

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda item 12

CX/RVDF 00/13
February 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twelfth Session

Washington, D.C., 28 - 31 March 2000

CONSIDERATION OF THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION

(prepared by Australia)

1. The elaboration of the Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation corresponds to Step 1 of the Codex Elaboration Procedure for Codex MRLs. Codex Circular Letter CL 1999/14-RVDF was distributed to Codex Member countries in July 1999 requesting proposals for veterinary drugs to be added to the Priority List. The only reply received by the deadline was from Australia.
2. Australia proposed the addition of triflumuron, amoxicillin, cefuroxime sodium, clorsulon, sulfatroxazole, novobiocin sodium, erythromycin, apramycin and amprolium. Information provided by Australia in support of the nominations is contained in Annex 1.
3. A late submission was received from the European Community (EC) to the effect that the EC is unaware of any trade or public health problems associated with a new veterinary medicinal product used in food producing animals that would necessitate a recommendation by the EC for consideration by JECFA.
4. The EC noted that, for more than 600 substances, safety and residue evaluations have been carried out in the EU in recent years and to avoid duplication of efforts, it is not appropriate to identify any further substance for inclusion in the priority list. The EC proposed, as an alternative, that summary reports for the 600 substances for which MRL evaluations have been done could be provided to the Committee. The comments of the EC are contained in Annex 3.
5. Also attached (Annex 2) for the reference of the Committee, is the list of those drugs requiring evaluation as agreed at the Eleventh Session of the Committee¹.
6. The Committee is invited to consider the proposals of Australia on the basis of the information in Annex 1 taking into consideration the report of the ad hoc working group on priorities, which will be convened under the chairship of Australia on 27 March 2000, and the comments of the EC.

¹ ALINORM 99/31, Appendix VII.

PROPOSALS FOR VETERINARY DRUGS TO BE INCLUDED IN THE PRIORITY LIST

1.	Proposal For Inclusion Submitted by	Australia
2.	Drug Name	Triflumuron
3.	Trade Names	'Starycide', 'Zapp'
4.	Chemical Names	1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea
5.	Names and Addresses of Basic Producers	Bayer Australia Limited (Animal Health) 875 Pacific Highway PO Box 903 Pymble NSW Australia 2073
6.	Justification for Use	Triflumuron is a chiton inhibitor, introduced for use where resistance to other chemicals was a problem
7.	Veterinary Use Pattern	Used for the control of body lice <i>Bovicola ovis</i> on sheep off-shears and lambs at foot. The product is administered as a single pour-on application.
8.	Countries where Drug is Registered	Australia & ?
9.	National Maximum Residue Levels (mg/kg)	Australia Sheep, edible offal 0.1 Sheepmeat [in the fat] 2 Edible offal [except sheep] 0.05 Meat [except sheep meat] [in the fat] 0.05
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	Sheep muscle, liver, kidney and fat
11.	List of Data Available.	Pending
12.	Date Data Could be Submitted to JECFA	Pending

1.	Proposal For Inclusion Submitted by	Australia
2.	Drug Name	Amoxicillin
3.	Trade Names	'Clavulox', 'Ampicloxx', 'Amoxil', 'Betamox'
4.	Chemical Names	D-(-)-alpha-amino-p-hydroxybenzyl penicillin trihydrate
5.	Names and Addresses of Basic Producers	Pfizer Animal Health 38-42 Wharf Road PO Box 57 West Ryde NSW Australia 2114 Novartis Animal Health Australasia 140-150 Bungaree Road Pendle Hill NSW Australia 2145 PO Box 548 Wentworthville NSW Australia 2145
6.	Justification for Use	Antibiotic, highly active against a wide range of gram -ve and gram +ve bacteria
7.	Veterinary Use Pattern	Administered as either an i/m injection to cattle and sheep or an intramammary infusion to dairy cows or for disease control in poultry
8.	Countries where Drug is Registered	Australia, USA, EU and many other countries

9.	National Maximum Residue Levels (mg/kg)	<p>Australia</p> <p>Cattle milk 0.01</p> <p>Mammalian edible offal 0.01</p> <p>Mammalian meat 0.01</p> <p>Poultry, edible offal of 0.01</p> <p>Poultry meat 0.01</p> <p>Sheep milk 0.01</p> <p>USA</p> <p>Cattle edible tissue 0.01</p> <p>EU</p> <p>All food producing animals:</p> <p>Muscle 0.05</p> <p>Fat 0.05</p> <p>Liver 0.05</p> <p>Kidney 0.05</p> <p>Milk 0.004</p>
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	Poultry meat, kidney and liver, and cattle and sheep milk, meat, kidney and liver
11.	List of Data Available.	Pending
12.	Date Data Could be Submitted to JECFA	Pending

1.	Proposal For Inclusion Submitted by	Australia
2.	Drug Name	Cefuroxime sodium
3.	Trade Names	'Cepravin'
4.	Chemical Names	[6R-[6 α ,7 β (Z)]]-3-[[(Aminocarbonyl)oxy]methyl]-7-[[2-furanyl(methoxyimino)acetyl]amino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid
5.	Names and Addresses of Basic Producers	Schering-Plough Animal Health 71 Epping Road PO Box 777 North Ryde NSW Australia 2113
6.	Justification for Use	Second generation semi-synthetic cephalosporin, used as intramammary in lactating cows; resistant to degradation by β -lactamase enzymes produced by both gram positive and gram negative pathogens
7.	Veterinary Use Pattern	Intramammary infusion
8.	Countries where Drug is Registered	Australia
9.	National Maximum Residue Levels (mg/kg)	<p>Australia</p> <p>Cattle meat 0.1</p> <p>Cattle edible offal 0.1</p> <p>Cattle milk 0.1</p>
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	Milk, meat, kidney and liver of cattle
11.	List of Data Available.	Pending
12.	Date Data Could be Submitted to JECFA	Pending

1.	Proposal For Inclusion Submitted by	Australia												
2.	Drug Name	Clorsulon												
3.	Trade Names	'Ivomec Plus'												
4.	Chemical Names	4-amino-6-(trichloroethenyl)-1,3-benzenedisulfonamide												
5.	Names and Addresses of Basic Producers	Merck, Sharp and Dohme (Australia) Pty Ltd Level 6, 76 George Street Parramatta NSW Australia 2150 Locked Bag 5023 Parramatta NSW Australia 2124												
6.	Justification for Use	Used in conjunction with ivermectin on cattle. Interferes with glycolysis and thereby derives the fluke of its main source of energy.												
7.	Veterinary Use Pattern	Subcutaneous injection												
8.	Countries where Drug is Registered	Australia, USA, EU and many other countries.												
9.	National Maximum Residue Levels (mg/kg)	<p>Australia</p> <table> <tr> <td>Cattle edible offal</td> <td>0.1</td> </tr> <tr> <td>Cattle meat</td> <td>0.1</td> </tr> </table> <p>USA</p> <table> <tr> <td>Cattle kidney</td> <td>1.0</td> </tr> </table> <p>EU</p> <table> <tr> <td>Cattle muscle</td> <td>0.05 (provisional)</td> </tr> <tr> <td>Cattle liver</td> <td>0.15 (provisional)</td> </tr> <tr> <td>Cattle kidney</td> <td>0.40 (provisional)</td> </tr> </table>	Cattle edible offal	0.1	Cattle meat	0.1	Cattle kidney	1.0	Cattle muscle	0.05 (provisional)	Cattle liver	0.15 (provisional)	Cattle kidney	0.40 (provisional)
Cattle edible offal	0.1													
Cattle meat	0.1													
Cattle kidney	1.0													
Cattle muscle	0.05 (provisional)													
Cattle liver	0.15 (provisional)													
Cattle kidney	0.40 (provisional)													
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	Cattle meat, kidney and liver												
11.	List of Data Available.	Pending												
12.	Date Data Could be Submitted to JECFA	Pending												

1.	Proposal For Inclusion Submitted by	Australia						
2.	Drug Name	Sulfatroxazole						
3.	Trade Names	'Leotrox Injection'						
4.	Chemical Names	4-amino-N-(3,4-dimethyl-5-oxazolyl)benzene sulfonamide						
5.	Names and Addresses Primary Registrants	Boehringer Ingelheim Pty. Ltd. 85 Waterloo Road North Ryde NSW 2113						
6.	Justification for Use	Use against primary and secondary bacterial infections due to susceptible organisms in cattle, sheep, pigs, horses						
7.	Veterinary Use Pattern	Intravenous or intramuscular injection at 15 mg/kg bodyweight dose						
8.	Countries where Drug is Registered	Australia						
9.	National Maximum Residue Levels (mg/kg)	<p>Australia</p> <table> <tr> <td>Cattle milk</td> <td>0.1</td> </tr> <tr> <td>Mammalian edible offal</td> <td>0.1</td> </tr> <tr> <td>Mammalian meat</td> <td>0.1</td> </tr> </table>	Cattle milk	0.1	Mammalian edible offal	0.1	Mammalian meat	0.1
Cattle milk	0.1							
Mammalian edible offal	0.1							
Mammalian meat	0.1							
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	Cattle milk, meat, liver and kidney						
11.	List of Data Available.	Pending						
12.	Date Data Could be Submitted to JECFA	Pending						

1.	Proposal For Inclusion Submitted by	Australia
2.	Drug Name	Novobiocin sodium
3.	Trade Names	'Albadry Plus', 'Delta Albaplex', 'Mastop Suspension' and 'Special Formula 17900'
4.	Chemical Names	<i>N</i> -[7-[[3- <i>O</i> -(aminocarbonyl)-6-deoxy-5- <i>C</i> -methyl-4- <i>O</i> -methyl- β -L-lyxopyranosyl]oxy]-4-hydroxy-8-methyl-2-oxo-2 <i>H</i> -1-benzopyran-3-yl]-4-hydroxy-3-(3-methyl-2-butenyl)benzamide
5.	Names and Addresses Primary Registrants	Pharmacia & Upjohn Pty. Ltd. 59 Kirby St Rydalmeire NSW 2116
6.	Justification for Use	i) Treatment and reduction in the incidence of staphylococcal and streptococcal mastitis during the dry period to calving; ii) Treatment of staphylococcal and streptococcal mastitis in lactating cows
7.	Veterinary Use Pattern	i) 400 mg/quarter udder; ii) 150 mg/quarter udder repeated after 24 hrs
8.	Countries where Drug is Registered	Australia, USA and others
9.	National Maximum Residue Levels (mg/kg)	Australia Cattle edible offal 0.1 Cattle meat 0.1 Cattle milk 0.1 USA Cattle edible tissue 1.0 Poultry edible tissue 1.0
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	Cattle milk, meat, liver and kidney
11.	List of Data Available.	Pending
12.	Date Data Could be Submitted to JECFA	Pending

1.	Proposal For Inclusion Submitted by	Australia
2.	Drug Name	Erythromycin
3.	Trade Names	'Gallimycin', 'Erythromycin Water Soluble Powder'
4.	Chemical Names	(3 <i>R</i> , 4 <i>S</i> , 5 <i>S</i> , 6 <i>R</i> , 7 <i>R</i> , 9 <i>R</i> , 11 <i>R</i> , 12 <i>R</i> , 13 <i>S</i> , 14 <i>R</i>)-4-[(2,6-dideoxy-3- <i>C</i> -methyl-3- <i>O</i> -methyl- α -L-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[(3,4,6-trideoxy-3-dimethylamino- β -D-xylo-hexopyranosyl)oxy]oxacyclo-tetradecane-2,10-dione
5.	Names and Addresses Primary Registrants	Merial Australia Pty. Ltd. Level 6, 79 George St. Parramatta NSW 2150 C.C.D. Animal Health 351 Wentworth Avenue Pendle Hill NSW 2145
6.	Justification for Use	i) Treatment of pneumonia, bacterial respiratory infections, foot rot, metritis and mastitis in cattle; pneumonia, bacterial respiratory infections, metritis, scours and leptospirosis in pigs; pneumonia in sheep and lamb dysentery. ii) Erythromycin thiocyanate is used for treatment of chronic respiratory disease, coryza and cholera in poultry

7.	Veterinary Use Pattern	Deep intramuscular injection at 100 – 200 mg/50 kg bw for cattle, 100 – 300 mg/50 kg bw for pigs; 20 mg/kg bw for piglets; 100 mg/50 kg bw for sheep and 20 mg/2 kg bw for lambs. ii) 750 mg erythromycin thiocyanate/900 L drinking water for 3 to 5 days
8.	Countries where Drug is Registered	Many countries around the world
9.	National Maximum Residue Levels (mg/kg)	<p>Australia</p> <p>Eggs 0.3</p> <p>Mammalian edible offal 0.3</p> <p>Mammalian meat 0.3</p> <p>Milks 0.04</p> <p>USA</p> <p>Cattle edible tissue 0.1</p> <p>Pig edible tissue 0.1</p> <p>Poultry edible tissues 0.125</p> <p>EU</p> <p>Cattle,pigs,sheep,poultry (Provisional)</p> <p>Liver 0.40</p> <p>Kidney 0.40</p> <p>Fat 0.40</p> <p>Muscle 0.40</p> <p>Cattle & Sheep milk 0.04</p> <p>Poultry eggs 0.20</p>
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	Eggs Meat, milk, kidney and liver of cattle, pigs and sheep
11.	List of Data Available.	Pending
12.	Date Data Could be Submitted to JECFA	Pending

1.	Proposal For Inclusion Submitted by	Australia
2.	Drug Name	Apramycin
3.	Trade Names	'Apralan'
4.	Chemical Names	<i>O</i> -4-amino-4-deoxy- β -D-glucopyranosyl-(1 \rightarrow 8)- <i>O</i> -(8 <i>R</i>)-2-amino-2,3,7-trideoxy-7-(methylamino)-D-glycero- β -D-allo-octodialdo-1,5:8,4-dipyranosyl-(1 \rightarrow 4)-2-deoxy-D-streptamine
5.	Names and Addresses Primary Registrants	Elanco Animal Health A Division of Eli Lilly Australia Pty. Ltd. 112 Wharf Road West Ryde NSW 2114
6.	Justification for Use	i) Treatment of bacterial enteritis caused by susceptible strains of <i>E. coli</i> and other organisms in pigs. ii) Treatment of bacterial enteritis due to susceptible <i>E. coli</i> and Salmonella in calves an <i>E. coli</i> infections and other susceptible organisms in broilers
7.	Veterinary Use Pattern	165 g/tonne of feed fed as only ration for 14 days for use in pigs uup to 30 kg only. ii) <i>In the drinking water</i> 20 to 40 mg/kg bw for 5 days in calves, 10 mg/kg bw daily for disease control; 250 to 500 mg/L for 5 days for poultry.
8.	Countries where Drug is Registered	Australia, EU, USA and other countries

9.	National Maximum Residue Levels (mg/kg)	<p>Australia</p> <p>Mammalian edible offal 2</p> <p>Mammalian meat 0.05</p> <p>Poultry, edible offal 1</p> <p>Poultry meat 0.05</p> <p>USA</p> <p>Pig Kidney 0.1</p> <p>EU</p> <p>Cattle & Pig Meat 1.0 (provisional)</p> <p>Cattle & Pig Fat 1.0 (provisional)</p> <p>Cattle Liver 10.0 (provisional)</p> <p>Cattle Kidney 20.0 (provisional)</p> <p>Pig Liver 5.0 (provisional)</p> <p>Pig Kidney 5.0 (provisional)</p>
10.	Commodities for Which the Need for Establishing Codex MRLs is Required.	<p>Poultry meat, liver and kidney</p> <p>Meat, liver and kidney of cattle and pigs</p>
11.	List of Data Available.	Pending
12.	Date Data Could be Submitted to JECFA	Pending

1.	Proposal For Inclusion Submitted by	Australia
2.	Drug Name	Amprolium
3.	Trade Names	‘Amprosol’, ‘Coccivet’, ‘Amprolium Powder’, ‘Keymix’, ‘Amprolmix’
4.	Chemical Names	1-[(4-Amino-2-propyl-5-pyrimidinyl)methyl]-2-methylpyridinium chloride; 1-[(4-amino-2-propyl-5-pyrimidinyl)methyl]-2-picolinium chloride
5.	Names and Addresses Primary Registrants	<p>Controlled Medications Pty. Ltd. 4 Handley Cr Dandenong VIC 3175</p> <p>Merial Australia Pty. Ltd. Level 6, 79 George St. Parramatta NSW 2150</p> <p>Agrotech Australia Pty. Ltd. 21 Talofa Pl Castle Hill NSW 2154</p> <p>Vetafarm Pty. Ltd. 3 Bye St Wagga Wagga NSW 2650</p> <p>International Animal Health Products 18 Healey Circuit Huntingwood NSW 2148</p>
6.	Justification for Use	Prevention and treatment of coccidiosis in broilers, broiler breeders, replacement pullets, turkeys, ducks and pigeons
7.	Veterinary Use Pattern	240 mg/L in drinking water continuously for 5 to 7 days reduced to 120 mg/L for a further 5 to 7 days and reduced again to 64 mg/L for another 5 to 7 days OR incorporated as a powder in the feed at 250 g/2000 kg feed daily from the time that the birds are a day old up until market.
8.	Countries where Drug is Registered	Australia, USA and others

<p>9.</p>	<p>National Maximum Residue Levels (mg/kg)</p>	<p>Australia</p> <table border="0"> <tr> <td>Eggs</td> <td>4</td> </tr> <tr> <td>Poultry edible offal</td> <td>1</td> </tr> <tr> <td>Poultry meat</td> <td>0.5</td> </tr> </table> <p>USA</p> <table border="0"> <tr> <td>Cattle fat</td> <td>2.0</td> </tr> <tr> <td>Cattle kidney</td> <td>0.5</td> </tr> <tr> <td>Cattle liver</td> <td>0.5</td> </tr> <tr> <td>Cattle & Poultry muscle</td> <td>0.5</td> </tr> <tr> <td>Poultry kidney</td> <td>1.0</td> </tr> <tr> <td>Poultry liver</td> <td>1.0</td> </tr> </table>	Eggs	4	Poultry edible offal	1	Poultry meat	0.5	Cattle fat	2.0	Cattle kidney	0.5	Cattle liver	0.5	Cattle & Poultry muscle	0.5	Poultry kidney	1.0	Poultry liver	1.0
Eggs	4																			
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Poultry kidney	1.0																			
Poultry liver	1.0																			
<p>10.</p>	<p>Commodities for Which the Need for Establishing Codex MRLs is Required.</p>	<p>Meat, liver, kidney and eggs of poultry</p>																		
<p>11.</p>	<p>List of Data Available.</p>	<p>Pending</p>																		
<p>12.</p>	<p>Date Data Could be Submitted to JECFA</p>	<p>Pending</p>																		

PRIORITY LIST OF VETERINARY DRUGS SCHEDULED FOR EVALUATION OR REEVALUATION

1. 54th Meeting of JECFA in February 2000

Status	Substance
Full evaluation	Cyhalothrin Dicyclanil Lincomycin Melengestrol acetate Metrifonate Temephos
Re-evaluation	
Residues	Ivermectin Cypermethrin alpha-Cypermethrin Flumequine
Analytical method	Dihydrostreptomycin/streptomycin

2. 56th Meeting of JECFA in February 2001

Status	Substance
Full evaluation	nil
Re-evaluation	
Residues	Imidocarb
Analytical method	Dihydrostreptomycin/streptomycin

3. 58th Meeting of JECFA in February 2002

Status	Substance
Full evaluation	nil
Re-evaluation	
Residues & analytical method	Thiamphenicol Phoxim

OTHER COMMENTS IN RESPONSE TO CL 1999/14-RVDF

EUROPEAN COMMUNITY

The European Community is currently not aware of trade or public health problems in connection with a new veterinary medicinal product used in food producing animals, which would necessitate a recommendation by the European Community for a consideration by JECFA/Codex.

The European Community also notes that for more than 600 substances safety and residue evaluations have been carried out in the EU during recent years under the provisions of Council Regulation (EEC) No 2377/90.

Therefore, in order to avoid duplication of efforts the European Community concludes that it may not be appropriate at present to identify any further substance for inclusion in the priority list for evaluation by JECFA.

Alternatively, the European Community presents the list of substances, for which MRL evaluations have been carried out in the European Community. Summary reports for the substances mentioned are available and can if desired be provided to the Codex Committee.

For the substances included in Annex I and Annex III of Regulation 2377/90, the analytical methods could be made available to Codex, where applicants would agree to their release.