Approved March 17, 1987
Date

MINUTES OF THE HOUSE COMMITTEE ON AGRICULTURE AND SMALL BUSINESS.

The meeting was called to order by Representative Clifford V. Campbell at
Chairperson

9:03 a.m./~~p.m.~~ on March 2, 1987 in room 423-S of the Capitol.

All members were present except: Representatives Dean, Solbach, who were excused.

Committee staff present: Norman Furse, Revisor of Statutes Office
Raney Gilliland, Legislative Research Department
Pat Brunton, Committee Secretary

Conferees appearing before the committee: Larry D. Woodson, Director, Division of Inspections, State Board of Agriculture
Chris Wilson, Director, Governmental Relations, Kansas Fertilizer and Chemical Association, Inc.
Jarold W. Boettcher, Vice President, Boettcher Enterprises, Inc., Beloit, Kansas and Co-Chairman, Legislative Committee, Kansas Fertilizer and Chemical Association
Joe Lieber, Executive Vice President, Kansas Cooperative Council

Larry D. Woodson testified on HB 2519 which has to do with mixed feed testing stating that the bill will enable the inspectors to perform more efficiently the duties for which they are now responsible - that being protecting the consumer by helping to assure safe feed stuffs that meet label guarantees, Attachment I.

Hearings were closed on House Bill 2519.

Hearings were held on House Bill 2520 - anhydrous ammonia testing, with Larry D. Woodson testifying in favor of the bill. He stated that the registering of facilities will allow improved monitoring of proposed facilities, better accountability of installations, and will enhance enforcement of regulations in existing facilities, Attachment II.

Chris Wilson testified on House Bill 2520, opposing the bill in regards to registration fees for anhydrous ammonia facilities and reactors, Attachment III.

Jarold W. Boettcher testified in opposition to HB 2520 stating a need for more time to study the bill and provide input, Attachment IV.

Joe Lieber testified in opposition to HB 2520 stating a concern in regards to fees.

A question and answer period followed each of the testimonies.

Representative Denise Apt made a motion to approve committee minutes of February 17, February 18, February 19, and February 24. Representative Susan Roenbaugh seconded and the motion passed.

The meeting adjourned at 9:53 a.m.

The next meeting of the House Agriculture and Small Business Committee will be Tuesday, March 3, 1987, at 9:00 a.m. in Room 423-S.

GUEST LIST

COMMITTEE: HOUSE AGRICULTURE AND SMALL BUSINESS DATE: March 2, 1987

NAME (PLEASE PRINT)	ADDRESS	COMPANY/ORGANIZATION
Mary Harper	Healy	AAM
Larry D. Woodson	TOPEKA	KBOA
Glen H Searcy	Topeka	KBOA
Scott C. Bangert	Topeka	KBOA
Wilbur Leonard	Topeka	Kans Ks Farm Org.
Howard W. Tice	Hutchinson	KAWG
Byron Ulery	Beloit	Farmway Coop
Jim Hilbig	Beloit	" "
John Blythe	Manhattan	Ks Farm Bureau
Joe Lieber	Topeka	Ks Co-op Council
Chris Wilson	Hutchinson	Ks Fertilizer & Chemical Assn
Jarold Boettcher	Beloit	Boettcher Enterprises KFCA
Delvan Phillips	Topeka	KSBoA
Archie Hurst	Topeka	"
Larry Woodson	"	"
Kenneth M. Wilke	"	"

PRESENTATION TO THE

HOUSE COMMITTEE ON AGRICULTURE AND SMALL BUSINESS

by

Larry D. Woodson
Division of Inspections

Good Morning. Mr. Chairman, Members of the House Committee on Agriculture and Small Business. My name is Larry Woodson, Director of the Division of Inspections, with the Kansas State Board of Agriculture. With me today are: Archie Hurst, Assistant Director and Glen Searcy, Control Supervisor; all of the Kansas State Board of Agriculture.

H.B. 2519, addresses the amendment of the Kansas Feeding Stuffs Law, to include a provision regarding Good Manufacturing Practices, or GMP's. It is the position of the Kansas State Board of Agriculture, that GMP's, which have been adopted by some 22 states, would allow the agency to assure that good practices are being used to manufacture feeding stuffs in the state of Kansas. As more emphasis is placed on the quality of safe feed for our livestock, it is even more important that we take a more active role.

Generation Two, the new FDA Inspection Program, changed the guidelines that FDA followed by concentrating their efforts on firms that utilized the more dangerous drugs, or ones used in higher concentrations. Those firms not utilizing the drugs in this category, were no longer inspected for GMP by FDA. This responsibility now falls on the state.

The next questions addresses GMP's. What are we talking about? Quality control or quality assurance?

Basically, GMP's address procedures, equipment, labels, storage, etc.- those items that would, and do, effect the final product. An example of poor manufacturing practices would be a firm trying to mix five ton of feed with

ATTACHMENT I

March 2, 1987

medication in a four ton mixer. The consistency would not be homogeneous. Poorly maintained equipment, improper handling, poor storage of drugs, poor measuring and weighing procedures and others are addressed by GMP's.

These are reasons to adopt the GMP's in the Kansas Feeding Stuffs Law:

1. The inspectors could work more efficiently in the territory by detecting and addressing potential violations at the place of manufacture of feed. The key areas are: maintenance and construction of facilities and equipment, work area and storage areas, components, cleanout procedures, labeling, records and reports. If these GMP's were included in the law, the inspector could pinpoint problems more quickly and address those problems, rather that to rely on randomly sampling and analyzing feed to find the violations. Contamination is hard to detect by laboratory analysis, unless the contaminate is named and analysis requested. The control did rely on FDA's GMP's, however, as Generation 2 was implimented, the FDA registration of small facilities was dicontinued, leaving the mix mill - the one closest to the feeder, without GMP inspections - and consequently, the feeder is subject to the possiblity of receiving contaminated feed. Also, the small mixer mills may be using super potent drugs, which their equipment would not have the ability to properly mix. Since FDA will not register and inspect this type of operation, it will be the states' responsibility to inspect and report drugs which they do not have clearance to use - those drugs which can cause injury to animals, if not properly mixed or cause residues in meat, milk or eggs.
2. The state can make the inspections and not rely on the Federal agency. State inspectors are qualified to perform inspections.

The uniform feed law, published in the AAFCO (Association of American Feed Control Officials) official publication, contains the adopting of Good Manufacturing Practices. A copy of the GMP's (Good Manufacturing Practices) Regulations is attached.

It is our position that there would be no significant fiscal impact upon industry. Secondly, no additional expenses will be incurred by the agency.

It will enable the inspectors to perform more efficiently the duties for which they are now responsible - that being protecting the consumer by helping to assure safe feed stuffs that meet label guarantees.

If you have any questions, I, or our staff, will be glad to answer them, or find the answers.

Text of the Food and Drug Administration's Good Manufacturing Practice Regulations

EDITOR'S NOTE: Below is the text of the Food & Drug Administration's Good Manufacturing Practices. These GMPs were published by FDA in the Nov. 30, 1976, Federal Register and were revised in the March 3, 1986, Federal Register.

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

Part 210 is amended by revising the part heading as set out above.

In §210.3 by revising paragraph (b)(13) and (14), to read as follows:

§210.3 Definitions.

(b)***

(13) The term "medicated feed" means any Type B or Type C medicated feed as defined in §558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of Part 225 of this chapter.

(14) The term "medicated premix" means a Type A medicated article as defined in §558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of Part 226 of this chapter.

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

Subpart A—General Provisions

Sec.

Subpart B—Construction and Maintenance of Facilities and Equipment

Subpart C—Product Quality Control

Subpart D—Packaging and Labeling

Subpart E—Records and Reports

Subpart F—Facilities and Equipment

Subpart G—Product Quality Assurance

Subpart H—Labeling

Subpart I—Records

Subpart A—General Provisions

§225.1 Current good manufacturing practice.

(a) Section 501 (a) (2) (B) of the Federal Food, Drug, and Cosmetic Act provides that a drug (including a drug contained in a medicated feed) shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirement of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(b)(1) The provisions of this part set forth the criteria for determining whether the manufacture of a medicated feed is in compliance with current good manufacturing practice. These regulations shall apply to all types of facilities and equipment used in the production of medicated feeds, and they shall also govern those instances in which failure to adhere to the regulations has caused nonmedicated feeds that are manufactured, processed, packed, or held to be adulterated. In such cases, the medicated feed shall be deemed to be adulterated within the meaning of section 501(a)(2)(B) of the act, and the nonmedicated feed shall be deemed to be adulterated within the meaning of section 402(a)(2)(D) of the act.

(2) The regulations in §§225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed application is required. The regulations in §§225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which approved medicated feed applications are not required.

§ 225.10 Personnel.

(a) Qualified personnel and adequate personnel training and supervision are essential for the proper formulation, manufacture, and control of medicated feeds. Training and experience lead to proper use of equipment, maintenance of accurate records and detection and prevention of possible deviations from current good manufacturing practices.

(b) (1) All employees involved in the manufacture of medicated feeds shall have an understanding of the manufacturing or control operation(s) which they perform, including the location and proper use of equipment.

(2) The manufacturer shall provide an on-going program of evaluation and supervision of employees in the manufacture of medicated feeds.

Subpart B—Construction and Maintenance of Facilities and Equipment

§ 225.20 Buildings.

(a) The location, design, construction and physical size of the buildings and other

production facilities are factors important to the manufacture of medicated feed. The features of facilities necessary for the proper manufacture of medicated feed include provision for ease of access to structures and equipment in need of routine maintenance; ease of cleaning of equipment and work areas; facilities to promote personnel hygiene; structural conditions for control and prevention of vermin and pest infestation; adequate space for the orderly receipt and storage of drugs and feed ingredients and the controlled flow of these materials through the processing and manufacturing operations, and the equipment for the accurate packaging and delivery of a medicated feed of specified labeling and composition.

(b) The construction and maintenance of buildings in which medicated feeds are manufactured. processed, packaged, labeled or held shall conform to the following:

(1) The building grounds shall be adequately drained and routinely maintained so that they are reasonably free from litter, waste, refuse, uncut weeds or grass, standing water and improperly stored equipment.

(2) The building(s) shall be maintained in a reasonably clean and orderly manner.

(3) The building(s) shall be of suitable construction to minimize access by rodents, birds, insects and other pests.

(4) The buildings shall provide adequate space and lighting for the proper performance of the following medicated feed manufacturing operations:

(i) the receipt, control and storage of components.

(ii) component processing.

(iii) Medicated feed manufacturing.

(iv) Packaging and labeling.

(v) Storage of containers, packaging materials, labeling and finished products.

(vi) Routine maintenance of equipment.

§ 225.30 Equipment

(a) Equipment which is designed to perform its intended function and is properly installed and used is essential to the manufacture of medicated feeds. Such equipment permits production of feeds of uniform quality, facilitates cleaning and minimizes spillage of drug components and finished product.

(b) (1) All equipment shall possess the capability to produce a medicated feed of intended potency, safety and purity.

(2) All equipment shall be maintained in a reasonably clean and orderly manner.

(3) All equipment, including scales and liquid metering devices, shall be of suitable size, design, construction, precision and accuracy for its intended purpose.

(4) All scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently as may be necessary to insure their accuracy.

(5) All equipment shall be so constructed and maintained as to prevent lubricants and coolants from becoming unsafe additives in feed components or medicated feed.

(6) All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of clean-out procedure(s).

§ 225.35 Use of work areas, equipment, and storage areas for other manufacturing and storage purpose.

(a) Many manufacturers of medicated feeds are also involved in the manufacture, storage or handling of products which are not intended for animal feed use, such as fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides. Manufacturing, storage or handling of non-feed and feed products in the same facilities may cause adulteration of feed products with toxic or otherwise unapproved feed additives.

(b) Work areas and equipment used for the manufacture or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture of fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides unless such articles are approved drugs or approved food additives intended for use in the manufacture of medicated feed.

Subpart C—Product Quality Control

§ 225.42 Components.

(a) A medicated feed, in addition to providing nutrients, is a vehicle for the administration of a drug, or drugs, to animals. To ensure proper safety and effectiveness, such medicated feeds must contain the labeled amounts of drugs. It is necessary that adequate procedures be established for the receipt, storage and inventory control for all such drugs to aid in assuring their identity, strength, quality and purity when incorporated into products.

(b) The receipt, storage and inventory of drugs, including undiluted drug components, medicated premixes and semiprocessed (i.e., intermediate premixes, in-plant premixes and concentrates) intermediate mixes containing drugs, which are used in the manufacture and processing of medicated feeds, shall conform to the following:

(1) Incoming shipments of drugs shall be visually examined for identity and damage. Drugs which have been subjected to conditions which may have adversely affected their identity, strength, quality or purity shall not be accepted for use.

(2) Packaged drugs in the storage areas shall be stored in their original closed containers.

(3) Bulk drugs shall be identified and stored in a manner such that their identity, strength, quality and purity will be maintained.

(4) Drugs in the mixing areas shall be properly identified, stored, handled and controlled to maintain their integrity and identity. Sufficient space shall be provided for the location of each drug.

(5) A receipt record shall be prepared and maintained for each lot of drug received. The receipt record shall accurately indicate the identity and quantity of the drug, the name of the supplier, the supplier's lot number or an identifying number assigned by the feed manufacturer upon receipt which relates to the particular shipment, the date of receipt, the condition of the drug when received and the return of any damaged drugs.

(6) A daily inventory record for each drug used shall be maintained and shall list by manufacturer's lot number or the feed manufacturer's shipment identification number at least the following information:

(i) The quantity of drugs on hand at the beginning and end of the work day (the beginning amount being the same as the previous day's closing inventory if this amount has been established to be correct); the quantity shall be determined by weighing, counting or measuring, as appropriate.

(ii) The amount of each drug used, sold or otherwise disposed of.

(iii) The batches or production runs of medicated feed in which each drug was used.

(iv) When the drug is used in the preparation of a semiprocessed intermediate mix intended for use in the manufacture of medicated feed, any additional information which may be required for the purpose of paragraph (b) (7) of this section.

(v) Action taken to reconcile any discrepancies in the daily inventory record.

(7) Drug inventory shall be maintained of each lot or shipment of drug by means of a daily comparison of the actual amount of drug used with the theoretical drug usage in terms of the semiprocessed, intermediate and finished medicated feeds manufactured. Any significant discrepancy shall be investigated and corrective action taken. The medicated feed(s) remaining on the premises which are affected by this discrepancy shall be detained until the discrepancy is reconciled.

(8) All records required by this section shall be maintained on the premises for at least one year after complete use of a drug component of a specific lot number or feed manufacturer's shipment identification number.

§ 225.58 Laboratory controls.

(a) The periodic assay of medicated feeds for drug components provides a measure of performance of the manufacturing process in manufacturing a uniform product of intended potency.

(b) The following assay requirements shall apply to medicated feeds:

(1) For feeds requiring approved Medicated Feed Applications (Form FDA 1900)

for their manufacture and marketing: At least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter. At least one of these assays shall be performed on the first batch using the drug. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested.

(2) (Reserved)

(c) The originals or copies of all results of assays, including those from State feed control officials and any other governmental agency, shall be maintained on the premises for a period of not less than 1 year after distribution of the medicated feed. The results of assays performed by State feed control officials may be considered toward fulfillment of the periodic assay requirements of this section.

(d) Where the results of assays indicate that the medicated feed is not in accord with label specifications or is not within permissible assay limits as specified in this chapter, investigation and corrective action shall be implemented and an original or copy of the record of such action maintained on the premises.

(e) Corrective action shall include provisions for discontinuing distribution where the medicated feed fails to meet the labeled drug potency. Distribution of subsequent production of the particular feed shall not begin until it has been determined that proper control procedures have been established.

§ 225.65 Equipment cleanout procedures.

(a) Adequate cleanout procedures for all equipment used in the manufacture and distribution of medicated feeds are essential to maintain proper drug potency and avoid unsafe contamination of feeds with drugs. Such procedures may consist of cleaning by physical means; e.g., vacuuming, sweeping, washing. Alternatively, flushing or sequencing or other equally effective techniques may be used whereby the equipment is cleaned either through use of a feed containing the same drug(s) or through use of drug-free feedstuffs.

(b) All equipment, including that used for storage, processing, mixing, conveying and distribution that comes in contact with the active drug component feeds in process or finished medicated feed shall be subject to all reasonable and effective procedures to prevent unsafe contamination of manufactured feed. The steps used to prevent unsafe contamination of feeds shall include one or more of the following, or other equally effective procedures:

(1) Such procedures shall, where appropriate, consist of physical means (vacuuming, sweeping or washing), flushing, and/or sequential production of feeds.

(2) If flushing is utilized, the flush material shall be properly identified, stored and used in a manner to prevent unsafe contamination of other feeds.

(3) If sequential production of medicated feeds is utilized, it shall be on a predetermined basis designed to prevent unsafe contamination of feeds with residual drugs.

Subpart D—Packaging and Labeling

§ 225.80 Labeling

(a) Appropriate labeling identifies the medicated feed and provides the user with directions for use which, if adhered to, will assure that the article is safe and effective for its intended purposes.

(b) (2) Labels and labeling, including placards, shall be received, handled and stored in a manner that prevents labeling mixups and assures that correct labeling is employed for the medicated feed.

(b) (1) Labels and labeling, including placards, upon receipt from the printer shall be proofread against the Master Record File to verify their suitability and accuracy. The proofread label shall be dated, initialed by a responsible individual and kept for one year after all the labels from that batch have been used.

(3) In those instances where medicated feeds are distributed in bulk, complete labeling shall accompany the shipment and be supplied to the consignee at the time of delivery. Such labeling may consist of a placard or other labels attached to the invoice or delivery ticket or manufacturer's invoice that identifies the medicated feed and includes adequate information for the safe and effective use of the medicated feed.

(4) Label stock shall be reviewed periodically, and discontinued labels shall be discarded.

Subpart E—Records and Reports

§ 225.102 Master record file and production records.

(a) The Master Record File provides the complete procedure for manufacturing a specific product, setting forth the formulation, theoretical yield, manufacturing procedures, assay requirements(s) and labeling of batches or production runs. The production record(s) include(s) the complete history of a batch or production run. This record includes the amounts of drugs used, the amount of medicated feed manufactured and provides a check for the daily inventory record of drug components.

(b) The Master Record File and production records shall comply with the following provisions:

(1) A Master Record File shall be prepared, checked, dated and signed or initialed by a qualified person and shall be retained for not less than one year after production of the last batch or production run of medicated feed to which it pertains. The Master Record File or card shall include at least the following:

(i) The name of the medicated feed.

(ii) The name and weight percentage or measure of each drug or drug combination and each nondrug ingredient to be used in manufacturing a stated weight of the medicated feed.

(iii) A copy or description of the label or labeling that will accompany the medicated feed.

(iv) Manufacturing instructions or reference thereto that have been determined to yield a properly mixed medicated feed of the specified formula for each medicated feed produced on a batch or continuous operation basis, including mixing steps, mixing times and, in the case of medicated feeds produced by continuous production run, any additional manufacturing directions including, when indicated, the setting of equipment.

(v) Appropriate control directions or reference thereto, including the manner and frequency of collecting the required number of samples for specified laboratory assay.

(2) The original production record or copy thereof shall be prepared by qualified personnel for each batch or run of medicated feed produced and shall be retained on the premises for not less than one year. The production record shall include at least the following:

(i) Product identification, date of production and a written endorsement in the form of a signature or initials by a responsible individual.

(ii) The quantity and name of drug components used.

(iii) The theoretical quantity of medicated feed to be produced.

(iv) The actual quantity of medicated feed produced. In those instances where the finished feed is stored in bulk and actual yield cannot be accurately determined, the firm shall estimate the quantity produced and provide the basis for such estimate in the Master Record File.

(3) In the case of a custom formula feed made to the specifications of a customer, the master Record File and production records required by this section shall consist either of such records or of copies of the customer's purchase orders and the manufacturer's invoices bearing the information required by this section. When a custom order is received by telephone, the manufacturer shall prepare the required production records.

(4) Batch production records shall be checked by a responsible individual at the end of the working day in which the product was manufactured to determine whether all required production steps have been performed. If significant discrepancies are noted, an investigation shall be instituted immediately, and the production

record shall describe the corrective action taken.

(5) Each batch or production run of medicated feed shall be identified with its own individual batch or production run number, code, date or other suitable identification applied to the label, package, invoice or shipping document. This identification shall permit the tracing of the complete and accurate manufacturing history of the product by the manufacturer.

§ 225.110 Distribution records.

(a) Distribution records permit the manufacturer to relate complaints to specific batches and/or production runs of medicated feed. This information may be helpful in instituting a recall.

(b) Distribution records for each shipment of a medicated feed shall comply with the following provisions:

(1) Each distribution record shall include the date of shipment, the name and address of purchaser, the quantity shipped and the name of the medicated feed. A lot or control number, or date of manufacture or other suitable identification shall appear on the distribution record or the label issued with each shipment.

(2) The originals or copies of the distribution records shall be retained on the premises for not less than one year after the date of shipment of the medicated feed.

§ 225.115 Complaint files.

(a) Complaints and reports of experiences of product defects relative to the drug's efficacy or safety may provide an indicator as to whether or not medicated feeds h ave been manufactured in conformity with current good manufacturing practices. These complaints and experiences may reveal the existence of manufacturing problems not otherwise detected through the normal quality control procedures. Timely and appropriate follow-up action can serve to correct a problem and minimize future problems.

(b) The medicated feed manufacturer shall maintain on the premises a file which contains the following information:

(1) The original or copy of a record of each oral and written complaint received relating to the safety and effectiveness of the product produced. The record shall include the date of the complaint, the complainant's name and address, name and lot or control number or date of manufacture of the medicated feed involved, and the specific details of the complaint. This record shall also include all correspondence from the complainant and/or memoranda of conversations with the complainant and a description of all investigations made by the manufacturer and of the method of disposition of the complaint.

(2) For medicated feeds requiring an approved Medicated Feed Application (Form FDA 1900), records and reports of clinical and other experience with the drug shall be maintained and reported, appropriately identified with the number(s) of the Form FD-1800 to which they relate, to the Bureau of Veterinary Medicine, 5600 Fishers Lane, Rockville, Md. 20857, in duplicate, pursuant to § 510.301 of this chapter.

Subpart F—Facilities and Equipment

§225.120 Buildings and grounds.

Buildings used for production of medicated feed shall provide adequate space for equipment, processing, and orderly receipt and storage of medicated feed. Areas shall include access for routine maintenance and cleaning of equipment. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation.

§225.130 Equipment.

Equipment shall be capable of producing a medicated feed of intended potency and purity, and shall be maintained in a reasonably clean and orderly manner. Scales and liquid metering devices shall be accurate and of suitable size, design, construction, precision, and accuracy for their intended purposes. All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of cleanout procedure(s).

§225.135 Work and storage areas.

Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture and storage of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved for use in the manufacture of animal feed.

Subpart G—Product Quality Assurance

§ 225.142 Components.

Adequate procedures shall be established and maintained for the identification, storage, and inventory control (receipt and use) of all Type A medicated articles and Type B medicated feeds intended for use in the manufacture of medicated feeds to aid in assuring the identity, strength, quality, and purity of these drug sources. Packaged Type A medicated articles and Type B medicated feeds shall be stored in designated areas in their original closed containers. Bulk Type A medicated articles and bulk Type B medicated feeds shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. All Type A medicated articles and Type B medicated feeds shall be used in accordance with their labeled mixing directions.

§225.158 Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

§225.165 Equipment cleanout procedures.

Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

Subpart H—Labeling

§225.180 Labeling.

Labels shall be received, handled, and stored in a manner that prevents label mixups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

Subpart I—Records

§225.202 Formula, production, and distribution records.

Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution.

PRESENTATION
TO THE
HOUSE COMMITTEE ON AGRICULTURE AND SMALL BUSINESS
MARCH 2, 1987
BY
LARRY D. WOODSON

GOOD MORNING MR. CHAIRMAN, MEMBERS OF THE HOUSE AGRICULTURE AND SMALL BUSINESS COMMITTEE. MY NAME IS LARRY WOODSON AND I AM THE DIRECTOR OF THE DIVISION OF INSPECTIONS WITH THE STATE BOARD OF AGRICULTURE. ACCOMPANYING ME TODAY ARE ARCHIE HURST, ASST. DIRECTOR/DAIRY COMMISSIONER, GLEN SEARCY, SUPERVISOR OF THE CONTROL SUB-PROGRAM, AND DEVERN PHILLIPS, ANHYDROUS AMMONIA SPECIALIST.

HOUSE BILL 2520 ADDRESSES THE REGISTRATION OF NH_3 FACILITIES, PORTABLE REACTOR UNITS AND ESTABLISHES A FEE FOR SUCH.

THE KANSAS ANHYDROUS AMMONIA LAW (2-1212) STATES THAT THE BOARD IS AUTHORIZED AND DIRECTED TO MAKE AND PROMULGATE REGULATIONS FOR THE SAFE HANDLING, STORAGE, AND TRANSPORTATION OF ANHYDROUS AMMONIA; FOR ESTABLISHMENT OF MINIMUM GENERAL SAFETY STANDARDS COVERING THE DESIGN, CONSTRUCTION, LOCATION, INSTALLATION AND OPERATION OF EQUIPMENT FOR THE STORAGE, HANDLING AND TRANSPORTATION OF SUCH PRODUCT BY TANK TRUCK, TANK TRAILER . . . . SAID REGULATIONS SHALL BE SUCH AS ARE REASONABLY WARRANTED FOR THE SAFETY OF THE PUBLIC AND PERSONS USING SUCH MATERIAL.

MORE THAN 800 FACILITIES ARE INVOLVED IN STORING, DISPENSING AND SELLING ANHYDROUS AMMONIA FOR AGRICULTURAL PURPOSES IN KANSAS. THESE INSTALLATIONS OPERATE NEARLY 13,000 NURSE TANKS WHICH TRAVEL ON KANSAS HIGHWAYS.

ATTACHMENT II
March 2, 1987

THE SAFETY STANDARDS ESTABLISHED BY THE BOARD OF AGRICULTURE ARE OFTEN VIEWED BY OWNERS AS THE OPTIMUM THAT A FACILITY SHOULD TARGET ITS SAFETY PROGRAM FOR, NOT THE MINIMUM STANDARD AS ESTABLISHED.

WHILE THE REGULATIONS REQUIRE OWNERS OR OPERATORS OF ANHYDROUS AMMONIA FACILITIES TO SUBMIT DRAWINGS AND APPLICATIONS TO THE SECRETARY PRIOR TO THE INSTALLATION OF NEW OR EXPANDED FACILITIES, THIS REGULATION IS NOT ALWAYS COMPLIED WITH. NEW OR EXPANDED FACILITIES ARE DISCOVERED BY INSPECTORS AFTER THE EQUIPMENT IS IN PLACE AND THE FACILITY IS OPERATING.

THE REGULATIONS HAVE ALWAYS REQUIRED NOTIFICATION BY THE OWNER OR OPERATORS IN THE EVENT OF AN ACCIDENT OR INCIDENT INVOLVING ANHYDROUS AMMONIA. OFTEN THESE TOO ARE LEARNED OF LONG AFTER THE FACT BY ACCESS TO NEWSPAPER ARTICLES, DISCUSSIONS WITH OTHER FACILITY OPERATORS, AND OCCASIONALLY BY ATTORNEYS REPRESENTING INJURED PARTIES OF AN ANHYDROUS ACCIDENT.

THE DANGERS OF MISHANDLING A HAZARDOUS MATERIAL SUCH AS ANHYDROUS AMMONIA AND THE IMPROPER INSTALLATION OF FACILITIES CAN BE SUBSTANTIALLY REDUCED BY MODIFICATION OF THE EXISTING ANHYDROUS AMMONIA LAW TO REQUIRE ALL FACILITIES USING AND DISPENSING ANHYDROUS AMMONIA TO BE REGISTERED.

THE REGISTERING OF FACILITIES WILL ALLOW IMPROVED MONITORING OF PROPOSED FACILITIES, BETTER ACCOUNTABILITY OF INSTALLATIONS, AND WILL ENHANCE ENFORCEMENT OF REGULATIONS IN EXISTING FACILITIES.

KANSAS FERTILIZER AND CHEMICAL ASSOCIATION, INC.
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STATEMENT OF THE

KANSAS FERTILIZER & CHEMICAL ASSOCIATION

TO THE

HOUSE AGRICULTURE & SMALL BUSINESS COMMITTE

CLIFFORD CAMPBELL, CHAIRPERSON

SUSAN ROENBAUGH, VICE CHAIRPERSON

REGARDING HB 2520

MARCH 2, 1987

Mr. Chairman and members of the Committee, I am Chris Wilson, Director of Governmental Relations of the Kansas Fertilizer and Chemical Association (KFCA). Our members are agricultural fertilizer and chemical retail dealers, manufacturers and distributors. We oppose HB 2520, regarding registration fees for anhydrous ammonia facilities and reactors, at this time, because we don't understand the rationale for the bill. We have been told that the purpose of the bill is to identify facilities before they are constructed, in order to avoid any safety or regulatory violations in the facilities. We agree that the Board of Agriculture should be informed about construction of new facilities or reactors, and it is our understanding that notification of the Board and the State Fire Marshall prior to installation is already required. We strongly agree with this requirement, and we think there should be substantial fines for those who do not notify as required. But we fail to see how an annual fee for registering all facilities and reactors is the answer to identifying the new facilities. If the purpose of the bill is simply to maintain a list of all facilities and reactors in the state, that's also appropriate, but we feel the fees are higher than should be needed to maintain such a list.

In as far as we have been able to determine, only one other state requires registration of reactors. The Texas Air Control Board has a one-time registration for reactors, and requires that operators notify them when reacting in the state.

Other than Texas, Kansas is the only state with reporting requirements. By comparison, Nebraska has no requirements, but has at least 15-20 times

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the tonnage being reacted as does Kansas. Operators must notify both KDHE and the Board of Agriculture ammonia inspector prior to reacting in Kansas. At present, there are only two Kansans who operate reactors and only four other companies who bring portable reactor units into the state. All commercial reactor units are constructed in Illinois. HB 2520 would bring in only about $2,000 annually to the Board of Agriculture, but would assess a $250.00 fee per unit on the same people every year.

We want to be supportive of the Board of Agriculture in every way possible, and we understand that additional revenue is needed. Our industry has been very open to regulation and paying fees over the years. We asked for the pesticide dealer registration law and the chemigation law. We are already a major source of revenue for the Board. The fertilizer tonnage fees support not only fertilizer inspections, but the seed inspection program and other areas of the Board's budget as well. Fifteen percent of all fees collected from the industry are used to help fund the Board's central office, Secretary of Agriculutre and other personnel and overhead.

In summary, we support the Board's desire to be notified prior to installation of new anhydrous ammonia facilities and understand the need for additional revenue. We question the method outlined in this bill and the level of fees it would establish.

Thank you for your consideration of our position.

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TESTIMONY BEFORE THE HOUSE AGRICULTURAL COMMITTEE, KANSAS HOUSE OF REPRESENTATIVES, THE CAPITOL, TOPEKA, KANSAS, MARCH 2, 1987

BY: JAROLD W. BOETTCHER, 521 N. Campbell, Beloit, Ks. 67420

REPRESENTING: BOETTCHER ENTERPRISES, 118 West Court, St., Beloit, Ks. 67420

KANSAS FERTILIZER & CHEMICAL ASSOCIATION

My name is Jarold Boettcher. I am Vice President with Boettcher Enterprises, Inc., 118 West Court St., Beloit, Ks. Our Company has approximately 30 retail outlets for fertilizer and ag. chemicals, primarily in Northcentral Kansas. I am also Co-Chairman of the Legislative Committee for the Kansas Fertilizer and Chemical Association, which is an industry group representing fertilizer and chemical dealers across the State of Kansas. I am here today to give testimony on House Bill 2520. I understand this bill was introduced Friday, March 27, 1987, and these hearings were scheduled at that time. Despite the short notice, we were informed and appreciate the opportunity to address the House Agricultural Committee on this bill.

First, speaking for both our Company, Boettcher Enterprises, and for the Kansas Fertilizer and Chemical Association, we support regulation of our industry as being in the public interest. We have good communications with the State Board of Agriculture and are consulted regularly on areas of common interest and concern. For example, several of our members participated in the revisions of the regulations affecting anhydrous ammonia which went into effect in 1986. We are aware of the need to locate and inspect anhydrous ammonia storage tanks and ammonia reactors. In principal, therefore, we support the idea of registration of such ammonia storage tanks as a means to provide for regular inspection to insure compliance with existing regulations. We are inspected regularly at our Company, the locations of our storage tanks are known, and it is only fair that someone else be subject to the same inspection and

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be required to bring their facilities into compliance with existing regulations. Some kind of registration law, which has enforcement provisions and penalties for non-compliance may therefore be necessary. I am personally aware that the State Board of Agriculture has been considering the possibility of requiring registration, although I was not aware that any such registration was going to be proposed in 1987.

Second -- regarding the fee structure in the proposed House Bill 2520. The fertilizer industry in the State of Kansas already pays more than the cost of regulation of our industry through the tonnage tax. We have asked the State Board of Agriculture for an analysis of where the tonnage tax revenues are expended and been told that such funds do support other Board of Ag programs. Therefore, more fees from the fertilizer industry are not justified, particularly as the fee structure in the proposed bill is very agressive in amount and much larger than the actual costs of a registration program. It is a common perception at the National level among politicians that Businesses just pass on costs, such as increased taxes and fees. Those of you on this committee wwho are in busness would surely agree that this Pass-Through is rarely, if ever, possible. The Fertilizer Industry is NOT in a position to absorb increased costs itself. Moreover, IF it were possible to pass on costs, the group that would absorb such increased costs and fees would be FARMERS. Asking farmers to absorb higher costs is simply unfair and unjustifiable. We cannot afford a policy of tax and spend, tax and spend. Farmers are consolodating and cutting back; the Fertilizer Industry is consolodating and cutting back; and perhaps the State Board of Agriculture may have to do the same, namely to consolodate and cut back. We are adjusting to a new environment with survival as an important objective. The status quo for any of us, farmers, industry or government may not be justified in this new environment. We all need to do better with the resources we have.

Third, the law is impotent as presently written with no enforcement of penalties prescribed. We who do comply get to pay more under this new bill; those who don't bother to comply simply go on. Simple equity causes me to protest.

Fourth, this subject is much too important to be handled in a few minutes on a Monday morning, with the bill having only been introduced last Friday. We need more time to study it and to provide input. The door is being opened too widely, too quickly, without adequate justification for the fees being proposed. Our industry association has good representation in Topeka. If they were not on their toes, this bill could have been introduced, hearings held, and passed without those who are going to be affected and taxed having any input. I think there was a war fought over similar principals two hundred years ago -- something about tea, I believe. The time schedule we are on has given us no time to respond adequately and constructively. The time period being allowed gives at least the appearance of a revenue grab. It is sometimes necessary to speak out and oppose a bad law, even if we acknowledge the need to do something about registration. This is a bad law; now is not the time; this is not the place.

Thank you.

Jarold W. Boettcher