate |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83647 |

| | |
|------------------------------|---|
| Application no.: | 108783 |
| Active constituent/s: | Acepromazine Maleate |
| Applicant name: | Mavlab Pty Ltd. |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83648 |

| | |
|------------------------------|---|
| Application no.: | 108785 |
| Active constituent/s: | Clomipramine Hydrochloride |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83650 |

| | |
|------------------------------|--|
| Application no.: | 108787 |
| Active constituent/s: | Niclosamide |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products. |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83652 |

| | |
|------------------------------|---|
| Application no.: | 107728 |
| Active constituent/s: | Omeprazole 30% |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83207 |

| | |
|------------------------------|---|
| Application no.: | 107086 |
| Active constituent/s: | Sodium Salicylate |
| Applicant name: | Abbey Laboratories Pty Ltd |
| Applicant ACN: | 156 000 430 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 82901 |

| | |
|------------------------------|---|
| Application no.: | 109021 |
| Active constituent/s: | Gonadotrophin, Serum |
| Applicant name: | Intervet Australia Pty Limited |
| Applicant ACN: | 008 467 034 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83817 |

| | |
|------------------------------|---|
| Application no.: | 109023 |
| Active constituent/s: | Magnesium L Aspartate |
| Applicant name: | Ceva Animal Health Pty Ltd |
| Applicant ACN: | 002 692 426 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83818 |

| | |
|------------------------------|---|
| Application no.: | 108801 |
| Active constituent/s: | Neomycin Sulphate |
| Applicant name: | CCD Animal Health Pty Ltd |
| Applicant ACN: | 151 737 950 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83660 |

| | |
|------------------------------|---|
| Application no.: | 108803 |
| Active constituent/s: | Piperazine Dihydrochloride |
| Applicant name: | CCD Animal Health Pty Ltd |
| Applicant ACN: | 151 737 950 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83662 |

| | |
|------------------------------|---|
| Application no.: | 108802 |
| Active constituent/s: | Oxytetracycline Hydrochloride |
| Applicant name: | CCD Animal Health Pty Ltd |
| Applicant ACN: | 151 737 950 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83661 |

| | |
|------------------------------|---|
| Application no.: | 108825 |
| Active constituent/s: | Bromhexine Hydrochloride |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 1 February 2017 |
| Approval no.: | 83670 |

| | |
|------------------------------|---|
| Application no.: | 108851 |
| Active constituent/s: | Chorionic Gonadotrophin |
| Applicant name: | Intervet Australia Pty Limited |
| Applicant ACN: | 008 467 034 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83693 |

| | |
|------------------------------|---|
| Application no.: | 108855 |
| Active constituent/s: | Prednisolone |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83697 |

| | |
|------------------------------|---|
| Application no.: | 108865 |
| Active constituent/s: | N-Octyl Bicycloheptene Dicarboximide |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83705 |

| | |
|------------------------------|---|
| Application no.: | 108938 |
| Active constituent/s: | Crospovidone |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 2 February 2017 |
| Approval no.: | 83762 |

| | |
|------------------------------|---|
| Application no.: | 108937 |
| Active constituent/s: | Phenobarbitone |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 3 February 2017 |
| Approval no.: | 83761 |

2. VARIATIONS OF ACTIVE CONSTITUENT

| | |
|------------------------------|---|
| Application no.: | 108719 |
| Active constituent/s: | Hydrocortisone |
| Applicant name: | Ceva Animal Health Pty Ltd |
| Applicant ACN: | 002 692 426 |
| Summary of variation: | Variation of relevant particulars or conditions of an approved active constituent |
| Date of variation: | 1 February 2017 |
| Approval no.: | 82439 |

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 Instrument No. 4 (MRL Standard) 2012*. 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 Instrument No. 4 (MRL Standard) Amendment Instrument 2017 (No. 3)*.

The amendments will be incorporated into the compilation of the [Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#).

The *MRL Standard* is accessible via the ComLaw website www.comlaw.gov.au or the links above.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: 02 6210 4897

Fax: 02 6210 4840

Email: enquiries@apvma.gov.au

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

In the previous notice, the APVMA gazetted amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*, have been made.

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 Instrument No. 4 (MRL Standard) Amendment Instrument 2017 (No. 2)*) 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 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 Government of Australia and the Government of New Zealand 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.

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

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 February 2017)**

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 sunseting.

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: Pirimicarb

Permitted residue: Sum of pirimicarb, demethyl-pirimicarb and the N-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb

| | |
|---------------------------|-----|
| Fruit [except strawberry] | 0.5 |
|---------------------------|-----|

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

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]

| | |
|--|-----|
| All other foods except animal food commodities | 0.2 |
|--|-----|

Agvet chemical: Imazamox

Permitted residue: Imazamox

| | |
|--|------|
| All other foods except animal food commodities | 0.05 |
|--|------|

Monepantel

Permitted residue: Monepantel

| | |
|---------------|-------|
| Cattle fat | 7 |
| Cattle kidney | 1 |
| Cattle liver | 2 |
| Cattle meat | 0.3 |
| Milks | *0.05 |

Agvet chemical: Pirimicarb

Permitted residue: Sum of pirimicarb, demethyl-pirimicarb and the N-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb

| | |
|--|------|
| All other foods except animal food commodities | 0.05 |
| Blackberries | T2 |
| Fruit [except blackberries; strawberry] | 0.5 |

Agvet chemical: Propiconazole

Permitted residue: Propiconazole

| | |
|--|------|
| All other foods except animal food commodities | 0.05 |
|--|------|

Agvet chemical: Pyriproxyfen

Permitted residue: Pyriproxyfen

| | |
|--|--------|
| All other foods except animal food commodities | 0.1 |
| Chervil | T5 |
| Coriander (leaves, roots, stems) | T5 |
| Galangal, Greater | T*0.05 |
| Galangal, Lesser | T*0.05 |
| Mizuna | T5 |
| Rose and dianthus (edible flowers) | T5 |
| Rucola (rocket) | T5 |
| Turmeric, root | T*0.05 |

Agvet chemical: Spirotetramat

Permitted residue: Sum of spirotetramat, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat

| | |
|--|-----|
| All other foods except animal food commodities | 0.1 |
|--|-----|

INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20—Maximum residue limits in the *Australia New Zealand Food Standards Code*. Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

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: 6 pm (ADST) 7 March 2017

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT

Submissions received after this date will only be considered 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.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: 02 6210 4897

Fax: 02 6210 4840

Email: enquiries@apvma.gov.au

Variations to Schedule 20 of the *Australia 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. 14) gazetted on 1 November 2016 (No. APVMA 22).

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

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Schedule 20. A copy of the Amendment Instrument (No. APVMA 3, 2017) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislation available on the Legislation website at www.legislation.gov.au/.

Based on dietary exposure assessments and current health standards, the APVMA and 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 Government of Australia and the Government of New Zealand 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.

Food Standards Australia New Zealand (FSANZ) made Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) in relation to these variations and no comment was received in response to that notice.

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
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4897

Fax: (02) 6210 4840

Email: enquiries@apvma.gov.au



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

***Australia New Zealand
Food Standards Code —
Schedule 20 — Maximum residue limits Variation
Instrument No. APVMA 2, 2017***

I, Jason Lutze, Executive Director, Scientific Assessment and Chemical Review and 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*.

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

Dated this Second day of February 2017

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 2, 2017*.

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 No. APVMA 3, of 7 February 2017.

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

Agvet chemical: Propamocarb

Permitted residue: Propamocarb (base)

| | |
|------------------|-----|
| Leafy vegetables | T20 |
|------------------|-----|

Agvet chemical: Sulfoxaflor

Permitted residue: Sulfoxaflor

| | |
|---|-------|
| Dried grapes (currants, raisins and sultanas) | 10 |
| Fruiting vegetables, other than cucurbits | 1 |
| Grapes [except wine grapes] | 3 |
| Wine grapes | *0.01 |

Agvet chemical: Tebuconazole

Permitted residue: Tebuconazole

| | |
|--|------|
| Mung bean (dry) | T0.2 |
| Pulses [except mung bean (dry); soya bean (dry)] | T1 |

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

Agvet chemical: Azoxystrobin

Permitted residue: Azoxystrobin

| | |
|-------------------------------|------|
| Adzuki bean (dry) | T0.7 |
| Common bean (dry) (navy bean) | T0.7 |
| Mung bean (dry) | T0.7 |

Agvet chemical: Fluopicolide

Permitted residue: Fluopicolide

| | |
|--------------------------------------|--------|
| All other foods | T0.01 |
| Bulb vegetables [except onion, bulb] | T3 |
| Edible offal (mammalian) | T*0.01 |
| Eggs | T*0.01 |
| Fruiting vegetables, cucurbits | T0.5 |
| Lettuce, head | T30 |
| Lettuce, leaf | T30 |
| Meat (mammalian) (in the fat) | T*0.01 |
| Milks | T*0.01 |
| Onion, bulb | T0.1 |
| Poppy seed | T0.5 |
| Potato | T0.05 |
| Poultry, edible offal of | T*0.01 |
| Poultry meat (in the fat) | T*0.01 |

Agvet chemical: Propamocarb

Permitted residue: Propamocarb (base)

| | |
|--|--------|
| Bulb vegetables [except onion, bulb] | T30 |
| Edible offal (mammalian) | T*0.01 |
| Eggs | T*0.01 |
| Fruiting vegetables, cucurbits | T5 |
| Leafy vegetables [except lettuce, head; lettuce, leaf] | T20 |
| Lettuce, head | T70 |
| Lettuce, leaf | T70 |
| Meat (mammalian) | T*0.01 |
| Milks | T*0.01 |
| Onion, bulb | T0.5 |
| Poppy seed | T5 |
| Potato | T0.05 |
| Poultry, edible offal of | T*0.01 |
| Poultry meat | T*0.01 |

Agvet chemical: Propiconazole

Permitted residue: Propiconazole

| | |
|--------|------|
| Pulses | T0.3 |
|--------|------|

Agvet chemical: Sulfoxaflor

Permitted residue: Sulfoxaflor

| | |
|---|-------|
| Beans (dry) | 0.7 |
| Fruiting vegetables, other than cucurbits [except sweet corn (corn-on-the-cob)] | 1 |
| Grapes | *0.01 |
| Sweet corn (corn-on-the-cob) | *0.01 |
| Tree nuts [except macadamia nuts] | 0.02 |

Agvet chemical: Tebuconazole

Permitted residue: Tebuconazole

| | |
|---------------------------------|----|
| Pulses [except soya bean (dry)] | T1 |
|---------------------------------|----|

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

Agvet chemical: Clothianidin

Permitted residue: Clothianidin

| | |
|--|------|
| Fruiting vegetables, cucurbits | T0.5 |
| Fruiting vegetables, other than cucurbits [except mushrooms; sweet corn (corn-on-the-cob)] | T0.7 |

Cancellation of Product Registrations and Label Approvals at the Request of the Holder

At the request of the holder, the APVMA has cancelled the product registration and the associated label approval of the following product:

| Product no | Product name | Approval holder | Cancelled labels | Date of effect |
|------------|---|------------------------------|--|-----------------|
| 45894 | Reporcin Porcine Somatotropin for Injection | Zamira Life Sciences Pty Ltd | 45894/01 45894/02 45894/0499 45894/0509 45894/0803 45894/0902 | 20 January 2017 |

The following instructions set out how a person can deal with the cancelled product registration and label approvals.

SUPPLY

A person may supply or cause to be supplied product registrations and products bearing the labels 45894/01, 45894/02, 45894/0499, 45894/0509, 45894/0803, 45894/0902 manufactured prior to 20 January 2017 at wholesale and retail level, until the 20 January 2018. After 20 January 2018 it will be an offence against the Agvet Codes to have possession or custody of the products with the intention to supply, or to supply the products.

USE

A person may continue to use the products according to its label instructions until 20 January 2018.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product registrations and products bearing the labels 45894/01, 45894/02, 45894/0499, 45894/0509, 45894/0803, 45894/0902 in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the products (after the registration has been cancelled until 20 January 2018).

The supply and use of the products must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product listed in the table 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
PO Box 6182
SYMONSTON ACT 2609

Phone: +61 2 6210 4749

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Email: chemicalreview@apvma.gov.au

Cancellation of Product Registrations and Label Approvals at the Request of the Holder

At the request of the holder, the APVMA has cancelled the product registrations and the associated label approvals of the following products:

| Product no | Product name | Approval holder | Cancelled labels | Date of effect |
|------------|--|----------------------------|--|-----------------|
| 52995 | Cypafly Buffalo Fly Spray | Elanco Australasia Pty Ltd | 52995/0500 52995/0509 | 20 January 2017 |
| 57793 | Deposel Slow Release Selenium Injection for cattle and sheep | Elanco Australasia Pty Ltd | 57793/0104 57793/0503 57793/1104 | 20 January 2017 |
| 37052 | Biocare Biotin 1.5 MG/G | Elanco Australasia Pty Ltd | 37052/01 37052/0402 | 20 January 2017 |

The following instructions set out how a person can deal with the cancelled product registrations and label approvals.

SUPPLY

A person may supply or cause to be supplied product registrations and product bearing label approvals 52995/0500, 52995/0509, 57793/0104, 57793/0503, 57793/1104, 37052/01, 37052/0402 manufactured prior to 20 January 2017 at wholesale and retail level, until the 20 January 2018.

After 20 January 2018 it will be an offence against the Agvet Codes to have possession or custody of the product registrations and label approvals with the intention to supply, or to supply the products.

USE

A person may continue to use the products according to its label instructions until 20 January 2018.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product registrations and product bearing label approvals 52995/0500, 52995/0509, 57793/0104, 57793/0503, 57793/1104, 37052/01, 37052/0402 in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the products after the registration has been cancelled until 20 January 2017. The supply and use of the products (must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

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

APVMA CONTACT:

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