

Zilmax Feedyard and Supplier Certification Plan

Zilmax Feedyard Certification (ZFC) General Requirements and Processes

- ZFC process/training will be managed in person by qualified Merck Animal Health personnel.
- All feedyards will be required to complete ZFC training, independent of using Type A or Type B Zilmax supplements.
- Each feedyard location will complete a training program, providing it with the knowledge and tools to utilize Zilmax appropriately in its cattle feeding operation.
- For any individual involved with Zilmax feeding, there will be a verification process to confirm that all individuals have completed ZFC training. Trainees will be tested to evaluate their understanding of the proper use of Zilmax. Individual ZFC training logs with the feedyard's certification record will be kept in the Merck Animal Health database.
- Feedyards will be provided access to an on-line training module for refresher training, as well as new employee training.
- Consulting or staff veterinarians and nutritionists will be required to complete the ZFC training program before the yard they are affiliated with can be certified.
- Feedyard employees and consultants will be required to complete re-certification annually.
- During the certification process, Standard Operating Procedures (SOPs) for each feedyard will be adopted and recorded with certification in the database. SOPs must include but not be limited to:
 - Human safety/handling requirements
 - Equine safety
 - Zilmax inventory control
 - Daily production records
 - Feed milling - Zilmax inclusion and validation process(s)
 - Sequencing of feed/flushing of mill
 - Excessive Zilmax feed production and spillage
 - Feed delivery (pen management)
 - Assay protocol/out-of-tolerance investigation
 - Withdrawal management (feed)
 - Withdrawal management (cattle)
 - Pen identification
 - Stray cattle and cattle movement management
 - Action plan for inadvertent shipment of cattle with potential residue risk
- The End-User Zilmax Supply Agreement with Merck Animal Health identifies preferred Zilmax supplier(s) and sets forth guidance for use, SOPs and stipulations of retaining certification.
- Access to purchase Zilmax will be allowed once feedyards have completed training and certification according to Merck Animal Health's Zilmax Feedyard Certification Plan. In addition, feedyards will be required to follow Merck Animal Health's Best Management Practices Plan for selecting cattle to be fed Zilmax.

Ongoing Certification Requirements

- A homogeneity test is required with certification within 30 days of first feeding and as stipulated in the Zilmax Supply Agreement.
- Feed milling/mixing, process changes or significant ration dry matter changes (greater than 10%) require updated homogeneity tests within 30 days of process/ration change.

- At least four feed assays of Zilmax type C feeds and subsequent withdrawal rations will be performed by Merck Animal Health each year. At least one assay will be conducted at random (unannounced or unscheduled). Failed assays (outside of 75% to 115% of expected level on a 90% dry matter basis) will be investigated, documented and assays retaken as stated in the SOPs.
- Merck Animal Health and certified feedyard/organization shall review and/or update SOPs annually or as needed.
- Annual re-certification by qualified Merck Animal Health personnel will be managed in person.

Certification Database

- Allows Merck Animal Health to manage Zilmax supply to end-user feedyards by utilizing agreements with third-party authorized suppliers (i.e., distributors and feed manufacturers).
- Records/stores additional items like certifications, assay results, supplier authorization and SOPs.
- Feedyards will identify preferred Zilmax supplier(s), and Merck Animal Health will notify approved suppliers that a feedyard has met all requirements to purchase and feed Zilmax.

Zilmax Suppliers

- Merck Animal Health will have a limited number of Authorized Zilmax Distributors which allows Merck Animal Health to manage and track the sales of Zilmax from these distributors to Certified Feedyards.
- All authorized Zilmax Distributors will be required to complete Zilmax Feedyard Certification Training.
- Sales of Zilmax will be managed by Merck Animal Health through the Certification Database and Zilmax End-User Agreements.

Zilmax End-User Agreement

The formal agreement between Merck Animal Health and Feedyard customer/organization outlining conditions of ZFC and the use of Zilmax will:

- Identify preferred Zilmax suppliers.
- Identify list of packers to receive ZFC notification.
- Formal agreement outlines elements of certification:
 - Timelines on training(s)
 - Timeline for SOP development
 - Timeline for completion of homogeneity tests
 - Conditions outlining new homogeneity tests
- Non-compliance with SOPs terminates agreement.
- Out of compliance on withdrawal/residue issues terminates agreement.
- Use/transfer of Zilmax in/to non-certified facilities terminates agreement.

Zilmax has a withdrawal period of 3 days prior to harvest. Not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves. Not to be fed to cattle in excess of 90 mg/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb./head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed. For complete information, refer to the product label.