



For nutritionists and  
supplement manufacturers

# Veterinary feed additive safety guidelines



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# 1. Introduction

The guidelines are designed to provide a readily accessible reference source of veterinary feed additives for nutritionists, formulators and supplement manufacturers. The information held within the guidelines can be used in a multiple of ways including as a reference, reporting

assistant, contributor to operations QA programs, framework provider for managing possible toxicity events, and an assistant tool for developing and implementing sample collection, storage and testing protocols.



## 2. Veterinary feed additive safety guidelines

### 2.1 Laboratory testing

#### 2.1.1 Veterinary feed additives

Method of testing veterinary feed additives in either supplements (dry or liquid), finished feed or animal tissues (liver, kidney or muscle) uses High Performance Liquid Chromatography (HPLC) or Mass Spectrometry (MS), or combination of both analysis methods known as Liquid Chromatography tandem Mass Spectrometry (LC/MS/MS). These methods are accepted analytical assessments for all feedlot veterinary feed additives. Virginiamycin testing can also include microbiological methods, enzyme linked immunosorbent assays, and thin layer chromatography as well as HPLC and LC/MS/MS.

The HPLC method for dry supplements and finished feed requires extraction of the additive from the sample, with a mixture of methanol and water. After extraction, the sample is diluted, filtered and measured with HPLC.

The combination LC/MS/MS method for liquid supplements involves extracting the analytes from the samples by sonication in an aqueous methanol solution. The extract is then centrifuged, diluted and filtered. Quantitative and confirmatory analysis is performed simultaneously by LC/MS/MS and relies on an internal standard calibration.

Sensitivity of these analysis methods depend on the form in which the veterinary feed additive is held. Liquid supplements are challenging to fully recover veterinary feed additives, particularly ionophores. To promote consistency of sampling, dilution of sample is used. However, this in turn reduces the concentration of the ionophore. Analysis sensitivity can range from 80-95%, depending on laboratory methodology and capacity. Recovery levels from dry supplements and finished feed are greater with sensitivity levels of greater than 95%. A recovery of at least 90% is required in both finished feed and dry or liquid supplements to identify variation in concentrations and/or cross contamination from veterinary feed additives.

Commercial laboratories use quality management systems (QMS) to support and verify their testing procedures. QMS rely on international standards ISO17025, ISO15189 and Good Laboratory Practice (GLP). The ISO17025 assesses testing and calibrations, ensuring technical confidence through method validation and equipment calibration. ISO15189 covers quality and competence, promoting accurate reporting and staff qualifications. GLP assesses data integrity, repeatability and document control. In Australia, QMS are supported and audited by NATA (National Association of Testing Authorities).

#### 2.1.2 Heavy metals

Heavy metals are minerals that can interfere with metabolism within the body, cause toxicity, and/or accumulate in tissue creating a human health risk. Heavy metals are naturally occurring (rocks, soil, water) with some essential for life such as iron, copper and zinc. The heavy metals of concern are those that persist in the environment, can bio-accumulate through the food chain and cause toxic effects at low levels. The heavy metals of concern include arsenic, cadmium and lead.

Heavy metals in combination with veterinary chemicals and pesticides are monitored by the National Residue Survey (NRS), which has operated within the Department of Agriculture, Fisheries and Forestry (DAFF) since 1992. NRS is funded by industries through levies and direct contracts.

The primary source of heavy metal contamination risk for feedlot cattle is through association with minerals contained within dry and liquid mineral supplements. Maximum Residue Limits (MRL's) exist for lead and cadmium in Australia and the EU for beef muscle, liver and kidney.

Risk of heavy metal contamination can be assessed in feedstuffs or animal tissue (muscle, kidney, liver) by sampling and analysing for heavy metals of interest. Laboratories provide a cost for testing all heavy metals. Analysis is conducted by either Inductively Coupled Plasma Mass Spectrometry (ICP-MS) or Atomic Absorption Spectroscopy (AAS).

### 2.1.3 Domestic and international testing

Recommend contacting laboratory and confirming their confidence in testing veterinary feed additives, particularly when included in liquid supplements. Testing of ionophores in liquid supplements require additional sample preparation. Laboratories that do not routinely assess ionophores in liquid supplements will have low sensitivity (greater error) and poor recovery. A recovery of at least 90% is required in both finished feed and supplements (dry or liquid) to identify variation in concentration and/or cross contamination from veterinary feed additives.

## 2.2 Feedlot veterinary feed additive safety guidelines

### 2.2.1 Regulatory requirements and prescriptions

Statutes and regulations of the Commonwealth and State/Territory govern the control of veterinary feed additives use. To meet these requirements across all Australian jurisdictions, the following requirements include:

- Only use registered veterinary chemicals according to their label directions.
- Ensure the nutritionist or veterinarian provides written advice on inclusion rate and duration of medicated feed treatment.
- Prescription animal remedies (S4) products can only be used or prescribed by registered veterinarians and require additional oversight and record keeping:
  - » Written instructions on dose rate and duration of use.
  - » Ensure withholding period (WHP) /export slaughter interval (ESI) is adhered to (from last day of exposure).
  - » Identification of treated animals to ensure they cannot be sent to slaughter inside WHP/ESI.

These principles apply whether the S4 feed additive is supplied directly and overseen by the consulting veterinarian, or provided indirectly in a product such as a dry concentrate or liquid supplement via a prescription. An example of a prescription required for the inclusion of an S4 veterinary feed additive in a complete feed, or liquid supplement, or dry concentrate/premix is attached in the Appendix.

A *bona fide* veterinarian-client relationship is required for the dispensing or supply of an S4 by prescription. A *bona fide* veterinarian-client-patient relationship exists where each of the following occurs:

- The veterinarian has responsibility for making professional judgements regarding the health and welfare of the animals and the need for treatment.
- The veterinarian has sufficient knowledge of the animals to make a preliminary diagnosis.
- The veterinarian can monitor and treat the animals appropriately to support their health and welfare.

The animals in a *bona fide* veterinarian-client-patient relationship must have been directly examined by the veterinarian, or the animals must have been seen recently enough for the veterinarian to have sufficient knowledge of the animals – as evidenced by the veterinary patient records to make a preliminary diagnosis. “Recent enough” is defined as within the last 12 months for large animals.

Veterinarians are expected to assess the client’s skills and ability to understand instructions and correctly administer drugs prior to prescribing. The veterinarian must inform the client regarding proper use of the drug, including dosage, route and method of administration, possible side-effects, and withholding periods or export slaughter intervals.

Veterinary feed additives other than S4’s do not require a prescription, and their use and application of withholding periods can be based on reference to the label directions, with the inclusion of the veterinary feed additive on the label.

Where feed additives including registered veterinary products, whether S4 or otherwise, are supplied in a form without a label (e.g., as a bulk liquid supplement or bulk dry concentrate) the specifications of the supplement must be held by the receiving feedlot and consistency with this specification of each batch of liquid supplement must be verified at delivery before unloading. The order number, delivery docket, invoice, and liquid supplement specification provide evidence of medicated feed deliveries.

Withholding periods must be applied in the feedlot management software, or in the absence of such a feedlot management programme, the feedlot must maintain a physical record of treated cattle and withholding periods (e.g., a sign with the expiry date attached to the medicated pen) in addition to paper records.

To prevent veterinary additive separation or reaction within a supplement due to differences in physical (particle size, carrier matrix, solubility) or chemical (concentration, compatibility with other additives) characteristics, it is recommended that the supplement manufacture remain responsible for addition of the veterinary feed additive during manufacture rather than having the veterinary feed additive included in a premix. This avoids the risk of using an inappropriate registered veterinary feed additive for the type of supplement being manufactured (liquid, meal, pellet). Failure to account for physical and chemical characteristics of different registered products even though they supply the same type of additive and concentration can result in animal performance and health challenges. Very careful attention needs to be paid to the form of the active ingredient contained in the product prescribed by the veterinarian.

Records of feeding of veterinary compounds must be kept for two years (three years WA), and this requirement applies to all veterinary feed additives, whether S4 or otherwise. Substantial penalties apply for failure to meet the above requirements.

### 2.2.1.1 Schedule classification and requirements

Scheduling is a national classification system that controls how medicines and chemicals are made available. The current classification system is described in **Table 1**. The purpose of schedule classification is to protect public and animal health and establish controls on how medicines and chemicals are accessed and applied. The schedules are published in the Poisons Standard and are given legal effect through State and Territory legislation.

**Table 1:** Schedule classification and requirements (tga.gov.au)

| Schedule classification | Definition                 | Requirements                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Unscheduled             | No necessity for control   | –                                                                                                                                                                                                                                                                                                                                                                                                          |
| S2                      | Pharmacy medicine          | Medicines available on the shelf at pharmacies.<br>Sale: Only by authorised practitioners, pharmacists, and persons licensed as poison sellers.<br>Storage: Must be kept apart from food.                                                                                                                                                                                                                  |
| S3                      | Pharmacist only medicine   | Medicines available from a pharmacist without a prescription.<br>Sale: Only by authorised practitioners and pharmacists. Sale must include providing opportunity to seek advice as to the use, dosage and risks.<br>Storage: Must be kept out of public access (in the dispensary, storeroom or in cabinets that can be locked).<br>Labelling: Product must be labelled with name and address of pharmacy. |
| S4                      | Prescription only medicine | Medicines that must be prescribed by an authorised healthcare or veterinary professional.<br>Sale: Only by authorised practitioners and pharmacists.<br>Storage: As for S3.<br>Dispensing: Additional requirements concerning details of prescription, records and responsibilities of dispensing.                                                                                                         |
| S5                      | Chemical caution           | Chemicals that are not likely to cause harm but require suitable packaging, including a strong warning and safety directions on label.<br>Sale: No license required.<br>Storage: Must be kept apart from food.                                                                                                                                                                                             |
| S7                      | Dangerous poison           | Chemicals with a high risk of causing harm in low doses, require accreditation to handle safely. Specific rules for selling, using or storing these chemicals.<br>Sale: Special conditions apply.<br>Storage: No public access.                                                                                                                                                                            |
| S8                      | Controlled drug            | Medicines or chemicals that have special rules for producing, supplying, distributing, owning and using. Only prescribed by authorised healthcare professional who may require a special prescribing permit.<br>Storage: Kept in steel safe. Locked when not in immediate use. To undergo specific stock checks twice a year.                                                                              |
| S9                      | Prohibited substance       | Chemicals that may be abused or misused. Illegal to produce, own, sell or use except if needed for medical or scientific research.                                                                                                                                                                                                                                                                         |
| S10                     | Banned                     | Highly dangerous chemicals.                                                                                                                                                                                                                                                                                                                                                                                |

### 2.2.1.2 Quality assurance

Quality assurance (QA) involves the monitoring and evaluation of production inputs and processors to achieve a minimum pre-determined and defined standard. The objectives of QA are to provide consistency and confidence in processes and outcomes and incorporate continual improvement of processes.

QA is incorporated into several recognised and independently audited quality standards. Examples include Good Manufacturing Practice (GMP), Hazard Analysis and Critical Control Points (HACCP), ISO9000 series of standards (International Organisation for Standardisation). QA programs relevant to parties involved with the manufacture, use and feeding of veterinary feed additives are described in **Table 2**.

**Table 2:** Quality assurance programs suitable for feedlot supply chain participants using veterinary feed additives

| Supply chain participant                | QA program and objective                                                                                         | Description                                                                                                                                                                                                     | Link                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Veterinarian feed additive manufacturer | <i>AVMPA GMP</i><br>Ensure products supplied in Australia are safe, reliable and effective for intended purpose. | Incorporates the AgVet Code requiring every step of manufacture meet required standards.<br>Requires manufacturers to use an effective quality control system to confirm the quality of products and processes. | <a href="http://apvma.gov.au/regulation">apvma.gov.au</a><br><a href="http://apvma.gov.au/manufacturing">/regulation</a><br><a href="http://apvma.gov.au/good-manufacturing-practice">/manufacturing</a><br><a href="http://apvma.gov.au/good-manufacturing-practice">/good-manufacturing-practice</a> |
|                                         | <i>FIAAA Code</i><br>Based on QA standards GMP, HACCP & ISO                                                      | Management responsibility and compliance with AgVet regulations.<br>Resource management and traceability of supply.<br>Product and component standards.<br>Quality document systems                             | <a href="http://fiaaa.com.au/">fiaaa.com.au/</a><br>Stewardship                                                                                                                                                                                                                                        |
|                                         | <i>FAMIqs</i>                                                                                                    | Address safety, quality and regulatory compliance to minimise hazards and ensure market provided with safe and legal ingredients.                                                                               | <a href="http://fiaaa.au/famiqs">fiaaa.au/famiqs</a>                                                                                                                                                                                                                                                   |
| Veterinarian                            | <i>Quality improvement</i>                                                                                       | Systems and documentation to prevent harm, identify better practice management and rely on evidence based veterinary medicine.                                                                                  | <a href="http://veterinary-practice.com">veterinary-practice.com</a>                                                                                                                                                                                                                                   |
| Supplement manufacturer                 | <i>FeedSafe</i><br>Incorporates GMP & HACCP                                                                      | Implementation of efficient management and recording systems.<br>High standards of feed safety, biosecurity and traceability.<br>Eliminate exotic disease risk.<br>Meet market requirements.                    | <a href="http://feedsafe.com.au">feedsafe.com.au</a>                                                                                                                                                                                                                                                   |
| Feedlot                                 | <i>NFAS</i>                                                                                                      | Demonstrates continual improvement, safety and integrity of grain-fed beef.                                                                                                                                     | <a href="http://nfas.org.au">nfas.org.au</a>                                                                                                                                                                                                                                                           |
|                                         | <i>GMP for home-mixed feed</i>                                                                                   | Improve quality of home mixed feeds fed to animals and minimise incidence of residues in animal produce.<br>Minimise sources of error or contamination.<br>Use quality ingredients.                             |                                                                                                                                                                                                                                                                                                        |

APVMA: Australian Pesticides and Veterinary Medicines Authority; FIAAA: Feed Ingredients and Additives Association of Australia; FAMIqs: Feed Additives and Pre-mixtures Quality System; NFAS: National Feedlot Accreditation Scheme

Figure 1: Flaveco 40 bag label

**DIRECTIONS FOR USE:**  
**RESTRAINTS:** DO NOT exceed recommended dose rates. DO NOT feed to any animal or bird not included in the label claims.  
**Beef Cattle:** DO NOT USE for improvement of productivity, growth promotion or feed conversion efficiency on any cattle destined for the EU market.  
**Dairy Cattle:** DO NOT USE in heifers or cows which are producing or may in the future produce milk or milk products which may be used or processed for human consumption.

**DOSAGE AND ADMINISTRATION:**  
 Mix thoroughly into the feed premix (vitamins, minerals and ingredients commonly used in commercial feeds), then add premix to bulk feed gradually and blend thoroughly.  
 Mix this preparation with all commercially available feeds at the following rates:

| Animal Feed                         | Recommended Inclusion of Flavophosphopol | Mixing rate of FLAVECO™40 per tonne of feed |
|-------------------------------------|------------------------------------------|---------------------------------------------|
| Broilers: starter & finisher ration | 1 - 2 ppm                                | 25 g - 50 g                                 |
| Turkey: starter                     | 2.5 ppm                                  | 62.5 g                                      |
| finisher                            | 1 ppm                                    | 25 g                                        |
| Laying hens:                        | 2 ppm                                    | 50 g                                        |
| Piglets up to 25 kg                 | 6 ppm                                    | 150 g                                       |
| Pigs 25 kg or more                  | 2 ppm                                    | 50 g                                        |
| Beef Cattle: milk replacer, starter | 10 ppm                                   | 250 g                                       |
| Beef Cattle:                        | 5 - 10 ppm                               | 125 g - 250 g                               |

**IN SUPPLEMENTS:**

|                                     | Per head per day | Per head per day     |
|-------------------------------------|------------------|----------------------|
| Beef Calves: milk replacer, starter | 10-20mg          | 0.25-0.5g FLAVECO™40 |
| Beef Cattle:                        | 10-20mg          | 0.25-0.5g FLAVECO™40 |

1 ppm is equivalent to 1 g active ingredient.

**GENERAL DIRECTIONS:**  
 FLAVECO™40, an antibiotic developed exclusively for nutritional use as a feed supplement in animals. It has no therapeutic application in human and veterinary medicine.  
 FLAVECO™40 has the following benefits:  
 - no residue in animal tissues or organs as the product is not absorbed by animal digestive system.  
 - no metabolites are created as the product is excreted intact.  
 - no cross-resistance with other antibiotics has been found.  
 - the product can be mixed with all form of feeds.

**COMPATIBILITY:**  
 FLAVECO™40 is compatible when mixed with feedstuffs, vitamins, minerals, amprolium, roxarsone, monensin, lasalocid, narasin, salinomycin and halofuginone.  
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 ™FLAVECO is a trademark of International Animal Health Products P/L.  
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**KEEP OUT OF REACH OF CHILDREN**  
**READ SAFETY DIRECTIONS BEFORE OPENING OR USING**  
**FOR ANIMAL TREATMENT ONLY**

**FLAVECO 40™**

**FEED SUPPLEMENT**

**ACTIVE CONSTITUENT:**  
 FLAVOPHOSPHOLIPOL 40 g/kg

FLAVECO™40 is a composition of dried strains of *Cephalosporium* sp. mycelium and calcium carbonate.

**For improvement of productivity by stimulating the growth rate and increasing feed conversion efficiency in poultry (broilers and turkeys), pigs, beef calves and beef cattle and increasing egg production in laying hens.**

**20 kg NET**

**WITHHOLDING PERIODS: MEAT: NIL, EGGS: NIL.**  
 Feed containing FLAVECO™40 may be provided to animals up to slaughter.

**TRADE ADVICE:**  
 Beef Cattle: Under EUCAS rules (in a segregated system), accredited cattle producers are not permitted to use this product for growth promotion or yield increase on animals destined for EU. Please consult the EUCAS rules for usage and documentation requirements.  
 EXPORT SLAUGHTER INTERVAL (ESI): This product does not have an ESI established. For advice on the ESI, contact the manufacturer on (02) 9672 7944 before using this product.

**SAFETY DIRECTIONS:**  
 The product will irritate the eyes and skin. Avoid contact with eyes and skin and do not inhale dust. When opening the container and mixing into feed wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves, goggles and disposable dust mask. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, goggles and contaminated clothing.

**FIRST AID:**  
 If poisoning occurs, contact a Doctor or Poisons Information Centre.  
 Phone Australia 131126; New Zealand (0800)POISON 0800764766.  
 Additional information is included in the Material Safety Data Sheet (MSDS).

**DISPOSAL:**  
 Shake and empty contents into medicated feed. Do not dispose of undiluted chemicals on-site. Puncture or shred and bury empty bags in a local authority landfill. If no landfill available, bury the bags below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Empty bags and product should not be burned.

**STORE BELOW 30° C (Room Temperature) IN A WELL-CLOSED CONTAINER IN A DRY PLACE.**

**APVMA Approval Number: 54232**

**BATCH: ?????**  
**EXPIRY: ??? 20??**

**Marketed by**  
 IAH SALES Pty Ltd  
 ABN: 57 109 433 883  
 18 Healey Circuit, Huntingwood NSW 2148  
 Telephone (02) 9672 7944  
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**eco ANIMAL HEALTH**

### 2.2.1.3 Interpreting labels and directions of use

Labels are most commonly seen on a feed additive bag as described in Figure 1. The APVMA provides general labelling recommendations in combination with more specific labelling (Veterinary Labelling Code, VLC) required for veterinary feed additives.

Using Figure 1 as an example, components of the label can be assessed:

- Signal heading (see red circle).
  - » prescription animal remedy = Schedule 4
  - » include other cautionary words or phrases
  - » direction to read directions before opening or using.
- Label displays the product name (Flavenco 40).
- Active constituent statement which includes name of constituent with concentration (see purple circle).
- Statement of claims for use defining what it is for and what animal (see green circle).
- Net contents statement (20kg NET).
- Directions for use (see orange square).
  - » restraints with the words 'DO NOT'
  - » dosage and administration defined in table describing feeding rates for different livestock
  - » general directions –these may include any other instructions or advice for the safe and effective use of the product. Figure 1 examples include warnings, withholding periods and compatibility for mixing with other products.

- Withholding period statements and trade advice (see black square).
- Safety directions (black square) – provision of safety directions are a state and territory requirement under poison and pesticide legislation.
- First aid instructions (black square) – specify initial action required to be taken to counteract the effects of exposure to the product.
- Disposal statements (black square) – provide advice on appropriate method of disposing unused product and used bags/containers.
- Storage statement (black square) – requirement to provide instructions for suitable storage.
- Contact details of the marketer (see yellow rectangle) – requirement to provide name and address responsible for marketing of veterinary feed additive.
- APVMA label approval number (light blue rectangle).
- Expiry date and Batch number – requirement to provide.

### 2.2.1.4 Off label use compared to label restraint

Off-label use refers to situations when a registered veterinary chemical is used in a manner that is not specified on the product label. Off-label use is a common practice by veterinarians and is based on emerging scientific evidence, clinical judgement or patient needs. However, the user is ultimately responsible to manage the risk of any adverse outcomes such as reaction by animal

or chemical residue. Off-label uses are recommended in gaining an appropriate permit from the Australian Pesticides and Veterinary Medicines Authority (APVMA).

A label restraint is an absolute limitation or restriction placed on the use of a veterinary product. The limitation is required to manage a risk associated with the use of the product in regard to human safety, public health, or environment. Risks include residues, antibiotic resistance or limitations to specific treatment periods. Label restraints are defined on the label using restraint statements including: 'DO NOT USE' or 'NOT TO BE USED' or 'USE ONLY.'

#### 2.2.1.5 MRL, ESI and LD50

The current maximum residue limits (MRL), export slaughter intervals (ESI) and LD50 levels (oral lethal dose) at which mortality is 50% for veterinary feed additives is provided in **Table 3**.

### 2.2.2 Physical and chemical properties of veterinary feed additives

#### 2.2.2.1 Calculating concentration of veterinary feed additives within supplement and finished feed

Accurately calculating concentrations of veterinary feed additives is critical to avoid toxicity events and ensure animals get the correct dose for a desired production/health response.

Challenges for determining the required inclusion level includes:

- concentration level of veterinary feed additive
  - » descriptions may include a percentage (10%), a number (100) or a concentration (100g/kg or 100,000mg/kg)
- units
  - » concentrations are expressed as g/kg, mg/kg
  - » inclusion levels are expressed as kg/tonne
  - » ability to account for changes in units avoids errors and risk of over or under, including feed additives by 10, 100 or 1,000 times
- dry matter of veterinary feed additive
  - » many additives are supplied in a dry form
  - » additives provided in a solution require adjustment to account for dry matter content
  - » determine whether stated concentration is provided on an as-fed or dry matter basis
- desired dose rate
  - » concentration in finished feed (mg/kg DM)
  - » daily requirement (mg/head/day)
  - » dose by body weight (mg/kg/body weight)
- average dry matter intake
- inclusion level of supplement in finished feed
- finished feed dry matter.



**Table 3:** Veterinary feed additive toxic dose rates (LD50), export slaughter interval (ESI) and maximum residue limit (MRL)

| Veterinary feed additive               | Clinical signs of toxicity                                                                                                                                                                                                                                                                   | LD 50* or reported toxicity                                                                                                                                                                                              | ESI Days                         | MRL mg/kg                                |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------------|
| <b>Antibiotics</b>                     |                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                          |                                  |                                          |
| <i>Flavophospholipol (bambermycin)</i> |                                                                                                                                                                                                                                                                                              | >2,000mg/kg (mice, rat)                                                                                                                                                                                                  | Nil                              | 0.01 (fat, meat, kidney, liver)          |
| <i>Tetracyclines</i>                   |                                                                                                                                                                                                                                                                                              | >5,000mg/kg (rat)                                                                                                                                                                                                        |                                  |                                          |
| <i>Oxytetracycline (OTC)</i>           | The low oral absorption of both oxytetracycline and chlortetracycline makes oral toxicity highly unlikely (Riviere and Papich, 2009).                                                                                                                                                        |                                                                                                                                                                                                                          | 5                                |                                          |
| <i>Chlortetracycline (CTC)</i>         |                                                                                                                                                                                                                                                                                              | >2,314mg/kg (rat)                                                                                                                                                                                                        | 5 prophylactic<br>10 therapeutic | 0.1(meat)<br>0.6 (kidney)<br>0.3 (liver) |
| <i>Tylosin</i>                         |                                                                                                                                                                                                                                                                                              | 600mg/kg (rat)                                                                                                                                                                                                           | Nil                              | 0.1 (meat, edible offal)                 |
| <i>Virginiamycin</i>                   |                                                                                                                                                                                                                                                                                              | 7,000mg/kg (mice, rat)                                                                                                                                                                                                   | Nil                              | 0.1 (meat)<br>0.2 (fat, edible offal)    |
| <i>Monensin</i>                        | <ul style="list-style-type: none"> <li>- Scouring</li> <li>- Anorexia</li> <li>- Weakness, lethargy and possibly difficulty standing (ataxia)</li> <li>- Signs of respiratory distress (dyspnoea)</li> <li>- Recumbency and death (Potter et al, 1984)</li> </ul>                            | 26.4 mg/kg BW (Potter et al, 1984)<br>For a 450kg steer = 11,880 mg<br>At 25mg/kg dietary DM intake, and a DMI of 10kg/hd/d the intake would be 250mg/450kg = 0.6mg/kg. Therefore, the LD50 = 44 times the normal intake | Nil                              | 0.05 (meat, edible offal)                |
| <i>Lasalocid</i>                       | <ul style="list-style-type: none"> <li>- Scouring</li> <li>- Anorexia (Galitzer, 1984)</li> <li>- Muscle tremors</li> <li>- Tachycardia</li> <li>- Rumen atony (Galitzer et al, 1986).</li> </ul>                                                                                            | No deaths at 10mg/kg, deaths at 50mg/kg with severity and clinical signs (Galitzer 1984)                                                                                                                                 | Nil                              | 0.05 (meat)<br>0.7 (edible offal)        |
| <i>Salinomycin</i>                     | <ul style="list-style-type: none"> <li>- Dyspnoea</li> <li>- Exercise intolerance</li> <li>- Chronic cardiomyopathy (Bastianello et al, 1996)</li> </ul>                                                                                                                                     | 90mg/kg diet DM resulted in the death of 8 out of 39 clinical cases out of a total of 380 cattle fed the TMR for 77 days. BW of the cattle was not reported (Bastianello et al, 1996)                                    | Nil                              | 0.05 (meat)<br>0.7 (edible offal)        |
| <i>Narasin</i>                         | <ul style="list-style-type: none"> <li>- Anorexia</li> <li>- Drooling and dysphagia</li> <li>- Lethargy, ataxia, and stiff gait</li> <li>- Possibly jugular pulse</li> <li>- Pulmonary oedema</li> <li>- Hydrothorax</li> <li>- Myopathy and cardiomyopathy (Wouters et al, 1997)</li> </ul> | Approx. 15mg/kg (Wouters et al, 1997)                                                                                                                                                                                    | Nil                              | 0.05 (meat, edible offal)                |

The following examples provide three scenarios for calculating inclusion level of a feed additive.

1. Addition of feed additive to finished feed

| Feed additive name                   | ZnMet50                                                                                                                              |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Feed additive dry matter             | 98%                                                                                                                                  |
| Feed additive concentration g/kg     | 50                                                                                                                                   |
| Target level in finished feed DM     | 72.0mg/kg DM                                                                                                                         |
| Finished feed DM %                   | 79.0%                                                                                                                                |
| Target level in finished feed as fed | = Target level x Finished feed DM<br>= 72.0 x 79% = 56.88mg/kg                                                                       |
| Inclusion level in finished feed     | = 56.88 / additive DM x 1,000 / additive concentration<br>= 56.88 / 98% x 1,000 / 50<br>= 1,161mg/kg OR 1,161g/tonne OR 1.16kg/tonne |

2. Addition of feed additive (low concentration) to a supplement

| Feed additive name                   | Tylan250                                                                                                                      |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Feed additive dry matter             | 98%                                                                                                                           |
| Feed additive concentration g/kg     | 250                                                                                                                           |
| Target level in finished feed DM     | 11.0mg/kg DM                                                                                                                  |
| Finished feed DM %                   | 72.0%                                                                                                                         |
| Target level in finished feed as fed | = Target level x Finished feed DM<br>= 11.0 x 72% = 7.92mg/kg                                                                 |
| Inclusion level of supplement        | 4.0%                                                                                                                          |
| Target level in supplement           | = 7.92 / 4.0% = 198mg/kg                                                                                                      |
| Inclusion level in supplement        | = 198 / additive DM x 1,000 / additive concentration<br>= 198 / 98% x 1,000 / 250<br>= 808mg/kg OR 808g/tonne OR 0.81kg/tonne |



3. Addition of feed additive (high concentration) to a supplement

| Feed additive name                   | RumensinTECH                                           |
|--------------------------------------|--------------------------------------------------------|
| Feed additive dry matter             | 98%                                                    |
| Feed additive concentration g/kg     | 800                                                    |
| Target level in finished feed DM     | 22.0mg/kg DM                                           |
| Finished feed DM %                   | 72.50%                                                 |
| Target level in finished feed as fed | = Target level x Finished feed DM                      |
|                                      | = 22.0 x 72.5% = 15.95mg/kg                            |
| Inclusion level of supplement        | 6.0%                                                   |
| Target level in supplement           | = 15.95 / 6.0% = 265.8mg/kg                            |
| Inclusion level in supplement        | = 265.8 / additive DM x 1,000 / additive concentration |
|                                      | = 198 / 98% x 1,000 / 800                              |
|                                      | = 339mg/kg OR 339g/tonne or 0.339kg/tonne              |

4. Addition of feed additive in a supplement for a per head intake

| Feed additive name                   | ZnMet50                                                |
|--------------------------------------|--------------------------------------------------------|
| Feed additive dry matter             | 98%                                                    |
| Feed additive concentration g/kg     | 50                                                     |
| Target level in finished feed DM     | 72.0mg/kg DM                                           |
| Finished feed DM %                   | 79.0%                                                  |
| Target level in finished feed as fed | = Target level x Finished feed DM                      |
|                                      | = 72.0 x 79% = 56.88mg/kg                              |
| Inclusion level in finished feed     | = 56.88 / additive DM x 1,000 / additive concentration |
|                                      | = 56.88 / 98% x 1,000 / 50                             |
|                                      | = 1,161mg/kg OR 1,161g/tonne OR 1.16kg/tonne           |



### 2.2.3 Physical and chemical properties of veterinary feed additives with risk assessment framework

For liquid supplements, particle size is the most important physical characteristic of veterinary feed additives as they are not soluble, but rather suspended or blended into formulations. Liquid supplement manufacturers' only use additives with particle size of less than 75µm. Larger particles risk separation. Granular based ionophores are not accepted at liquid supplement plants and should never be used for formulation in liquid supplement formulations.

For dry supplement manufacturers', the preference is to avoid using veterinary feed additive products with concentrations greater than 100,000mg/kg. Products with high concentrations are supplied to the feed mill in a premix form. Benefits of using a premix are described in **4.3.3.2 Medicated premixes**. The premix reduces the physical and chemical characteristics of the feed additive which interferes with distribution and activity. Characteristics and risk assessment of veterinary feed additives are described in **Table 4**.

### 2.2.4 Best practice management and formulation parameters

The best practice management is designed to promote the production of safe and high-quality products as well as preserving the environment and contributing to social wellbeing. For supplement manufacture and supply importance components of BPM include:

- source ingredients from reputable suppliers
- invest in staff through training and providing a safe workplace culture
- minimise waste
- follow directions of use
- avoid cross contamination
- establish and maintain reliable recording systems.

#### 2.2.4.1 Dry and liquid supplements

Manufacturers of dry and liquid supplements use formulation guidelines for ingredient inclusion and nutrient level as described in **Table 5**. The guidelines account for the manufacturer's infrastructure and process and are designed to promote integrity and consistency of supplement during transport and storage.

Liquid manufacturers recommend blended or suspension supplements be stored in a cone bottom tank. Cone bottom tanks reduce the likelihood of accumulation –

particularly if the separation of components occurs and allows the contents of the tank to fully empty, as discharge is at the lowest point. Liquid supplement manufacturers include the use of suspending agents for both blend and suspension products to promote integrity of supplement during transport and storage.

Particle size of limestone, magnesium carbonate and monensin are critical for integrity and safety of liquid supplements. Liquid supplement manufacturers will not accept monensin in granular form due to separation and toxicity risk. Desired particle size of monensin is less than 75µm. Other ionophores are selected with particle size of no more than 100µm. Required particle size of limestone is 75µm. Larger limestone particles risk separation. Preferred magnesium carbonate particle size is 40 to 45µm. Smaller particles have greater surface area, promoting binding capacity and reduced risk of separation, particularly of insoluble ingredients such as limestone (0.0013g/100g) and magnesium carbonate (0.06g/100g).

**Table 5:** Summary of supplement manufacture formulation recommendations responses (expressed as percentage) with formulation specifications provided as minimum (MIN) or maximum (MAX) inclusion on a percentage basis for ingredient and nutrient)

| Formulation recommendation – ingredient and nutrient levels |                                         |                                              |
|-------------------------------------------------------------|-----------------------------------------|----------------------------------------------|
|                                                             | Meal <sup>1</sup> / Pellet <sup>2</sup> | Blend <sup>3</sup> / Suspension <sup>4</sup> |
| Dry matter %                                                | NA                                      | 60–75 / 65–70                                |
| MIN % Carrier <sup>5</sup>                                  | 20 / 50                                 | 20–35                                        |
| MAX % Limestone                                             | 10 / 15                                 | NA / 30                                      |
| MAX % Urea                                                  | 20 / 10                                 | 10–30                                        |
| MIN % Vegetable oil                                         | 1–3                                     | NA                                           |
| MIN % Protein meal                                          | 10 / 15                                 | NA                                           |
| MAX % Magnesium carbonate                                   | NA                                      | 3–5                                          |
| MAX % Combined salts                                        | NA                                      | 15–35 / 20–40                                |

<sup>1</sup>A meal is a blended combination of dry ingredients of similar particle size (cereal grain is rolled or hammer milled) using vegetable oil to suppress dust and reduce separation.

<sup>2</sup>A pellet is dry ingredients combined into a pellet using a pellet press.

<sup>3</sup>A blend is a molasses based liquid supplement without limestone.

<sup>4</sup>A suspension is a molasses based liquid supplement with limestone.

<sup>5</sup>Carrier refers to cereal grain, grain by-products or protein meal for dry supplements and molasses for liquid supplements

**Table 4:** Physical and chemical characteristics including risk assessment framework of veterinary feed additives

| Antimicrobial class and examples of individual antimicrobial products                                                                                    | Dose rate and concentration of active ingredient                                                                                                                             | Spectrum                                                                                                                                                                      | Distribution                                                                                                               | Excretion                                                                                                       | Form            | ASTAG Rating <sup>b</sup>  | Risk                         | Risk mitigation                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------|----------------------------|------------------------------|-----------------------------------------------------------------------------------------------|
| <b>Antibiotics</b>                                                                                                                                       |                                                                                                                                                                              |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| <i>Flavophospholipol (bambermycin)</i>                                                                                                                   | 5–10mg/kg finished feed                                                                                                                                                      | Primarily Gram +ve                                                                                                                                                            | Negligible absorption from the gut                                                                                         | Effectively 100% of bambermycin is excreted unchanged in the faeces                                             | Powdered premix | Not used in human medicine | Active residues in effluent  | Effluent containment system plus not used in human medicine plus no cross resistance reported |
| Flaveco 40 (International Animal Health)                                                                                                                 | 40g flavophospholipol/kg premix + 5g/kg product                                                                                                                              |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| <b>Mode of action:</b> inhibition of cell enzyme (trans-glycosylase) and cell wall synthesis                                                             |                                                                                                                                                                              |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| <i>Trimethoprim Potentiated Sulphonamides</i>                                                                                                            |                                                                                                                                                                              | Broad                                                                                                                                                                         | Limited absorption of sulphadiazine across the gut and negligible absorption of trimethoprim (likely inactivated in rumen) | Non-absorbed sulphonamides excreted in faeces as a mix of active and metabolised drug                           | Powdered premix | Low                        | Limited residues in effluent | Effluent containment system to allow degradation on site                                      |
| Sulphadiazine/Trimethoprim Sulphatrim (International Animal Health)                                                                                      | 62.5mg/kg BW/d<br>Sulphadiazine 400g/kg<br>Trimethoprim 80g/kg<br>= 2.27kg premix/tonne finished feed for a 400kg animal eating 2.5% of BW as dry matter and a 90% DM ration | <i>Escherichia coli</i> ,<br><i>Haemophilus</i> ,<br><i>Pasteurella</i> ,<br><i>Salmonella</i> ,<br><i>Staphylococcus</i> ,<br><i>Streptococcus</i> ,<br><i>Campylobacter</i> |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| <b>Mode of action:</b> inhibit bacterial synthesis of required co-factor (tetrahydrofolic acid) in the synthesis of thymidine, purines and bacterial DNA |                                                                                                                                                                              |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| <i>Tetracyclines</i>                                                                                                                                     |                                                                                                                                                                              | Broad                                                                                                                                                                         | Poorly absorbed across the gut and bound by calcium, magnesium and iron                                                    | Excretion of active drug as it is not metabolised: 60% in the urine and 40% in the faeces (mainly via the bile) | Granular premix | Low                        | Active residues in effluent  | Effluent containment system to allow degradation on site                                      |
| Oxytetracycline (OTC)<br>Terramycin 200 (Zoetis)                                                                                                         | 200 to 400mg/kg finished feed                                                                                                                                                |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| Oxytetracycline 200 (CCD Animal Health)                                                                                                                  | 200g OTC/kg premix<br>1–2 kg premix/tonne finished feed                                                                                                                      |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| Chlortetracycline (CTC)<br>Aurofac 200 Granular Feed Supplement (Zoetis)                                                                                 | 200g CTC/kg premix.<br>0.5 to 2kg premix/tonne finished feed                                                                                                                 |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| CTC-Eco 200 Granular (IAH)                                                                                                                               | = Prophylactic dose: 100mg/kg finished feed                                                                                                                                  |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| Chlormix CTC 200                                                                                                                                         | = Therapeutic dose: 400 mg/kg finished feed (US studies have used 350mg/kg)                                                                                                  |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| CTC 200 G (Prime Animal Health)                                                                                                                          |                                                                                                                                                                              |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |
| <b>Mode of action:</b> Inhibits protein synthesis (prevents tRNA attachment to RNA ribosome complex)                                                     |                                                                                                                                                                              |                                                                                                                                                                               |                                                                                                                            |                                                                                                                 |                 |                            |                              |                                                                                               |

**Mode of action:** inhibits cell membrane function

| Antimicrobial class and examples of individual antimicrobial products           | Dose rate and concentration of active ingredient               | Spectrum                        | Distribution                                                                                                                                                                    | Excretion                                                                                    | Form                         | ASTAG Rating <sup>b</sup>                                                                | Risk     | Risk mitigation                                                                                                                                                                                                                                                        |
|---------------------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------|------------------------------------------------------------------------------------------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ionophores</b>                                                               |                                                                |                                 |                                                                                                                                                                                 |                                                                                              |                              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| <i>Monensin</i>                                                                 | 20–33mg/kg finished feed                                       | Primarily Gram +ve and coccidia | Ionophores act locally in the rumen and are readily absorbed across the digestive tract wall – accurate dosing is essential due to propensity for rapid absorption from the gut | Hepatic metabolism, with 50% of the ingested dose excreted as active ionophore in the faeces | Powdered premix              | Not used in human medicine and no evidence of cross resistance with other antimicrobials | Toxicity | Addition of appropriate products to liquid supplements at the liquid supplement plant, strict QC with the commissioning and supply of premixes/concentrates to ensure the target inclusion is supplied, regular (daily) monitoring of product inclusion at the feedlot |
| Moneco 100 (International Animal Health)                                        | 100g monensin sodium/kg premix + 200 and 400g/kg products      |                                 |                                                                                                                                                                                 |                                                                                              |                              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| Monemix 100 Premix (Abbey Laboratories)                                         | 100g monensin sodium/kg premix + 800g/kg product               |                                 |                                                                                                                                                                                 |                                                                                              |                              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| PhibroMonensin 100 and 400 Monensin Feed Additive Premix (Phibro Animal Health) | 100g monensin sodium/kg premix<br>400g/kg monensin             |                                 |                                                                                                                                                                                 |                                                                                              |                              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| Rumensin 100 Premix (Elanco Animal Health)                                      | sodium/kg premix + 200 and 800g/kg products                    |                                 |                                                                                                                                                                                 |                                                                                              |                              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| Monendox 100 Granulate Feed Additive                                            | 100g monensin sodium/kg premix + 200, 400 and 800g/kg products |                                 |                                                                                                                                                                                 |                                                                                              | Granular premix <sup>c</sup> |                                                                                          |          | Do not use granular products in liquid supplements                                                                                                                                                                                                                     |
| Elanco Rumensin Technical                                                       | 800g/kg monensin                                               |                                 |                                                                                                                                                                                 |                                                                                              | Powdered premix              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| <i>Salinomycin</i>                                                              |                                                                |                                 |                                                                                                                                                                                 |                                                                                              |                              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| Saleco 120 (International Animal Health)                                        | 15mg/kg finished feed<br>120g salinomycin sodium/kg premix     |                                 |                                                                                                                                                                                 |                                                                                              |                              | Not used in human medicine                                                               | Toxicity |                                                                                                                                                                                                                                                                        |
| Salindox 120 G Micro-granulate Feed Additive (Prime Animal Health)              | 120g salinomycin sodium/kg premix + 60 and 240g/kg products    |                                 |                                                                                                                                                                                 |                                                                                              | Granular premix              |                                                                                          |          | Do not use granular products in liquid supplements                                                                                                                                                                                                                     |
| Cosistax 120 Granular (Phibro Animal Health)                                    | 120g salinomycin sodium/kg premix                              |                                 |                                                                                                                                                                                 |                                                                                              | Granular premix              |                                                                                          |          |                                                                                                                                                                                                                                                                        |
| Salinomix 240 Granular Premix (Abbey Laboratories)                              | 240g salinomycin sodium/kg premix                              |                                 |                                                                                                                                                                                 |                                                                                              | Granular premix              |                                                                                          |          |                                                                                                                                                                                                                                                                        |

<sup>a</sup> Export slaughter intervals can vary with product and can change over time – they should be routinely checked against the label and for any new product.

<sup>b</sup> ASTAG (Australian Strategic and Technical Advisory Group on Antimicrobial Resistance) Importance Ratings and Summary of Antibacterial Uses in Humans in Australia v1.1, 2015.

<sup>c</sup> Note that granular products are not to be used in liquid supplements.

Particle size of limestone, magnesium carbonate and monensin are critical for integrity and safety of liquid supplements. Liquid supplement manufacturers will not accept monensin in granular form due to separation and toxicity risk. Desired particle size of monensin is less than 75µm. Other ionophores are selected with particle size of no more than 100µm. Required particle size of limestone is 75µm. Larger limestone particles risk separation. Preferred magnesium carbonate particle size is 40 to 45µm. Smaller particles have greater surface area, promoting binding capacity and reduced risk of separation, particularly of insoluble ingredients such as limestone (0.0013g/100g) and magnesium carbonate (0.06g/100g).

#### 2.2.4.2 Medicated premixes

Veterinary medications and small inclusion nutrients such as trace minerals, vitamins and other low inclusion additives are generally supplied in a premix. The benefits of using a premix include:

- Improve distribution and the opportunity for all animals to receive the desired daily dose rate.
- Enhanced ability of medication to achieve consistent target dose rates across the entire pen by reducing medication potency and removing negative characteristics such as electrostatic charge, reactivity, pH, taste, density and fineness.
- -Reduced effect of loading error.
- Reduced risk of cross contamination and requirement for flushing procedures.
- Avoids interactions between ingredients which alter potency or generate a chemical reaction.
  - » Direct contact with acids, ammonium salts and magnesium.
  - » Contact with strong bases (e.g. caustic soda).
  - » Contact with oxidising agents (e.g. reactive metal salts such as copper sulphate).

Components of a premix include:

- Carrier
  - » Designed to physically hold medications to enhance uniform distribution.
  - » Physical characteristics of the carrier are similar to medication leading to enhanced distribution and reduce separation: particle size, particle shape, particle density, flowability and ability to compress (reduce packaging volume).
  - » Type of carrier needs to account for form of supplement (liquid or dry), liquid carrier examples include: salt, dextrose; dry carrier examples include rice hulls, limestone, ground corn, millrun.
- Diluent
  - » Diluent used to extend or dilute concentration of medication within the premix, in other words increase the inclusion level.
  - » Diluents are low cost but provide consistent particle size, such as limestone.
- Binding agent
  - » Provide adhesion on the surface of carriers to increase holding capacity of medication.
  - » Reduce dust and separation risk, maintain consistency and homogeneity of premix and reduce electrostatic charge and loss as dust or fines.
  - » Common binding agent is mineral oil (inert).

- Antioxidant
  - » Reduce oxidative degradation of susceptible ingredients (fat soluble vitamins).
  - » Improve stability of binding agent if using fats or vegetable oil.

A guide to premix manufacture and formulation recommendations is provided in **Table 6**. Premixes are designed for finished feed inclusion levels of 0.2 to 0.5%.

**Table 6:** Premix manufacture and formulation recommendations

| Ingredient and loading order | Inclusion                                                               |      |
|------------------------------|-------------------------------------------------------------------------|------|
|                              | MIN%                                                                    | MAX% |
| Carrier                      | 35.0                                                                    |      |
| Diluent                      | 10.0                                                                    |      |
| Mineral oil                  | 1.0                                                                     | 1.0  |
| Antioxidant                  | 0.1                                                                     | 0.1  |
| Medication                   | As required to achieve desired active medication level in finished feed |      |

#### 2.2.4.3 Micromachines

Micromachines are specialised equipment for the administration of concentrated micro medications and other low inclusion ingredients directly into batches of finished feed. Ingredients suitable for micromachines include:

- Vitamins
- health additives (organic trace minerals)
- chromium
- yeasts
- direct-fed microbials)
- ionophores
- prescription antibiotics (Tylan, virginiamycin, CTC, OTC).

There are two types of micromachines (Hutchenson, 2014).

1. Weight lost: Storage bins fitted with individual scales which can run simultaneously. Weighed ingredient/s are transferred to the finished feed directly by pneumatic, mechanical or water flush systems.
2. Weight gain: Bins discharge individually into a common hopper on scales, the weigh system records the accumulating weight and switches off when the required quantity reached. The combined ingredients are transferred to the finished feed directly as described for the weight lost type micromachine or transferred to finished feed via a mixing chamber and added as a liquid slurry.

Water is often used as a method of final transfer after the micro ingredients are weighed and conveyed from the bin. Pressured water transfers ingredients into the mixer with a flush of water that follows to clear the line ready for the next batch.

A micromachine with multiple bin capacity has not been set up in Australia at this stage. Technical capability, service of equipment (calibration, maintenance, software control) and cost has been a limitation. Individual additive companies do supply and maintain single delivery bins. These operate separate to batching software, controlled by delivery operator based on load size.

Benefits of micro machines in Australia include:

- Flexibility for changing dose rates by batch rather than having a set rate per tonne.
- Improved uniform delivery and mixing rather than dealing with ingredients directly into the mixer.
- Avoids the requirement to extend micro ingredients through premixes, saving freight and manufacturing costs.
- Safety in handling bags of individual medications.
- Improved inventory control and usage of feed additives.

Considerations for investing in micro machines include:

- Requirement for licensing as the concentration level of feed additive ingredients are classified as S4.
- Low turnover of micro ingredients requires re-bagging, increasing cost.
- Investment in separate climate-controlled room/s for secure storage (lockable area if classed as S4) of micro ingredients and operation of micromachine.
- Operated by trained staff with understanding of the risks associated with handling highly concentrated micro ingredients (see 4.3.4).
- Good stock management procedures (first in first out, expiry dates, batch numbers) and records (see 4.3.4).
- Regular validation of scale system accuracy by calibration.
- Daily checking of each bin ensuring sufficient product is available to avoid interruption to weighing and to promote the flow of product from the bin.

2.2.5 Veterinary feed additive records, storage and safe handling

Manufacturing operations should source and maintain current copies of veterinary products relevant MSDS (Material Safety Data Sheet).

Information required for maintaining records for storage and use of veterinary feed additives is provided in **Table 7**.

Table 7: Veterinary feed additive records

| Record information                    | Example                                            |
|---------------------------------------|----------------------------------------------------|
| Produce name                          | Rumensin Technical                                 |
| Manufacturer name                     | Elanco Animal Health                               |
| Manufacturer contact and mobile       | James Cook, XXX XXX XXX                            |
| Active ingredient                     | Monensin sodium                                    |
| Concentration of active ingredient    | 800,000mg/kg                                       |
| Batch #                               | 654321                                             |
| Expiry date                           | 06/03/2026                                         |
| Storage requirements                  | Store below 30°C (room temperature) in a dry place |
| Bag weight                            | 52.8kg                                             |
| APVMA #                               | 55725                                              |
| Registration coverage                 | All states of Australia                            |
| Schedule Classification               | S4                                                 |
| Veterinary prescription (if required) | Nil                                                |

Storage requirements for veterinary feed additives include:

- Store additives in clean, dry, sealable labelled containers.
- Keep additives in sealed containers when not in use.
- Hold additives in a well-ventilated area.
- Ensure the storage area is dry, not exposed to direct sunlight and below 30°C air temperature.
- If spills occur:
  - » clean up immediately
  - » avoid all personal contact, including inhalation
  - » use dry cleanup procedures (sweep, shovel, vacuum), but avoid generating dust
  - » place spilled product in clean dry sealable labelled container.

Recommendations for veterinary feed additive handler safety include:

- Obtain and review relevant MSDS (Material Safety Data Sheet).
  - » Ensure staff have read and understand the directions provided by the MSDS.
- Avoid all personal contact (eyes, skin) including inhalation.
- Wear protective clothing (cotton overalls), buttoned to the neck with washable elbow length PVC gloves, goggles and half facepiece respirator with dust cartridge/cannister.
- Wash hands, arms and face with soap and water immediately after handling.
- Wash gloves, goggles and contaminated clothing after each daily use.
- Avoid creating dust when handling additives.
- Avoid sources of static electricity for explosive risk mitigation.

All S4 additives (all antibiotics with the exception of flavophospholipol/bambergmycin) have a legal requirement to observe the relevant state regulations regarding prescription and supply. S4 additives should be held in a lockable room with access only available to authorised persons.

### 2.2.6 Prevention of cross contamination and mixer flush procedure

Cross contamination can occur within a mixer when finished feed containing a veterinary feed additive is inadvertently transferred to cattle that do not require medication. This can occur when:

- Carryover feed remains in the mixer.
- Concentrated medication is loaded directly into the mixer rather than in a diluted premix form. Veterinary feed additives can possess very small particle size, increasing surface area and resulting electrostatic charge. These particles can adhere to surfaces within the mixer.

Developing systems to eliminate or reduce the risk of cross contamination is critical for maintaining product integrity. Strategies which reduce risk of cross contamination include:

- dedicated batching and mixing equipment for feeding medicated feed
- cleaning protocols for equipment used for delivery of medicated feed
- implement flushing protocol.

Flushing is the practice of cleaning and clearing equipment and systems after the addition of medicated additive. This may involve running a neutral product through the system to clear out any remnant ingredients.

- Controlled Production Scheduling.
  - » Group feeds with the same ingredients in succession
  - » Schedule non-medicated feeds first, then move onto medicated feeds which reduces the number of flushes required.
- Quality Control Measures.
  - » Conduct routine testing of raw materials and finished products to detect contaminants or unwanted ingredients.
- Employee Training.
  - » Train staff on the importance of cross-contamination and prevention methods including proper handling of veterinary feed additives.
- Tracking Systems to monitor veterinary feed additive movement throughout the manufacturing process, helping to identify potential contamination points.

Procedure for flushing mixer includes:

1. Preparation – Review production schedule and confirm when the best time to flush is e.g. changing from medicated feed to non-medicated feed.
2. Ensure appropriate ingredients for flushing is available (limestone or silage) and notify personnel of flushing activity.
3. Ensure that all personnel involved in the flush wear appropriate PPE (gloves, masks, goggles etc).
4. Follow personal hygiene protocols, including handwashing.
5. Remove any remaining feed residue from within the mixer.
6. Effective flushing requires sufficient ingredients to be loaded into mixer to cover the mixing components and majority of surfaces.
7. Flush material will need to be separated and quarantined. This material can be used later, in rations containing medicated feed.
8. Record keeping – Document the flush procedure, including the:
  - a. date and time of the flush.
  - b. personnel involved
  - c. equipment flushed
  - d. observations or issues concerned.
9. Maintain records for traceability and regulatory compliance.

10. Validate the process by taking samples from the flushed equipment to test for residuals.

### 2.2.7 Antimicrobial use and surveillance

Antimicrobial reporting of use and surveillance of resistance in agricultural livestock is critical to:

- maintain effectiveness of “last line” antibiotics
- minimise transfer of resistance to other bacteria
- avoid creating multi-resistant bacterial strains such as *Staphylococcus aureus* (MRSA)
- maintain functionality and availability of antibiotics for disease control in both humans and livestock.

In Australia, antimicrobial resistance surveillance occurs in two areas:

1. Bacteria that effect health of cattle.  
Primary focus on bacteria involved in the bovine respiratory disease (BRD) complex. Specific bacterial include *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*.
2. Bacteria which infect food and effect human health.  
Primary focus on *E.coli*, *Enterococcus*, *Salmonella* and *Campylobacter* species.

In Australia, antimicrobials for use in feedlots can only be provided through prescription from a veterinarian. Veterinarians implement ‘prudent use’ strategies when determining appropriate treatment regime. Prudent use strategies include identifying appropriate antibiotic for diagnosis, treatment program, dose rate and method of administration, define WHP and ESI and include review and monitor outcomes of treatment strategies.

Australia does not have a national surveillance program for monitoring antimicrobial resistance but relies on periodic surveillance with the objective of identifying presence and trends of antimicrobial resistance.

Antimicrobial surveillance focuses on bacteria which are present in livestock (faecal, caecum or carcass, pose a threat to human health by transfer along the food chain and provide indicator to the presence of resistance or resistant gene as described in **Table 9**).

**Table 9: Bacteria selected for surveillance of antimicrobial resistance in cattle (Webber & Valois, 2003)**

| Pathogens                                  | Zoonotic              | Commensal or indicator       |
|--------------------------------------------|-----------------------|------------------------------|
| <i>Pasteurella</i> spp (gram -ve)          | <i>Salmonella</i> spp | <i>Escherichia coli</i>      |
| <i>Haemophilus somni</i> (gram -ve)        |                       | <i>Enterococcus faecium</i>  |
| <i>Staphylococcus aureus</i> (gram -ve)    |                       | <i>Enterococcus faecalis</i> |
| <i>Streptococcus agalactiae</i> (gram -ve) |                       | <i>Enterococcus hirae</i>    |
| <i>Streptococcus uberis</i> (gram +ve)     |                       |                              |

Antimicrobial resistance is assessed across a specific range of antimicrobials as described in **Table 10**.

The antimicrobials of interest to beef cattle are those that have been rated as high importance and include the cephalosporins (ceftiofur antibiotics – Excenel and Excede) and streptogramins (virginiamycin).

The other high importance antibiotic is Polymyxin B, used to treat eye infections. Polymyxin is a last line treatment option for control of multi-resistance gram positive bacteria. Although the ceftiofur and virginiamycin are not currently used in human health, both risk potential to select resistance across groups of antimicrobials. All antimicrobials defined as high importance are classified as Schedule 4 and require a veterinary prescription for use. Off-label use is strictly prohibited.

The outcomes of the periodic surveillance conducted to determine antimicrobial resistance level and trends are described in **Table 11**. Results show that bacterial isolates resistant to highly important antimicrobials are low and remaining low.

The survey results show there is limited evidence of production practices such as grain feeding which increases risk of antimicrobial resistance. The ceftiofur and virginiamycin are the only antimicrobials likely to cause resistance and be a public health risk. However, any use of antimicrobials poses a risk to the development of antimicrobial resistance with the ability of bacteria to acquire and/or transfer antimicrobial mechanisms.

**Table 10:** Antimicrobial classes used to assess antimicrobial resistance in beef cattle (Webber & Valois, 2003)

| Antimicrobial class | Animal pathogens<br>Gram -ve | Animal pathogens<br>Gram +ve | <i>Salmonella/</i><br><i>Esxherichia coli</i> | <i>Campylobacter</i> | <i>Enterococcus</i> |
|---------------------|------------------------------|------------------------------|-----------------------------------------------|----------------------|---------------------|
| Aminoglycosides     | ⊕                            | ⊕                            | ⊕                                             |                      | ⊕                   |
| Amphenicols         | ⊕                            | ⊕                            | ⊕                                             |                      |                     |
| Beta-lactams        | ⊕                            | ⊕                            | ⊕                                             | ⊕                    | ⊕                   |
| Cephalosporins      | ⊕                            |                              | ⊕                                             |                      |                     |
| Glycopeptides       |                              | ⊕                            |                                               |                      | ⊕                   |
| Lincosamides        |                              | ⊕                            |                                               |                      |                     |
| Macrolides          |                              | ⊕                            |                                               | ⊕                    | ⊕                   |
| Quinolones          | ⊕                            | ⊕                            | ⊕                                             | ⊕                    | ⊕                   |
| Streptogramins      |                              |                              |                                               |                      | ⊕                   |
| Sulfonamides        | ⊕                            |                              | ⊕                                             |                      |                     |
| Tetracyclines       | ⊕                            | ⊕                            | ⊕                                             | ⊕                    | ⊕                   |

**Table 11:** Survey summary of antimicrobial resistance to bacterial isolates in beef cattle

| Year              | Bacterial isolates                   | Head# | Resistance %                                          | Conclusion                                                                                                     |
|-------------------|--------------------------------------|-------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| DAFF 2007         | E.coli                               | 194   | Both isolates: 1% Florfenicol and Tetracycline        | Low resistance to high importance antimicrobials                                                               |
|                   | Enterococcus                         |       | 9.5% Erythromycin and Virginiamycin                   |                                                                                                                |
| Barlow et al 2015 | E.coli<br>Salmonella                 | 910   | Nil resistance identified                             | As above                                                                                                       |
| Barlow et al 2017 | Enterococcus                         | 910   | 80.2% Flavomycin<br>94.2% Lincomycin                  | High resistance to antimicrobials not critically important<br>Low resistance to high importance antimicrobials |
| Barlow et al 2020 | E.coli<br>Salmonella<br>Enterococcus | 591   | 3.6% Ceftiofur<br>0.2% Ceftiofur<br>10% Virginiamycin | Low resistance to high importance antimicrobials                                                               |

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# 4. Appendix

## 4.1 Feedlot liquid supplement storage management and use

A survey of Australian feedlots was conducted to identify how liquid supplements are managed at the feedlot. Lot feeders were asked to take five duplicate samples from their storage tank during use at 95%, 75%, 50%, 25% and 5% of tank capacity. An additional duplicate sample was taken directly from the delivery tanker to provide a reference level.

The key storage and management practices which influence supplement integrity and consistency are outlined below. Monensin concentration (mg/kg DM) was used to quantify the effects.

### Key takeaways

- Greatest variability occurs when tanks are refilled before being completely emptied or when multiple tanks are used without full clean-out.
- Shared transfer lines can alter concentration through product carryover.
- Short-term storage (≤3 weeks) has minimal impact on concentration when supplements are managed correctly.
- To maintain consistent monensin delivery, tanks should be fully emptied where practical, regularly cleaned, and dedicated transfer systems used where possible.

| Scenario                 | Key observation                                                                                                                                                                                    | Impact on monensin concentration                                     |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Flat bottom tank         | Tank refilling occurs before complete emptying. Monensin concentration decreases immediately after refill and increases as the tank empties.                                                       | Variable concentration (+100 mg/kg DM range observed).               |
| Multiple tanks in use    | Residual supplement remains in tanks or tanks are not fully emptied/cleaned before refilling.                                                                                                      | Progressive increase in concentration over time due to accumulation. |
| Shared delivery          | Different liquid products (e.g. water, molasses, glycerol, vegetable oil or liquid supplements) are delivered through the same line. Variations in density and viscosity create carryover effects. | Moderate variation in concentration within the tank.                 |
| Usage within three weeks | Suspension supplements remain relatively stable when used within three weeks of delivery.                                                                                                          | Minimal change in concentration, remaining within specification.     |



Veterinary feed additive safety guidelines: For nutritionists and supplement manufacturers

## Liquid supplement storage

**Cone bottom tank**



Fitted with a shut-off valve, an isolation valve and a sampling outlet

**Flat bottom tank**



Not suitable – Outlet on the side of the tank; therefore, the supplement does not empty evenly, resulting in accumulated residues

**Multiple tanks**



Fully empty one tank before re-filling

**Single tank**



Flush cone annually with water

**Multiple liquid ingredients**

Water, vegetable oil, molasses, liquid supplement, glycerol

**Shared delivery line**

Increase shrink

**Separate delivery lines for each ingredient**



**Turnover period**

**More than three weeks**

Mix by recirculation, avoid prolonged mixing or aeration, regularly check supplement consistency, and reformulate for higher inclusion if required

**Within three weeks**

No additional management needed

**Reliable and stable supplement**

## 4.2 Prescription example

### Prescription for medicated feed

|                                     |                                   |
|-------------------------------------|-----------------------------------|
| <b>Feed manufacturer</b>            | <b>Lot feeder/Producer</b>        |
| Name _____                          | Name _____                        |
| Email _____                         | Account _____                     |
| Phone _____                         | Delivery address _____            |
| Address _____                       | _____                             |
| _____                               | _____                             |
| _____                               | _____                             |
| <b>Medicated feed</b>               | <b>Directions for use</b>         |
| Type (calf, supp) _____             | Daily feed rate (kg/hd/day) _____ |
| Form (crushed grain, pellets) _____ | Duration (days) _____             |
| Total amount mixed _____            | WHP Meat (days) _____             |
| Active ingredient _____             | WHP Milk (days) _____             |
| Product name _____                  |                                   |
| Mixing rate (kg/tonne) _____        | <b>Veterinarian</b>               |
| Treatment purpose _____             | Date _____                        |
| _____                               | Name _____                        |
|                                     | Email _____                       |
|                                     | Phone _____                       |
|                                     | Address _____                     |
|                                     | _____                             |
|                                     | _____                             |
| <b>Animals treated</b>              |                                   |
| Location _____                      |                                   |
| Species _____                       |                                   |
| Type _____                          |                                   |
| Age _____                           |                                   |
| Number _____                        |                                   |

Precautions: Ensure that animals or birds other than those specified on this form DO NOT have access to this medicated feed.

Veterinarian Practice name, principal veterinarian, address, contact person/s, phone and email.

## Notes

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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