State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-SEVENTH SESSION

H. F. No. 1926

01/26/2012 Authored by null
The bill was read for the first time and referred to the Committee on Agriculture and Rural Development Policy and Finance
02/08/2012 Adoption of Report: Pass and re-referred to the Committee on Government Operations and Elections
02/13/2012 Adoption of Report: Pass and Read Second Time
02/16/2012 Calendar For The Day
Read Third Time
Passed by the House and transmitted to the Senate
02/27/2012 Passed by the Senate and returned to the House

A bill for an act

relating to agriculture; providing for voluntary certification of good manufacturing practices for commercial feed and feed ingredients; authorizing fees for voluntary certification; modifying rule provisions relating to animal feed; appropriating money; amending Minnesota Statutes 2010, section 25.40, subdivisions 1, 2, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapter 25; repealing Minnesota Rules, parts 1510.2220; 1510.2230.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[25.371] GOOD MANUFACTURING PRACTICES CERTIFICATE FOR COMMERCIAL FEED AND FEED INGREDIENTS.**

Subdivision 1. **Definition of words and terms.** In addition to the definitions in section 25.33, for the purpose of this section, the terms defined in this subdivision have the meaning given them.

(a) "Adulteration" means the presence of any poisonous or deleterious substance at a level that may render feed or feed ingredients injurious to human or animal health, as provided in section 25.37, paragraph (a).

(b) "Establishment" includes, but is not limited to, buildings, structures, facilities, equipment, and conveyances that receive, store, manufacture, process, package, label, transport, or distribute feed or feed ingredients.

(c) "Pest" means any objectionable animal, including, but not limited to, bats, birds, rodents, insects, and insect larvae.

Subd. 2. **Certificate application.** (a) A person may apply to the commissioner for a good manufacturing practices certificate for commercial feed and feed ingredients. Application for good manufacturing practices certificates must be made on forms provided or approved by the commissioner. The commissioner shall conduct inspections of

facilities for persons that have applied for or intend to apply for a good manufacturing practices certificate for commercial feed and feed ingredients from the commissioner. The commissioner shall not conduct an inspection under this section if the applicant has not paid in full the inspection fee for previous inspections. Certificate issuance shall be based on compliance with subdivisions 3 to 14, or United States Food and Drug Administration rules regarding preventive controls for animal feed.

(b) The commissioner may assess a fee for the inspection, service, and work performed in carrying out the issuance of a good manufacturing practices certificate for commercial feed and feed ingredients. The inspection fee must be based on mileage and the cost of inspection.

Subd. 3. **Personnel.** (a) Persons working in direct contact with feed and feed ingredients must conform to good hygienic practices to minimize the risk of adulteration.

(b) Persons who receive, store, manufacture, process, package, label, sample, transport, or distribute feed or feed ingredients must be trained for the persons' areas of responsibility.

Subd. 4. **Establishments.** (a) Establishments must be of a size, construction, and design to facilitate routine maintenance and cleaning.

(b) The grounds of establishments must be maintained in a condition that minimizes pest infestation of feed or feed ingredients.

Subd. 5. **Maintenance and housekeeping.** (a) Establishments must be kept in sufficient repair and condition to minimize the risk of adulteration.

(b) Establishments must be cleaned in a manner and at a frequency that minimizes the risk of adulteration.

(c) Establishments must implement procedures that are effective in minimizing pest infestation of feed or feed ingredients.

(d) Substances not approved for use in feed or feed ingredients must be received, stored, and used in a manner that minimizes the risk of adulteration, and in accordance with applicable laws and regulations. These substances must be physically separated from work areas and equipment used for the production or storage of feed and feed ingredients.

Subd. 6. **Equipment.** (a) All equipment, including scales, metering devices, and mixers must be of a suitable size, design, construction, precision, and accuracy for the equipment's intended purpose, and to minimize the risk of adulteration.

(b) All equipment, including scales, metering devices, and mixers must be designed to facilitate inspection and cleaning, and must be properly maintained and operated to minimize the risk of adulteration.

(c) All equipment must be constructed and maintained so as to minimize the risk of lubricants and coolants becoming adulterants in feed or feed ingredients.

(d) All scales and metering devices must be tested for accuracy upon installation and at least annually thereafter.

(e) All mixers must be tested to demonstrate the capability of the equipment to produce a homogeneous mix upon installation and periodically thereafter to ensure proper function. Mixers must be operated utilizing procedures that provide for proper mixing and proper mixing times as demonstrated by testing.

(f) Records sufficient to document the testing of equipment identified in paragraphs (d) and (e) must be maintained until a subsequent test is conducted or for one year from the date of the test, whichever is longer.

Subd. 7. **Receiving and storage for further manufacture.** Specifications and procedures effective in minimizing the risk of adulteration must be established and implemented to govern the acceptance, rejection, and storage of inbound feed or feed ingredients intended for further manufacturing of feed or feed ingredients. The procedures must include the following:

(1) feed or feed ingredients must be visually inspected during receiving to confirm identity and check required labeling;

(2) feed or feed ingredients to be used in the further manufacture of feed or feed ingredients must be stored in a manner that maintains the identity and minimizes the risk of adulteration;

(3) cleanout procedures must be established and implemented for equipment, conveyances, and storage structures or containers that are effective in minimizing the risk of adulteration of feed or feed ingredients;

(4) inventory practices, including inventory rotation, must be established and implemented for feed or feed ingredients to minimize the risk of adulteration; and

(5) records must be maintained identifying the immediate previous source, quantity, type or name, and date received for each feed or feed ingredient for at least one year from the date of disposition.

Subd. 8. **Manufacturing.** (a) A feed or feed ingredient that is considered adulterated must not be used in the manufacture of feed or feed ingredients unless made safe for the feed or feed ingredient's intended use.

(b) Procedures effective in minimizing the risk of adulteration and ensuring safety and identity must be established and implemented for the manufacture of feed or feed ingredients. The procedures must include the following:

(1) a description of the manufacturing operation, which may include, but is not limited to, feed or feed ingredient formulation, mixing, and production practices;

(2) measures effective in minimizing manufacturing errors that may result in adulteration of feed or feed ingredients. The measures must include, but are not limited to:

(i) cleanout practices, which may include sequencing, flushing, or other methods; and

(ii) measures to minimize the inclusion of physical adulterants, including metal, in feed or feed ingredients.

(c) Records sufficient to document the production history of the feed or feed ingredient manufactured in the establishment must be maintained for at least one year from the date of disposition.

Subd. 9. **Packaging.** (a) Packaged feed or feed ingredients must be packaged in a manner that maintains identity and minimizes the risk of adulteration.

(b) Bags and totes used as packaging for feed or feed ingredients must not be reused unless cleaned using effective and documented cleanout procedures.

(c) Records sufficient to document these cleanout procedures must be maintained for at least one year from the date of disposition.

Subd. 10. **Labeling.** (a) A label or other unique identifier must be affixed to, or accompany feed or feed ingredients to maintain identity and facilitate safe and effective use.

(b) Labels must be stored, handled, and used in a manner that minimizes errors.

(c) Obsolete labels must be discarded promptly.

Subd. 11. **Storage of finished feed or feed ingredients.** (a) Finished feed or feed ingredients must be stored in a manner that minimizes the risk of adulteration. The bin, bulk tank, or other location where feed or feed ingredients are stored must be clearly identified.

(b) Inventory practices, including inventory rotation, must be established and implemented for feed or feed ingredients to minimize the risk of adulteration.

Subd. 12. **Inspection, sampling, and testing of incoming and finished feed or feed ingredients for adulterants.** (a) Finished feed or feed ingredients must be visually inspected for the presence of visible adulterants and verification of identity.

(b) When sampling and testing of feed or feed ingredients is performed by the establishment to monitor for adulteration, test results must be reviewed by trained personnel. Test results that indicate feed or feed ingredients are adulterated must be investigated by the establishment. Investigations may include, but are not limited to, review of:

(1) ingredient specifications used in the development of the formula;

(2) formula;

(3) production records; and

(4) sampling and testing methods.

(c) Records must be kept for at least one year after the investigation and review of test results for adulterants, and of any corrective action or actions taken when adulterants are detected. Records must not be used as the sole basis for official enforcement actions or penalties by the commissioner.

Subd. 13. **Transportation of feed or feed ingredients.** Feed or feed ingredients must be transported utilizing methods that minimize the risk of adulterations, including, but not limited to, the following:

(1) conveyances used to transport feed or feed ingredients must be inspected for cleanliness and structural integrity prior to loading;

(2) feed, feed ingredients, or other materials or substances that may pose a risk of adulterating feed or feed ingredients must not be loaded onto the same conveyance unless measures are taken to minimize risk; and

(3) records must be maintained for each feed or feed ingredient identifying the immediate subsequent recipient, quantity, type or name, unique identifier if available, and date shipped for at least one year from the date of disposition.

Subd. 14. **Voluntary recall; withdrawal.** (a) Sufficient records and other information concerning the identity and disposition of feed or feed ingredients must be maintained for at least one year from the date of disposition to permit the rapid and effective recall from the marketplace or withdrawal from feeding if a feed or feed ingredient is found to be adulterated.

(b) Voluntary recalls of feed or feed ingredients should be guided by procedures outlined by the United States Food and Drug Administration in the Code of Federal Regulations, title 21, section 7.

Subd. 15. **Expiration.** Subdivisions 1 and 3 to 14 expire upon the United States Food and Drug Administration's adoption of rules regarding preventative controls for animal feed.

Sec. 2. Minnesota Statutes 2010, section 25.40, subdivision 1, is amended to read:

Subdivision 1. **Adoption.** The commissioner may adopt rules for commercial feeds, pet foods, and specialty pet foods as are authorized in sections 25.31 to 25.43 and ~~such~~ other reasonable rules as may be necessary for the efficient enforcement of sections 25.31 to 25.43. In the interest of uniformity the commissioner shall by rule adopt, unless the

commissioner determines that they are inconsistent with the provisions of sections 25.31 to 25.43 or are not appropriate to conditions which exist in this state, the ~~following:~~

~~(a) the~~ official definitions of feed ingredients and official feed terms adopted by the Association of American Feed Control Officials and published in the official publication of that organization~~; and~~.

~~(b) any rule promulgated pursuant to the authority of the Federal Food, Drug, and Cosmetic Act, provided, that the commissioner would have the authority under sections 25.31 to 25.43 to adopt the rules.~~

Sec. 3. Minnesota Statutes 2010, section 25.40, subdivision 2, is amended to read:

Subd. 2. **Notice; public comment.** Before the issuance, amendment, or repeal of any rule authorized by sections 25.31 to 25.43, the commissioner shall publish the proposed rule, amendment, or notice to repeal an existing rule in a manner reasonably calculated to give interested parties, including all current license holders, adequate notice and shall afford all interested persons an opportunity to present their views orally or in writing, within a reasonable period of time. After consideration of all views presented by interested persons, the commissioner shall take appropriate action to issue the proposed rule or to amend or repeal an existing rule. The provisions of this subdivision notwithstanding, if the commissioner, pursuant to the authority of sections 25.31 to 25.43, adopts the official definitions of feed ingredients or official feed terms as adopted by the Association of American Feed Control Officials, ~~or regulations promulgated pursuant to the authority of the Federal Food, Drug, and Cosmetic Act,~~ any amendment or modification adopted by ~~said~~ the association ~~or by the secretary of health, education and welfare in the case of regulations promulgated pursuant to the Federal Food, Drug, and Cosmetic Act,~~ shall be adopted automatically under sections 25.31 to 25.43 without regard to the publication of the notice required by this subdivision unless the commissioner, by order specifically determines that ~~said~~ the amendment or modification shall not be adopted.

Sec. 4. Minnesota Statutes 2010, section 25.40, is amended by adding a subdivision to read:

Subd. 3. **Food and drug rules.** Applicable federal regulations including recodification contained in Code of Federal Regulations, title 21, parts 1 to 1299, not otherwise adopted herein, also are adopted as feed rules of this state.

Sec. 5. **REPEALER.**

Minnesota Rules, parts 1510.2220; and 1510.2230, are repealed.

Sec. 6. **EFFECTIVE DATE.**

Sections 1 to 5 are effective the day following final enactment.