Guidance to Wisconsin Medicated Feed Good Manufacturing Practices

This is a guidance document only, it is not a comprehensive manual for compliance, and does not constitute legal advice. It is the responsibility of the commercial feed manufacturer/distributor to ensure they are in compliance with the applicable laws and requirements. Following the guidance in this document does not preclude regulatory or compliance action by the Wisconsin Department of Agriculture, Trade, and Consumer Protection when authorized by state law, nor does it release any commercial feed manufacturer or distributor from legal responsibility or liability of any kind.

Inspection Overview

Manufacturers of medicated feed in Wisconsin are subject to random, unannounced inspections to ensure compliance with Wisconsin commercial feed regulations, Wis. Stat. § 94.72 and Wis. Admin. Code chapter ATCP 42, specifically the good manufacturing practices in Wis. Admin. Code § ATCP 42.46. Inspections offer a facility, and consumers, the opportunity to receive a regulatory perspective on the facility's ability to manufacture animal feed that is not adulterated and is properly labeled [reference Wis. Admin. Code § ATCP 42.46(1)].

Each inspection will review:

1. The current commercial feed license, if applicable;
2. Cleanliness and maintenance of buildings and equipment;
3. Control and storage of drug components;
4. Recordkeeping and record retention; and
5. Randomly selected feed labels.

Commercial Feed License

Each person or entity that distributes, manufactures, and/or labels a commercial feed or feed ingredient in Wisconsin is required to be licensed. The license requirement has three exceptions [reference Wis. Admin. Code § ATCP 42.02]:

- Distribution of packaged commercial feed as packaged and labeled by the entity listed on the label;
- Distribution of bulk commercial feed in the form received from and labeled by a licensee, except for net weight statement;
- Distribution of custom-mixes, if ingredients in the mixture were already reported as tonnage distributed by another licensee[1].

Typically, the exceptions apply to retailers such as convenience stores, or big box stores that merely distribute products made and labeled by another manufacturer. The license applications are available online: https://datcp.wi.gov/Pages/Programs_Services/CommercialFeedLicensingFormsandTonnageReporting.aspx.

Housekeeping

Regulations for cleanliness and maintenance of buildings and equipment are broad, to encompass the various manufacturing capabilities in the medicated feed industry. Specifically, buildings and equipment must be adequate for the purpose used, routinely cleaned and maintained, and kept free of unhealthful or unsanitary conditions [reference

[1] There is no requirement of a licensee to indicate to another business if they are or are not reporting tonnage and remitting inspection fees on commercial feed distributions. Licensees are to assume the tonnage is reported and inspection fees paid.

Wis. Admin. Code §§ ATCP 42.46(2) & (3)]. Buildings and equipment shall facilitate the manufacture of a proper animal food, and shall protect the incoming ingredients, blends in progress, and outgoing finished feeds from pests (rodents, vermin, birds, or insects), biological contaminants (e.g., infectious diseases, potentially harmful microorganisms), and the elements.

Specific to equipment, cleanliness is important to mitigate the risk of cross contamination. Ingredient build-up can occur on augers, ribbons, and paddles from molasses, oil, and other ingredients. Firms may include procedures such as sequencing, flushing, and/or physical clean-out (wet or dry) to proactively prevent cross-contamination.

Finally, scales must be accurate. Scale calibration occurs at the facility's option, via set weights, an official DATCP Weights & Measures inspection, or a third-party calibration service.

Non-Feed Materials

Areas and equipment used to manufacture, handle, or store commercial feeds may not be used to manufacture, handle, or store fertilizers or pesticides [reference Wis. Admin. Code § ATCP 42.46(4)]. The exception is if a pesticide or fertilizer is approved for use in animal feed, such as a pesticide for fly control in the manure of treated animals.

Drug Component Inventory

As with Federal regulation, medicated feed manufacturers are required to establish and maintain standard operating procedures for identifying, storing, and controlling inventories of Type A medicated articles and Type B medicated feeds used in manufacturing medicated feeds [reference Wis. Admin. Code § ATCP 42.46(6)(a)]. The purpose of the procedures is to preserve the identity, strength, quality and purity of the drug sources. Inventory, ideally, is tracked on paper via handwritten entries, referred to as the "theoretical" inventory. Next, the procedure establishes a specific frequency, adequate for the level of drug use in manufacturing at the facility, to which the theoretical inventory is compared to the actual/physical inventory. Last, firms should consider establishing an established variance via the inventory standard operating procedure. The significant discrepancy will be the point at which an investigation will occur to determine why the theoretical inventory does not match the actual inventory.

The emphasis with drug component inventory is to ensure drugs used in manufacturing are:

- clearly identified from receipt, during use, and through finished product;
- that the drugs are properly stored to maintain identity of the active drug ingredient itself and to maintain identity of the drug within different production runs of the component [reference Wis. Admin. Code § ATCP 42.46(6)(b)]; and
- drug components in inventory can be used before the drug expiration date.

Drug Component Use

Facilities manufacturing with animal drugs have a responsibility for ensuring medicated feeds are manufactured according to the drug source label for the active ingredient level and the indication (purpose) [reference Wis. Admin. Code § ATCP 42.46(6)(c)]. With medicated feeds, the label is the law. Therefore, if a drug source label does not include a specific indication, the drug source may not be used to manufacture a medicated feed for that indication. For example, some Type B medicated feeds are labeled for one, single indication or drug purpose. However, the drug may actually be approved for multiple uses or purposes. If the label only has one of the indications or purposes on it, then that single indication is the only reason that drug can be used in a feed.

In addition, a feed label containing all of the required medicated information – indication, drug level, use directions, and precautionary statements - must accompany the outgoing feed. Prior to manufacturing a medicated feed, especially if

the formula came from an outside nutritionist, take a minute to review the formula and indication. Verify the indication is approved for that drug, at the level requested (and calculated according to the formula). If the formula calls for a drug combination, confirm that the combination is allowed under the Federal approvals. Finally, ensure that the label intended to go with the feed contains adequate use directions and precautionary statements. Specifically, look for something to the effect of "feed X pounds per head per day or feed X pounds per pound of bodyweight per head per day". Use directions that say "feed according to your nutritionist's instructions" are not adequate.

Records

Facilities are required to keep records of all manufactured products, including product formulas, manufacturing dates, batch numbers, and shipment dates for one year from the date the feed was manufactured [reference Wis. Admin. Code § ATCP 42.46(8)]. The records requirement enables a facility to conduct a recall of specific batches of feed should an issue arise with any ingredient used in the feed. In the recent past, recalls have been related to copper levels, salt levels, and other issues, including medicated feed levels. Furthermore, records help to ensure that sequencing and/or flushing occur to avoid unsafe carryover of drug residues.

Facilities are also required to keep records of all custom-mixed feed for one year from the date the feed was manufactured [reference Wis. Admin. Code § ATCP 42.24(2)]. The records requirement enables a facility to identify affected batches of feed should an issue arise with any ingredient used in the feed. Information required to be within the retained records include:

- The name and address of the manufacturer;
- The name and address of the purchaser;
- The date on which the manufacturer sold or delivered the custom-mixed feed to the purchaser;
- The name of the custom-mixed feed;
- The net quantity of the custom-mixed feed;
- The name and net quantity of every commercial feed and every other ingredient used to manufacture the custom-mixed feed;
- All medicated feed information if the custom-mixed feed contains a drug; and
- Applicable use directions and precautionary statements. If any commercial feed used in manufacturing a custom-mixed feed is labeled with use directions or precautionary statements, the manufacturer of the custommixed feed shall provide those use directions and precautionary statements to the purchaser. **Other Good Manufacturing Practice Resources**

DATCP Resources:

- Medicated Feed Manufacturing Requirements Video - https://youtu.be/Osrc-NuuON0
- Field investigator contacts: https://datcp.wi.gov/Pages/Programs_Services/EnforcementInspection.aspx
  Feed Program contact: datcpfeed@wisconsin.gov or 608-224-4539

The following documents offer information about the Federal Food and Drug Administration (FDA) and feed manufacturer responsibilities. The materials are free and available upon request from the Center for Veterinary Medicine, Communications Staff, HFV-12, 7519 Standish Place, Rockville, Maryland 20855. Some of the materials are available on CVM's Internet Web Site at http://www.fda.gov/AnimalVeterinary/default.htm.

- FDA Compliance Program 7371.003 – Feed Contaminants Program
- Code of Federal Regulations, Part 225, Current Good Manufacturing Practice Regulations for Medicated Feeds
- Code of Federal Regulations, Part 558, New Animal Drugs for Use in Animal Feeds

- Guidance Document #68 -- Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors
- Guidance for Industry #72 – GMP's For Medicated Feed Manufacturers Not Required to Be Licensed with FDA