BRAZIL

Information on avilamycin for consideration to allow inclusion in the CCRVDF priority list.

1. Proposal for Inclusion Submitted by (Country):
   Brazil

2. Drug Name:
   Avilamycin

3. Trade Names:
   Surmax® (Surmax, Surmax 25, Surmax 50, Surmax 100, Surmax 200), Maxus®, (Maxus 100, Maxus 200, Maxus G200) Avilamix®

4. Chemical Names:
   Avilamycin A:
   O-(1R)-4-C acetyl-6-deoxy-2,3-O-methylene-D-hexopyranosylidene-(1-3)-2-O-(2-methyl-1-oxopropyl)-a-L-lyxopyranosyl-O-2,6-dideoxy-4-O-(3,5-dichloro-4-hydroxy-2-methoxy-6-methylbenzoyl)-8-D-arabino-hexopyranosyl-(1-4)-O-2,6-dideoxy-D-ribo-hexopyranosylidene-(1-3)-O-6-deoxy-4-O-methyl-β-D-galactopyranosyl-(1-4)-2,6-di-O-methyl-β-D-mannopyranoside.

   Avilamycin B:
   -4-C acetyl-6-deoxy-2,3-O-methylenhexopyranosylidene-(1-3)-2-O-acetyl-L-lyxo-pyranosyl O-2,6-dideoxy-4-O-(3,5-dichloro-4-hydroxy-2-methoxy-6-methylbenzoyl)-β-D-arabino-hexopyranosyl-(1-4)-O-2,6-dideoxy-D-ribo-hexopyranosylidene-(1-3-4)-O-2,6-dideoxy-3-C-methyl-D-arabino-hexo-pyranosyl-(1-3)-O-6-deoxy-4-O-methyl-β-D-galactopyranosyl-(1-4)-2,6-di-O-methyl-D-mannopyranoside.

   CAS registry number is: Avilamycin A: 69787-79-7
   Avilamycin B: 73240-30-9
5. Names and Address of Basic Producers:
   Elanco Animal Health
   A Division of Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN  46285, USA

6. Justification for Use:
   Avilamycin is an oligosaccharide antibiotic of the orthosomycin group. It is effective for improving
growth rate and feed efficiency in pigs and poultry, which is of practical importance in animal
husbandry, and has no effect on the quality of animal products. It has also been shown to be effective
in the prevention of necrotic enteritis in broilers and colibacillosis in growing pigs, which as
significant diseases of economic importance and have substantial effect on animal welfare. Data has
been recently generated to support the use of avilamycin in cases of enteritis in rabbits at the group
level for the prevention of mortality and digestive signs due to Clostridium perfringens susceptible to
avilamycin.

Note this is a summary of claims globally: Exact label claims vary between counties:

**Chicken:**
Increase weight gain and feed efficiency or otherwise described as a productivity/performance
enhancer or growth promoter
For improved lean gain percentage in the carcass.
As an aid in prevention, control or treatment of necrotic enteritis associated with Clostridium
perfringens in chickens.
Improved Egg Laying  Note: some countries specify that avilamycin is not to be used in laying hens.

**Turkey:**
Increase weight gain and feed efficiency or otherwise described as a productivity/performance
enhancer or growth promoter

**Swine:**
For the improvement of average daily gain and feed conversion efficiency or otherwise described as a
productivity enhancer or growth promoter.
For prevention, aid in the control of or control of Post-Weaning diarrhea associated with Escherichia
coli.

**Rabbit:**
In cases of enteritis in rabbits at the group level, prevention of mortality and digestive signs due to
Clostridium perfringens susceptible to avilamycin.

7. Veterinary Use Pattern (Exact label indications vary slightly by country):

**Chicken:**
Feed avilamycin continuously to chickens at a rate of 2.5 ppm -15 ppm (widest registered range) in
complete feeds for increase weight gain and feed efficiency and carcass yield.
Feed avilamycin continuously to chickens at a rate of 2.5 ppm -20 ppm (widest aggregated range) in
complete feeds as an aid in prevention, prevention, control or treatment of necrotic enteritis associated
with Clostridium perfringens in chickens.
Feed avilamycin continuously to chickens at a rate of 10 ppm -15 ppm (widest registered range) in
complete feeds for improved egg laying.

**Turkey:**
Feed avilamycin continuously to turkeys at a rate of 5 ppm -10 ppm in complete feeds for increased
weight gain and feed efficiency.
Swine:
Feed avilamycin continuously to pigs at a rate of 10 ppm - 80 ppm in complete feeds (widest registered range) for the improvement of average daily gain and feed conversion efficiency.

Feed avilamycin continuously to swine at a rate of 10 ppm - 80 ppm (widest aggregated range) in complete feeds for prevention, aid in the control of or control of Post-Weaning diarrhea associated with *Escherichia coli*.

Rabbit:
In-Feed Use: Administer for 4 weeks at the dose 7 mg/kg bodyweight. This corresponds to approximately 80 ppm in the complete feed (0.4 kg of Surmax 200 per ton of feed). Dosage in the feed should be adjusted in order to obtain 7 mg/kg bodyweight in cases of differing feed consumption.

8. Countries Where Drug is Registered:
Argentina, Australia, Bangladesh, Brazil, Chile, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, Guatemala, Honduras, Hong Kong, India, Indonesia, Iran, Israel, Jamaica, Japan, Jordan, Kuwait, Lebanon, Libya, Malaysia, Mexico, Morocco, Namibia, New Zealand, Nicaragua, Pakistan, Panama, Paraguay, Peru, Philippines, Romania, Russian Federation, Saudi Arabia, South Africa, South Korea, Sri Lanka, Syria, Taiwan, Thailand, Trinidad/Tobago, Tunisia, United Arab Emirates, Uruguay, Venezuela, Vietnam, Zimbabwe.

9. National Maximum Residue Levels:
See Appendix A for countries that currently have ADIs or MRLs set within their respective countries. Other countries in the absence of Codex MRLs accept MRLs from other major regions such as Europe and the United States. Latin and Central American countries often accept MRLs set by Brazilian MAPA.

10. Commodities for Which the Need for Establishing Codex MRLs Is Required:
Chicken, swine, rabbit:
Meat and other edible offal
Target tissues: Fat, Kidney, Liver, Muscle, Skin

11. List of Data (Toxicology, Metabolism, Residue) Available:
A. Identity
B. Data relevant to the toxicological evaluation of avilamycin
   i. Pharmacology
   ii. Acute subchronic and chronic toxicity/carcinogenicity, reproductive and developmental toxicity, genotoxicity
   iii. Target animal safety in registered species
   iv. Occupational exposure of feed mixers
C. Data relevant to the evaluation of residues in chicken, swine and rabbits.
   i. Chemical identity and properties
   ii. Metabolism
   iii. Use and dosage range
   iv. Residue depletion studies in chicken, swine and rabbits.
   v. Description of analytical procedures and recommendation of analytical procedures for regulatory authorities
12. Date Data Could Be Submitted to JECFA:
Six to seven months prior to meeting deadline date or as determined by JECFA. Anticipated date is 14th December, 2007

APPENDIX A
Avilamycin National ADI / MRL Citations
28 May 07

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Australia MRLs</th>
<th>Japan MRLs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avilamycin - Chicken</td>
<td>MRL: Poultry meat &amp; edible offal of = *0.05 mg/kg</td>
<td>Provisional MRL: Muscle = 0.03 ppm, Fat = 0.03 ppm, Liver = 0.03 ppm, Kidney = 0.03 ppm, Other edible offal = 0.03 ppm</td>
</tr>
<tr>
<td>Avilamycin - Swine</td>
<td>MRL: Pig meat &amp; edible offal of = (T)*0.05 mg/kg</td>
<td>Provisional MRL: Muscle = 0.03 ppm, Fat = 0.03 ppm, Liver = 0.03 ppm, Kidney = 0.03 ppm, Other edible offal = 0.03 ppm</td>
</tr>
<tr>
<td>Avilamycin - Turkey and/or Other Poultry</td>
<td>MRL: Poultry meat &amp; edible offal of = *0.05 mg/kg</td>
<td>Provisional MRL: Other poultry: Muscle = 0.05 ppm, Fat = 0.05 ppm, Liver = 0.05 ppm, Kidney = 0.05 ppm, Other edible offal = 0.05 ppm</td>
</tr>
</tbody>
</table>

(*) denotes that the MRL has been set "at or about" the limit of analytical quantitation.
(T) denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out in Australia or overseas, & will be reconsidered at some future date. This symbol is also used in cases where an MRL is being phased out.

CANADA
Canada is pleased to offer the following information and comments in response to the subject Circular Letter:

Annex 4: - Dexamethasone
Canada will soon have a method available for the determination of dexamethasone. This method is approaching validation and will be finalized and can be made available later this year. The method is included in the scope of ISO-17025 accreditation.

Annex 4: - Inclusion of Nitrofurans on the Priority List
Canada does not support the inclusion of nitrofurans on the JECFA Priority List for Evaluation or Re-Evaluation as the substance was previously reviewed by the 40th Session of JECFA in 1993 and most countries have subsequently banned its use.
GERMANY
1. Proposal for Inclusion Submitted by (Country):
   Germany
2. Drug Name:
   Tylosin
3. Trade Names:
   Tylan, different Generics
4. Chemical Names:

5. Names and Addresses of Basic Producers:
   Eli Lilly and Company Ltd.
   Elanco Animal Health Division
   2001 West Main Street, Greenfield
   IN 46140, Indiana, USA
6. Justification for Use:
   It is authorized world-wide and on the market
7. Veterinary Use Pattern:
   Treatment of infections with certain Gram-positive and Gram-negative bacteria and mycoplasmas
8. Countries Where Drug is Registered:
   World-wide
9. National Maximum Residue Levels:
   EU-MRLs for all food-producing animals: 100 µg/kg for Muscle, Fat, Liver and Kidney;
   50 µg/kg Milk, 200 µg/kg Eggs
10. Commodities for Which the Need for Establishing Codex MRLs Is Required:
    Poultry (Tissues and Eggs), Pig and Cattle tissues, Honey (see also Annex 4)
11. List of Data (Toxicology, Metabolism, Residue) Available:
    Complete list of a new data package will be provided
12. Date Data Could be Submitted to JECFA:
    Q4 2007

UNITED STATES OF AMERICA
In Circular Letter, CL 2006/52-RVDF, dated January 2007, the Secretary, Codex Alimentarius Commission, requests comments/information on the Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation.

The United States delegation is delighted to propose three compounds for consideration in the Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation.

1. Monensin for several target species
2. Narasin for poultry, swine and cattle
3. Tilmicosin for poultry and eggs

The United States believes that these compounds meet the selection criteria established by CCRVDF and provides as attachments, the necessary documentation for consideration.
1. Proposal for Inclusion Submitted by (Country)
   United States

2. Drug Name:
   Monensin

3. Trade Names:
   Coban®, Elancoban®, Elancogran®, Monensin QA, Monensin Granulated, Romensin®, Rumensin®, Rumensin® CRC, Rumensin® Controlled Release Capsule, Rumensin® Anti-Bloat Capsule, Rumensin® ABC, Rumensin® Granular, Rumensin® Liquid, Rumensin® Technical, Rumensin® Trough Treatment

4. Chemical Names:
   Stereoisomer of 2-[2-ethyloctahydro-3'methyl-5'[tetrahydro-6-hydroxy-6-(hydroxymethyl)]-3,5-dimethyl-2H- pyran-2-yl] [2,2'-bifuran'5'yl] ]-9-hydroxy-β-methoxy-α,γ,2, 8-,tetramethyl-1,6-dioxaspiro[4.5]decan-7-butanoic acid.
   The CAS registry numbers are:
   Monensin  17090-79-8
   Monensin Sodium 22373-78-0

5. Names and Address of Basic Producers:
   Elanco Animal Health
   A Division of Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN  46285, USA

6. Justification for Use:
   Monensin is a member of the group of polyether, carboxylic acid ionophores. Monensin is an anticoccidial drug and growth promotant in several target species and is also used in the management of metabolic diseases in cattle.
   The following claims and species have been provided as a general list and do not represent exact label indications.

   **Chicken, Turkey, Bobwhite Quail:**
   Feed additive for the control of coccidiosis in broiler chickens, replacement layers, growing turkeys, and bobwhite quail. Monensin is effective against all species of coccidia known to be pathogenic in:
   **Chickens**, including *Eimeria tenella, E. acervulina, E. maxima, E. mitis, E. necatix, and E. brunette*
   **Turkeys**, such as *E. adenoids, E. meleagritmitis, E. gallopavonis*
   **Bobwhite Quail**, *E. dispersa.*
   Complete feeds, formulated with Coban and Elancoban are fed to chickens, turkeys and bobwhite quail continuously.

   **Cattle:**
   In cattle, monensin improves the efficiency of rumen fermentation by reducing energy losses associated with formation of volatile fatty acids. Has shown to control clinical coccidiosis in ruminants.
   Control ketosis in lactating dairy cattle.

   **Calves (excluding veal calves):**
   For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii.*
**Dairy Cows:**
For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).

**Feedlot Cattle:**
For improved feed efficiency (cattle fed in confinement for slaughter).
For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

**Growing cattle on pasture or in dry lot (stocker and feeder and dairy and beef replacement heifers):**
For increased rate of weight gain.
For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

**Mature Reproducing Beef Cows:**
For improved feed efficiency when receiving supplemental feed.
For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

**Goats:**
For the prevention of coccidiosis caused by *Eimeria crandallis*, *Eimeria christensenii*, and *Eimeria ninakohlyakimovae* in goats maintained in confinement.

**Sheep:**
For increased rate of gain and improved feed efficiency.
As an aid for prevention of coccidiosis caused by *Eimeria ahsata*, *Eimeria ovinai*, *Eimeria parva*, *Eimeria intricata*, *Eimeria pallida* and *Eimeria ninakohlyakimovae*.

7. **Veterinary Use Pattern:**
The following use patterns have been provided as a representative list and do not represent exact label directions for use.

**Chicken and Turkey:** Monensin provided in a complete feed formulated up to the maximum approved use levels of 125 ppm for broiler chickens, 120 ppm for replacement layers, and 100 ppm for turkeys.

**Bobwhite Quail:** Monensin provided in a complete quail feed to provide 73 g/ton.

**Cattle:** Monensin provided in a complete feed formulated up to the maximum approved use levels of 40 ppm in feedlot cattle and 200 mg/head/day in a 0.45 kg feed supplement in pasture cattle has been found to be safe and effective.

**Calves (excluding veal calves):** Feed at a rate of 0.14 to 1.00 mg per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 mg of monensin per head per day.

**Dairy Cattle:**
- **Total Mixed Rations (“complete feed”):** Feed continuously to dry and lactating dairy cows a total mixed ration (“complete feed”) containing 11 to 22 g/ton monensin on a 100% dry matter basis.
- **Component Feeding Systems (including top dress):** Feed continuously to dry and lactating dairy cows a feed containing 11 to 400 g/ton monensin. The feed must be fed in a minimum of 1 pound of feed per cow per day to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. This provides cows with similar amounts of monensin they would receive by consuming total mixed rations containing 11 to 22 g/ton monensin on a 100% dry matter basis.

**Goats:** Feed continuously as sole ration at the rate of 20 g/ton. Not for use in lactating goats.

**Sheep:** Feed at a rate of not less than 11 nor more than 22 grams monensin per metric ton of total ration. Feed in complete feeds only.
Cattle Controlled Release Capsule: The intended use is in a device (controlled release capsule or CRC) that will release monensin in the rumen at a maximum rate of 400 mg/day to control ketosis in lactating dairy cattle.

8. Countries Where Drug is Registered:

**Coban Premix:**
Barbados, Brazil, Canada, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Jamaica, Namibia, Nicaragua, Panama, Puerto Rico, South Africa, Trinidad/Tobago, United States, Vietnam,

**Elancoban or Elancogran:**
Algeria, Argentina, Austria, Australia, Bangladesh, Belgium, Chile, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Finland, France, Germany, Hong Kong, Hungary, India, Indonesia, Iraq, Iran, Ireland, Israel, Italy, Jordan, Kuwait, Latvia, Lebanon, Libya, Malaysia, Mexico, Morocco, Namibia, Netherlands, New Zealand, Norway, Pakistan, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Saudi Arabia, Slovak Republic, Russian Federation, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sweden, Switzerland, Syria, Taiwan, Thailand, Ukraine, United Arab Emirates, United Kingdom, Uruguay, Venezuela, Uzbekistan, Vietnam, Zimbabwe,

**Coban or Monensin or Romensin or Rumensin Granular:**
Australia, China, India, Indonesia, Malaysia, Namibia, So. Africa, So. Korea, Thailand

**Monensin Pure or Rumensin Technical:**
Australia, New Zealand, South Africa,

**Romensin or Rumensin Premix (with and without microtracers), Rumensin Millmix or Rumantin:**
Argentina, Australia, Barbados, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, France, Germany, Guatemala, Honduras, Indonesia, Ireland, Italy, Japan, Mexico, Namibia, New Zealand, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saudi Arabia, South Africa, South Korea, Spain, United Arab Emirates, United Kingdom, United States, Uruguay, Uzbekistan, Venezuela, Zimbabwe

**Rumensin ABC or Rumensin CRC:**
Argentina, Brazil, Canada, Chile, Mexico, Namibia, New Zealand, South Africa, Uruguay

**Rumensin Capsule:**
Australia, New Zealand

**Rumensin Liquid:**
New Zealand

**Rumensin Trough Treatment:**
New Zealand

No veterinary prescription is required for monensin products in any part of the world.

9. National Maximum Residue Levels:

See the attached spreadsheet (Appendix A) for countries that currently have ADIs or MRLs set within their respective countries.

Other countries in the absence of Codex MRLs accept MRLs from other major regions such as Europe and the United States. Latin and Central American countries also refer to Brazilian MAPA set MRLs.

10. Commodities for Which the Need for Establishing Codex MRLs Is Required:

Cattle, goats, sheep:

Meat and other edible offal
Target tissues: Fat, Kidney, Liver, Muscle

Milk

Poultry:

Meat and other edible offal

Target tissues: Fat, Kidney, Liver, Muscle, Skin

Egg

11. List of Data (Toxicology, Metabolism, Residue) Available:
   A. Identity
   B. Data relevant to the toxicological evaluation of monensin
      i. Pharmacology
      ii. Acute subchronic and chronic toxicity/carcinogenicity, reproductive and developmental
          toxicology, genotoxicity
      iii. Target animal safety in registered species
      iv. Occupational exposure of feed mixers
   C. Data relevant to the evaluation of residues in cattle, calves, poultry, goats and sheep
      i. Chemical identity and properties
      ii. Metabolism
      iii. Use and dosage range
      iv. Residue depletion studies in cattle, calves, poultry, goats and sheep
      v. Description of analytical procedures and recommendation of analytical procedures for
         regulatory authorities

12. Date Data Could Be Submitted to JECFA:

Six to Seven months prior to meeting deadline date or as determined by JECFA.

1. Proposal for Inclusion Submitted by (Country):
   United States

2. Drug Name:
   Narasin

3. Trade Names:
   Monteban®, Maxiban®, Naravin®

4. Chemical Names:
   Narasin \[1976\] \(\text{na'ra sin}\). C\(\text{43}\) H\(\text{72}\) O\(\text{11}\) \(\text{2H-Pyran-2-acetic acid, } \alpha\text{-ethyl-6-[5-[2-(5-ethyltetrahydro-5-hydroxy-6-methyl-2H-pyran-2-y)]-15-hydroxy-2,10,12-trimethyl-1,6,8-trioxadispiro[4.1.5.3]pentadec-13-en-9-yl]-2-hydroxy-1,3-dimethyl-4-oxoheptyl]tetrahydro-3,5-dimethyl-}\); (2) \(\alpha\text{-Ethyl-6-[5-[2-(5-ethyltetrahydro-5-hydroxy-6-methyl-2H-pyran-2-y)]-15-hydroxy-2,10,12-trimethyl-1,6,8-trioxadispiro[4.1.5.3]pentadec-13-en-9-yl]-2-hydroxy-1,3-dimethyl-4-oxoheptyl]tetrahydro-3,5-dimethyl-2H-pyran-2-acetic acid.\)

The CAS registry number is 55134-13-9.
5. Names and Address of Basic Producers:
   Elanco Animal Health
   A Division of Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN  46285, USA

6. Justification for Use:

   Narasin is a polyether monocarboxylic acid antibiotic from a class of compounds called ionophores.
   Narasin is used as an anticoccidial drug and a growth promotant in chicken, swine, and cattle.

   **Chicken:**
   Narasin is currently approved for use as an anticoccidial in chickens both alone (as Monteban®, Naravin) and in combination with nicarbazin (as Maxiban®)
   The most widely used control measure for coccidiosis in chickens has been the continuous prophylactic use of anticoccidial medicaments in the feed. Narasin has been shown to control coccidiosis due to infection with both laboratory and field isolates of pathogenic chicken coccidia, while allowing unimpaired growth and feed utilization under both laboratory and practical broiler rearing conditions.


   **Swine:**
   Efficacy studies, have shown that narasin has a positive effect on weight gain and feed efficiency when fed to grower and grower-finisher swine at 15 to 30 ppm in a complete ration.

   Monteban:  Increase weight gain and to improve feed efficiency in grower and grower-finishing pigs.

   **Cattle:**
   Improved feed efficiency in lofted cattle

   Naravin:  (Australia only country with cattle claim):
   For improved feed efficiency in lofted cattle.

   *No veterinary prescription is required for Monteban, Maxiban, Naravin, in any part of the world.*

7. Veterinary Use Pattern (Exact label indications vary slightly by country:)

   **Monteban:**
   **Broilers only – Feed continuously as sole ration:**
   Feed Narasin continuously to broiler chickens at a rate of 60-80 ppm (54.5 to 72.6 grams/2000 lb ton in complete feeds.

   **Pigs – feed continuously as sole ration:**
   Feed to grower and grower-finisher swine at 15-30 ppm in a complete ration.

   **Maxiban:**
   For Use in Broiler Chicken Feed Only.  Feed continuously as the sole ration.

   Narasin and nicarbazin are fed in combination at the rate of 40 ppm (0.004% or 36.4 gms/ton) of narasin plus 40 ppm of nicarbazin in complete feed or at 50 ppm (0.005% or 45.5 gms/ton) of each.
Naravin:

Cattle

Thoroughly mix with ration to provided 5-13 g/tonne (ppm) narasin in the cattle ration. Rations containing silages or other wet foods should be corrected to a 90% dry matter basis. DO NOT FEED UNDILUTED.

8. Countries Where Drug is Registered:

Monteban:

Algeria, Argentina, Australia, Austria, Bangladesh, Barbados, Belgium, Brazil, Canada, China, Colombia, Costa Rica, Cyprus, Czech Rep., Denmark, Dom. Rep., Ecuador, Egypt, El Salvador, Finland, Germany, Guatemala, Honduras, Hong Kong, Hungary, India, Indonesia, Iran, Iraq, Ireland, Jamaica, Japan, Jordan, Kuwait, Lebanon, Libya, Mexico, Morocco, Namibia, Netherlands, New Zealand, Nicaragua, Norway, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Puerto Rico, Romania, Saudi Arabia, Slovak Rep, So. Africa, So. Korea, Spain, Kri Lanka, Sweden, Switzerland, Syria, Taiwan, Thailand, Trinidad/Tobago, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States, Uruguay, Venezuela, Vietnam,

Maxiban:

Argentina, Australia, Austria, Barbados, Belgium, Brazil, Canada, Chile, Colombia, Costa Rica, Cyprus, Czech Rep., Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Finland, France, Germany, Guatemala, Honduras, Hong Kong, Hungary, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Jamaica, Jordan, Lebanon, Libya, Malaysia, Mexico, Morocco, New Zealand, Netherlands, Nicaragua, Panama, Paraguay, Peru, Philippines, Portugal, Puerto Rico, Romania, Saudi Arabia, Slovak Rep, South Africa, South Korea, Spain, Sri Lanka, Sweden, Syria, Taiwan, Trinidad/Tobago, Ukraine, United Arab Emirates, United Kingdom, United States, Venezuela, Vietnam,

Naravin:

Australia

9. National Maximum Residue Levels:

See the attached spreadsheet (Appendix B) for countries that currently have ADIs or MRLs set within their respective countries.

Other countries in the absence of Codex MRLs accept MRLs from other major regions such as Europe and the United States. Latin and Central American countries often accept MRLs set by Brazilian MAPA.

10. Commodities for Which the Need for Establishing Codex MRLs Is Required:

Chicken, swine and cattle:

Meat and other edible offal

Target tissues: Fat, Kidney, Liver, Muscle, Skin

11. List of Data (Toxicology, Metabolism, Residue) Available:

A. Identity

B. Data relevant to the toxicological evaluation of narasin

i. Pharmacology

ii. Acute subchronic and chronic toxicity/carcinogenicity, reproductive and developmental toxicity, genotoxicity

iii. Target animal safety in registered species

iv. Occupational exposure of feed mixers
C. Data relevant to the evaluation of residues in chicken, swine and cattle.
   i. Chemical identity and properties
   ii. Metabolism
   iii. Use and dosage range
   iv. Residue depletion studies in chicken, swine and cattle.
   v. Description of analytical procedures and recommendation of analytical procedures for regulatory authorities

12. Date Data Could Be Submitted to JECFA:
    Six to seven months prior to meeting deadline date or as determined by JECFA.

1. Proposal for Inclusion Submitted by (Country)
   United States

2. Drug Name:
   Tilmicosin

3. Trade Names:
   Pulmotil® AC

4. Chemical Names:
   Tylosin, 4A-0-de(2,6-dideoxy-3-C-methyl-alpha-L-ribo-hexopyranosyl)-20-deoxy-20-(3,5-dimethyl-1-piperidinyl)-(20(cis:trans)).
   The CAS registry number is 108050-54-0.
   Synonym: 20-Deoxy-20-(3,5-dimethylpiperidin-1-yl)-desmycosin

5. Names and Address of Basic Producers:
   Elanco Animal Health
   A Division of Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN 46285, USA

6. Justification for Use:
   **Chicken and Turkey**: For the treatment of respiratory diseases caused by *Mycoplasma gallisepticum, Mycoplasma synoviae, Ornithobacterium rhinotracheale, Pasteurella multocida* and other organisms sensitive to tilmicosin.

7. Veterinary Use Pattern:
   To be included in drinking water at 75 mg tilmicosin per litre (0.3 mL Pulmotil AC per litre) for three days. In clinical trials this equated to a daily dose of approximately 20 mg/kg.

8. Countries Where Drug is Registered:
   Algeria, Argentina, Austria, Bangladesh, Belgium, Brazil, Colombia, Costa Rica, Cyprus, Czech Republic, Dominican Republic, Ecuador, Egypt, El Salvador, France, Germany, Greece, Guatemala, Honduras, Hungary, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Jordan, Lebanon, Libya, Luxembourg, Malaysia, Mexico, Morocco, Namibia, Netherlands, Nicaragua, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Slovak Republic, So. Africa, So. Korea, Spain, Sri Lanka, Switzerland, Syria, Taiwan, Thailand, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam,
9. National Maximum Residue Levels:
   See the attached spreadsheet (Appendix C) for countries that currently have ADIs or MRLs set within their respective countries.
   Other countries in the absence of Codex MRLs accept MRLs from other major regions such as Europe and the United States. Latin and Central American countries often accept MRLs set by Brazilian MAPA.

10. Commodities for Which the Need for Establishing Codex MRLs Is Required:
    Poultry:
    Meat and other edible offal
    Target tissues: Fat, Kidney, Liver, Muscle, Skin
    Egg

11. List of Data (Toxicology, Metabolism, Residue) Available:
    A. Identity
    B. Data relevant to the toxicological evaluation of tilmicosin
       i. Pharmacology
       ii. Acute subchronic and chronic toxicity/carcinogenicity, reproductive and developmental toxicology, genotoxicity
       iii. Target animal safety in registered species
       iv. Occupational exposure
    C. Data relevant to the evaluation of residues in poultry and eggs
       i. Chemical identity and properties
       ii. Metabolism
       iii. Use and dosage range
       iv. Residue depletion studies in poultry and eggs
       v. Description of analytical procedures and recommendation of analytical procedures for regulatory authorities

12. Date Data Could Be Submitted to JECFA:
    Six to seven months prior to meeting deadline date or as determined by JECFA.

**IFAH (INTERNATIONAL FEDERATION FOR ANIMAL HEALTH)**
IFAH thanks the Codex Alimentarius Commission for the opportunity given in Circular Letter CL: 2006/52-RVDF to make proposals for veterinary drugs to be added to the priority lists for subsequent recommendations to JECFA and wishes to propose the following compounds:
    Tilmicosin
    Avilamycin
    Tylosin
    Narasin
    Monensin
    Triclabendazole (proposal for re-evaluation)
We confirm that all 3 criteria for the inclusion of substances in the priority list as provided for in Annex 1 are satisfied for all the compounds listed. Information on each compound as requested in the template provided
for in Annex 2 has been submitted by the sponsor company through the various country delegations to Codex (except for triclabendazole where Annex 2 is not required).

However we understand that currently there is no plan to convene a meeting of JECFA devoted solely to veterinary drugs in February 2008 as originally envisaged which is disappointing, now that there appears to be a likelihood of several new compounds for evaluation. I am never the less, also informed that consideration is being given to convening a meeting of JECFA in the summer of 2008. IFAH wishes to express its strong desire that this meeting should be devoted to veterinary drugs so these new compounds can undergo evaluation as quickly as possible; any further delay to holding a JECFA meeting would be very regrettable. IFAH would therefore very much appreciate that the 17th CCRVDF can agree to a veterinary drug JECFA meeting in the summer of 2008.

In respect of Triclabendazole IFAH wishes to make the following remarks: The CCRVDF first set MRLs in 1993. Low MRLs were set for sheep because of a lack of data. In the assessment, JECFA at the time had suggested to conduct additional studies to determine the percentage of total residues detectable by the routine analytical method and to determine the residues of toxicological concern by conducting studies on the bioavailability of residues.

In 2005, Novartis Animal Health submitted a dossier to modify the Codex MRLs, which included the suggested additional studies and an updated Expert Report recommending new, increased MRLs. Following the assessment in 2006, JECFA proposed to slightly increase the MRLs for sheep but to lower the MRLs for cattle at the same time. The new MRLs for cattle are unreasonably low, particularly when compared to those approved in the two major use areas (European Union and Australia) and result in excessively long withdrawal periods. This puts producers in certain countries at an undue disadvantage and does not facilitate trade. It now seems that all the new data submitted was not considered by the Committee which is very regrettable.

IFAH had requested that the JECFA secretariat provide an opportunity around the time of the 66th JECFA meeting for discussions between the rapporteurs and the company experts as has previously been arranged in years past; this request was not agreed to. We find this response rather disappointing because the sponsor company is convinced that had there been such an opportunity to meet with the rapporteur for triclabendazole, what appears to have been some misunderstanding over the data submitted could have been cleared up and explanations given, thus possibly avoiding the need for this resubmission. In summary, despite industry’s best endeavors to support JECFA, here we have a situation where the new rules are causing a problem.

IFAH entirely accepts that JECFA is a committee of independent scientific experts, who in no way wish to be beholden to industry and the companies whose compounds JECFA members are evaluating. However JECFA is now one of the few if not the only “regulatory” committee worldwide which will not agree to open a transparent dialogue with companies who are the sponsors of compounds that the Committee is reviewing. IFAH finds this very disappointing particularly when its member companies are doing all they can to be cooperative and to bring new compounds forward for evaluation. IFAH therefore respectfully requests the 17th CCRVDF to reflect on this and then requests JECFA to respond to these industry concerns and re-consider its position on this matter.
# Appendix A – Monensin

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Australia MRLs</th>
<th>Canada MRLs</th>
<th>China MRLs</th>
<th>Europe - EMEA &amp; EFSA MRLs</th>
<th>Japan MRLs</th>
<th>Korea MRLs</th>
<th>NZ MRLs</th>
<th>South Africa MRLs</th>
<th>Taiwan</th>
<th>USA FDA/EPA 21CFR/40CFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monensin - Chicken</td>
<td>MRL: Poultry meat [in the fat] &amp; edible offal of = *0.05 mg/kg</td>
<td>MRL: Edible tissues = 0.05* ppm</td>
<td>Chicken/Turkey: Muscle: 1500 ppm Skin+Fat: 3000 ppm Liver: 4500 ppm</td>
<td>EFSA: ADI=180 µg/person</td>
<td>Provisional MRL: Muscle = 0.08 ppm Skin/Fat = 0.25 ppm Liver = 0.08 ppm Kidney = 0.08 ppm</td>
<td>Meat = 0.05 ppm</td>
<td>MRL: All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
<td>Meat, liver, kidney, fat, eggs = No MRL is required.</td>
<td>ADI = 12.5 µg/kg body weight per day</td>
<td>21CFR 556.420 MRL = not needed</td>
</tr>
<tr>
<td>Monensin - Cattle</td>
<td>MRL: Cattle meat &amp; edible offal of = *0.05 mg/kg Cattle milk = *0.01 mg/kg</td>
<td>MRL: Edible tissues = 0.05 ppm Milk = 0.01* ppm</td>
<td>The Edibles: 50 ppb</td>
<td>N/A</td>
<td>Provisional MRL: Muscle = 0.05 ppm Fat = 0.05 ppm Liver = 0.05 ppm Kidney = 0.05 ppm Other edible offal = 0.05 ppm Milk = 0.01 ppm</td>
<td>Meat = 0.05 ppm</td>
<td>MRL: All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
<td>Meat, liver, kidney, fat = 0.05 ppm Milk = 0.01 ppm</td>
<td>ADI = 12.5 µg/kg body weight per day</td>
<td>21CFR 556.420</td>
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<td>Monensin - Goat</td>
<td>MRL: Goat meat &amp; edible offal of = *0.05 mg/kg</td>
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<td>The Edibles: 50 ppb</td>
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<td>Provisional MRL: Refer to Other terrestrial mammals MRL</td>
<td>Meat = 0.05 ppm</td>
<td>MRL: All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
<td>ADI = 12.5 µg/kg body weight per day</td>
<td>21CFR 556.420</td>
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<td>Monensin - Quail</td>
<td>MRL: Poultry meat [in the fat] &amp; edible offal of = *0.05 mg/kg</td>
<td>N/A</td>
<td>The Edibles: 50 ppb</td>
<td>N/A</td>
<td>Provisional MRL: Refer to Other poultry MRL</td>
<td>MRL: All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
<td>Meat, liver, kidney, fat, eggs = No MRL is required.</td>
<td>ADI = 12.5 µg/kg body weight per day</td>
<td>21CFR 556.420</td>
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<td>Monensin - Sheep</td>
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<td>The Edibles: 50 ppb</td>
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<td>21CFR 556.420</td>
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<td>China MRLs</td>
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<td>Japan MRLs</td>
<td>Korea MRLs</td>
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<td>South Africa MRLs</td>
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<td>N/A</td>
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<td>Mammalian fats = 0.05 mg/kg</td>
<td>All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
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<td>Mammalian fats = 0.05 mg/kg</td>
<td>All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
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<td>Mammalian fats = 0.05 mg/kg</td>
<td>All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
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<td>Mammalian fats = 0.05 mg/kg</td>
<td>All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
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<td>Muscle = 0.05 ppm Fat = 0.05 ppm Liver = 0.05 ppm Kidney = 0.05 ppm Other edible offal = 0.05 ppm</td>
<td>Mammalian fats = 0.05 mg/kg</td>
<td>All food producing species fat, kidney, liver &amp; muscle = 0.05 mg/kg</td>
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</table>
## Appendix B – Narasin

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Australia MRLs</th>
<th>Canada MRLs</th>
<th>China MRLs</th>
<th>Europe - EMEA MRLs</th>
<th>Japan MRLs</th>
<th>NZ MRLs</th>
<th>Taiwan MRL</th>
<th>USA FDA/EPA 21CFR/40CFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narasin - Cattle</td>
<td>MRL: Cattle meat &amp; edible offal of = 0.05 mg/kg</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>MRL: Meat, liver, kidney, fat = 0.05 ppm</td>
<td>N/A</td>
</tr>
<tr>
<td>Narasin - Chicken</td>
<td>MRL: Poultry meat &amp; edible offal of = 0.1 mg/kg</td>
<td>MRL: Muscle = 0.05 ppm Fat + Skin: 600 ppm Liver: 1200 ppm Fat = 0.5 ppm</td>
<td>Muscle: 600 ppm Fat+Skin: 1200 ppm Liver: 1800 ppm</td>
<td>EFSA: ADI= 300 µg/person</td>
<td>Provisional MRL: Muscle = 0.05 ppm Fat = 0.05 ppm Liver = 0.05 ppm Kidney = 0.05 ppm Other edible offal = 0.05 ppm</td>
<td>Provisional MRL: Muscle = 0.1 ppm Fat = 0.5 ppm Liver = 0.3 ppm Kidney = 0.3 ppm Other edible offal = 0.3 ppm</td>
<td>MRL: Edible offal of Poultry = 0.5 mg/kg</td>
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</tr>
<tr>
<td>Narasin - Swine</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<td>Narasin - Turkey / Other Poultry</td>
<td>MRL: Poultry meat &amp; edible offal of = 0.1 mg/kg</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>MRL: Edible offal of Poultry = 0.5 mg/kg</td>
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</table>

(*) denotes that the MRL has been set "at or about" the limit of analytical quantitation.  
(T) denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out in Australia or overseas, & will be reconsidered at some future date. This symbol is also used in cases where an MRL is being phased out.

Provisional MRL = MRL set provisionally based on current local control limit or other countries MRLs. These MRLs will be evaluated in next 5 years to change the status from provisional to permanent MRLs. Other edible offal = Offals other than liver or kidney. The major target tissue is for small intestine.

ADI = 5 µg/kg body weight per day
MRL = 480 ppb abdominal fat 21CFR 556.428
## Appendix C (Tilmicosin)

<table>
<thead>
<tr>
<th>Molecule</th>
<th>China MRLs</th>
<th>Europe - EMEA &amp; EFSA MRLs</th>
<th>Japan MRLs</th>
<th>South Africa MRLs</th>
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</thead>
<tbody>
<tr>
<td>Tilmicosin - Chicken</td>
<td>ADI = 240 µg/person</td>
<td></td>
<td>Provisional MRL:</td>
<td>MRL:</td>
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<tr>
<td></td>
<td>MRL:</td>
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<td>Muscle &amp; fat = 0.08 ppm</td>
<td>All food producing species:</td>
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<tr>
<td></td>
<td>Muscle: 75 ppb</td>
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<td>Liver = 1.0 ppm</td>
<td>Fat &amp; muscle = 0.05 mg/kg</td>
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<tr>
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<td>Fat+Skin: 75 ppb</td>
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<td>Kidney = 0.3 ppm</td>
<td>Kidney = 0.14 mg/kg</td>
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<td>Liver: 1000 ppb</td>
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<td>Other edible offal = 0.3 ppm</td>
<td>Liver = 6.0 mg/kg</td>
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<tr>
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<td>Kidney: 250 ppb</td>
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<td></td>
<td>Not for use in animals from which eggs are produced for human consump.</td>
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</tr>
<tr>
<td>Tilmicosin - Turkey and/or Other Poultry</td>
<td>ADI = 240 µg/person</td>
<td></td>
<td>Provisional MRL:</td>
<td>MRL:</td>
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<td>MRLs:</td>
<td></td>
<td>Other Poultry:</td>
<td>All food producing species:</td>
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<tr>
<td></td>
<td>Muscle = 75 µg/kg</td>
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<td>Muscle, fat = 0.08 ppm</td>
<td>Fat &amp; muscle = 0.05 mg/kg</td>
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<td>Skin+Fat = 75 µg/kg</td>
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<td>Liver = 1.0 ppm</td>
<td>Kidney = 0.14 mg/kg</td>
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<td>Liver = 1000 µg/kg</td>
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<td>Kidney = 0.3 ppm</td>
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<td>Kidney = 250 µg/kg</td>
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<td>Other edible offal = 0.3 ppm</td>
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<td>Not for use in animals from which eggs are produced for human consump.</td>
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