

THE EFFECTS OF GOOD MANUFACTURING PRACTICE REGULATIONS
ON THE EFFICIENCY OF THE MIXING COST CENTER

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INTRODUCTION

Methods of mixing or preparing rations for livestock and poultry have probably existed for as long as man has practiced animal husbandry, but feed manufacturing as an industry had its origin in the late nineteenth or early twentieth century.

Early feed business was essentially a method for merchandising milling by-products, animal protein by-products and a few formula supplements. Feed manufacturers during this period were primarily grain milling companies which blended milling by-products with a limited number of feed ingredients and sold this product as animal feed.¹

The feed industry continued to be a simple manufacturing industry and experienced only a modest growth in volume during the early years of the twentieth century. Manufacturing consisted of little more than the processing of grain and the mixing of this grain with other ingredients.

Feed manufacturing experienced a more rapid increase in volume and manufacturing complexity following World War I. This increase continued until a sharp decline in commercial feed production occurred during the drought-depression period

¹Daniel J. Padberg, "The Mixed Feed Industry," Market Structure of the Agricultural Industries, ed. John R. Moore and Richard G. Walsh (Ames, Iowa: Iowa State University Press, 1966), pp. 266-267.

of the 1930's.

A near revolution has taken place during the last forty years in livestock and poultry production which has greatly influenced formula feed manufacturing. During this time period amazing progress was made in nutritional research and usage of new ingredients, identification of vitamins and their application in livestock rations, discovery of antibiotics, drugs and feed additives which proved effective in disease control and growth promotion. Formulation of special rations for improved animal performance and development of processing methods for improved feed efficiency have been other areas of tremendous progress.

The feed manufacturing industry was required to adapt to changes in livestock and poultry feed demands, many of which required extensive adjustment in plant facilities and operating procedures to maintain production efficiency. The industry was successful in this required transition from a simple processing and blending operation to a complex manufacturing industry.

Feed manufacturing experienced a nearly continuous growth in volume, number of ingredients and feed additives used, and variety and forms of rations offered for sale from 1941 to 1968.² Annual production of primary formula feeds

²R. W. Schoeff, "The Formula Feed Industry," Feed Manufacturing Technology, tech. ed. Harry B. Pfost (Chicago: American Feed Manufacturers Association, 1970), pp. 1-8.

increased from nearly 13 million tons in 1930 to 54 million tons in 1968.³

Manufactured feeds have not provided the total diet in the production of meat, milk and eggs. A large number of livestock and poultry have been fed grains and roughage that have not been processed by the feed industry, however, commercial feeds have been a significant part of the diet of all classes of domestic farm animals fed during recent years. Commercial feeds accounted for nearly two-thirds of the six and one-half billion dollars that farmers spent for feed in 1968.⁴

The efficiency of the feed manufacturing industry is important to the economical production of meat, milk and eggs. Producers of these foodstuffs are directly affected by the price of animal feeds since feed is a major production cost. Feed costs account for about two-thirds of their total production costs.⁵

Government Regulation of Animal Feeds

Regulation of manufactured animal feeds by

³Oakley M. Ray, "Formula Feed Output Shows Marked Grains, Promises to Increase Further," Feedstuffs, September 6, 1969, p. 48.

⁴R. W. Schoeff, "Statistics of the Formula Feed Industry," Feedstuffs, October 28, 1970, p. 11.

⁵Carl J. Vosloh, Jr., Costs and Economics of Scale In Feed Manufacturing. U.S. Department of Agriculture Marketing Research Report No. 815 (Washington: U.S. Government Printing Office, March, 1968), p. 1.

governmental agencies was insignificant in the early years of the feed industry. Minimum regulations were perhaps adequate for a number of years since feeds and manufacturing methods were uncomplicated. State feed control officials served as the regulatory agency in the enforcement of feed laws.

More ingredients and additives were incorporated into feeds as the industry matured and the need increased for additional regulations and their stricter enforcement by government. State feed control officials continued to serve as the major regulatory agency for several years. State feed control laws were not uniform among the states but areas of control included registration of feeds, labeling, misbranding of products, feed inspection and analysis, adulteration and product guarantee.

The original federal Food and Drug Act of 1906 was enacted to regulate the food and drug industries that were engaged in interstate commerce. This act had little real impact on the feed industry, since it was enacted primarily because of the growing concern of the consuming public to insure the wholesomeness of foodstuffs. This law defined food as adulterated if it contained added poisonous or deleterious ingredients injurious to health.

Animal feeds were specifically covered by federal regulations when the Federal Food, Drug and Cosmetic Act of 1938 was adopted. This act defined "food," in part, to mean articles used for food or drink by man or other animals.

Medicated feeds were also covered by this act since "drugs" were defined, in part, to mean articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

Despite the enactment of the Federal Food, Drug and Cosmetic Act of 1938 which clearly covered feed manufacturers engaged in interstate commerce, two officials of the Food and Drug Administration reported that state feed control officials retained the leadership in regulation of animal feeds until approximately 1954. Regulatory activities under federal law performed a supporting role to the state feed control agencies, particularly in cases where broader jurisdictions were needed.⁶

The Federal Food, Drug and Cosmetic Act of 1938 was the enabling legislation for federal regulation of animal feeds, but amendments adopted to this act in 1958 and 1962 resulted in a dramatic increase in federal regulation of the feed industry.

Extensive federal regulation of animal feed began in 1958 with the adoption of the Food Additives Amendment to the Federal Food, Drug and Cosmetic Act. This amendment required that any substance added to animal feeds must be generally recognized as safe or demonstrated safe for the animal under

⁶Charles G. Durbin and Jane F. Robens, "Scientific Development Dictates Control Changes," 1966 Feed Additive Compendium (Minneapolis, Minnesota: Miller Publishing Co., 1966), p. 5.

conditions of intended use and that edible products of the animal are safe for consumption by man or other animals.

The Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act were adopted in 1962. These amendments required all manufacturers of medicated feed to register each year with the Secretary of Health, Education and Welfare.⁷ Good manufacturing practices for medicated feed manufacturers were introduced by these amendments with a requirement that such practices become a part of the regulations.

The Food and Drug Administration responded to the provisions of the Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act. Good Manufacturing Practice in Manufacture, Processing, Packing or Holding Medicated Feeds Regulations became a part of the act when they were published in the Federal Register on May 11, 1965.⁸

Adoption of these regulations as a part of the Federal Food, Drug and Cosmetic Act became final only after they were published in the Federal Register as proposed regulations. Feed manufacturers, drug manufacturers, trade associations and other interested parties had an opportunity to file their opinions of the proposed regulations with the

⁷Persons or firms manufacturing medicated feeds for strictly their own use are exempt from the registration requirements.

⁸Hereinafter referred to as good manufacturing practice regulations.

Food and Drug Administration. Many suggestions by these groups were incorporated into the good manufacturing practice regulations, but the Food and Drug Administration has responsibility for the final decision as to the content of the regulations and their enforcement.

The good manufacturing practice regulations were not drastically different from the quality control procedures of major feed companies. Compliance with the good manufacturing practice regulations for these companies did not require much adjustment, but the regulations were new legal restrictions and management had to consider their influence on production efficiency.

The Problem

The feed manufacturing industry is a highly competitive industry. A high degree of production efficiency is needed because of the small profit margins prevalent in the industry. These economic characteristics of the feed industry have prevailed for many years, but recent federal government regulations covering the manufacture of medicated feeds have introduced new factors which have the potential of influencing production efficiency.

The Federal Food, Drug and Cosmetic Act of 1938 was a massive piece of regulatory legislation after the adoption of the good manufacturing practice regulations on May 11, 1965. Compliance with all aspects of this act was and continues to be of real concern to the feed industry. Industry

concern can be documented by the extensive volume of literature published since 1965 to improve the understanding of these regulations. A large number of conferences, meetings, training sessions and short courses dealing with compliance have also been conducted by trade associations, universities, and regulatory agencies.

A 1968 industry survey revealed that approximately 9,500 feed mills in the United States were registered with the Food and Drug Administration as drug establishments.⁹ Another source reported that there were approximately 12,000 feed mills in the United States in 1968.¹⁰ Computations based on this information indicated that approximately 79 percent of the feed mills in the United States during 1968 were required to comply with the good manufacturing practice regulations. This large segment of the feed industry must comply with the Food, Drug and Cosmetic Act and still maintain an efficient mill operation.

The good manufacturing practice regulations are especially significant to the economic operation of a feed mill. Regulations contained in these sections apply to individual mill facilities, practices, and procedures. Criteria to determine if feed manufacturers are in conformity with current good manufacturing practices for manufacturing

⁹Roger Bergland, "Mills' Tonnage of Feed Tops 100 Million," Feedstuffs, September 6, 1969, p. 3.

¹⁰R. W. Schoeff, "Market Structure of the Formula Feed Industry," Feedstuffs, September 6, 1969, p. 50.

medicated feed are specified in these regulations. The following is an outline of the pertinent contents of the sections. Numbering is keyed to the text of the regulations.¹¹

133.101 Buildings. Buildings shall be maintained in a reasonably clean and orderly manner and be of suitable size, construction and location to facilitate maintenance and operation of their intended purpose. They shall provide adequate space for placement of equipment and materials used in the manufacture, packaging, handling, and storage of medicated feeds. Adequate lighting and other physical facilities must be provided in the buildings to prevent unsafe contamination of raw materials or finished product. Washroom facilities must be provided.

133.102 Equipment. Equipment used for the manufacture or handling of medicated feeds or their components must be maintained in a reasonably clean and orderly manner. They must be of suitable size, design, and construction for their intended purpose. Equipment must also be constructed to facilitate cleaning, adjustment, and maintenance.

133.103 Personnel. Key employees responsible for manufacture and handling of medicated feed must have a

¹¹"Text of the Food and Drug Administration's Good Manufacturing Practice Regulations," 1967 Feed Additive Compendium (Minneapolis, Minnesota: Miller Publishing Co., 1967), pp. 35-38.

combination of education and experience that is adequate to assure proper manufacture and control of medicated feeds.

133.104 Components. Drug components used in the manufacture of medicated feeds shall be handled and stored in a manner to maintain their integrity and identification. Appropriate receipt and inventory records shall be maintained for one year. These records shall show the origin of the drug component, batches in which used and results of any testing of the drug components. Non-drug components shall be stored and handled in a manner to avoid unsafe contamination.

133.105 Formula and Production Records. A master formula of each medicated feed shall be prepared and maintained by a key employee and retained for one year following the last production of such formula. A production record for each run of medicated feed must be prepared and retained for one year. This production record shall include feed identification, date produced, quantity of drugs used and quantity of medicated feed produced.

133.106 Production and Control Procedures. Proper composition and labeling of medicated feeds shall be assured by using adequate production and control procedures. Each critical step in the process of manufacturing medicated feeds shall be performed in a manner which will assure the integrity of the final product. All products containing drugs shall

be received, identified, stored and handled in a manner to adequately prevent mixups or contamination. Equipment shall be maintained and operated in a manner as to prevent unsafe contamination of medicated feeds. Adequate cleaning of all equipment that has been in contact with medicated feed is required prior to the use of this same equipment in the manufacture of a different medicated feed or a non-medicated feed. An audit of the composition of finished medicated feed shall be maintained through a sampling and assay schedule. Medicated feed which is found in nonconformance with appropriate specifications shall not be distributed and subsequent production shall not begin until proper control procedures have been established.

133.107 Packaging and Labeling. Procedures shall be followed to assure that medicated feeds are properly labeled and that such labels contain adequate information for the safe and effective use of the medicated feed.

133.108 Laboratory Controls. Adequate specifications and test procedures shall be used to assure that drug components and medicated feeds conform to standards of identity, strength, quality and purity. Records of assay results of medicated feed must be maintained for one year subsequent to the distribution of the involved feed.

133.109 Distribution Records. Records shall be maintained for all shipments of medicated feed. Information in

these records shall be adequate to facilitate recall of any shipment. Distribution records shall be maintained for one year after the date of shipment.

133.10 Complaint Files. Complaints received by the feed manufacturer shall be evaluated and action shall be taken appropriate to the circumstances. A record of complaints and action taken by the feed manufacturer shall be maintained for two years.

The good manufacturing practice regulations are written in a general manner, but it is evident that they are applicable to all manufacturing processes used in the manufacture of medicated feeds. Due to this applicability to feed production, management personnel of feed manufacturing plants are confronted with two major problems with regard to efficient production of animal feeds while complying with the good manufacturing practice regulations.

The first problem is to determine the actual influence of these regulations on plant efficiency. The restrictive language of the regulations implies that efficiency would be decreased by compliance, but investigation might indicate otherwise.

A second problem exists in the determination of methods to use in overcoming decreased efficiency should it occur due to compliance requirements of the good manufacturing practice regulations.

An analysis of the influence that these regulations

had on all the manufacturing processes used in feed manufacturing was beyond the scope of this study. Therefore, it was necessary to isolate a portion of the total manufacturing operation for study.

The portion of plant operations used in this study was the mixing center as defined by the Midwest Feed Manufacturers Association.¹² The Midwest Feed Manufacturers Association separated the operation into the following eight cost centers: (1) ingredient receiving, (2) grain processing, (3) mixing, (4) pelleting, (5) packing, (6) warehousing, (7) high molasses, and (8) maintenance.

The mixing cost center was selected for this study since mixing is probably the most important operation in a feed mill and is the only operation that would be required to identify a plant as a feed mill.¹³ Another reason for selection of the mixing cost center for study was that all feed manufactured must pass through this cost center.

The Midwest Feed Manufacturers Association study reported the following definition of the mixing cost center.

The Cost Center begins at the point of storage of the materials to be used in mixing. The work includes the movement of all raw materials into the Cost Center,

¹²R. J. Witherspoon and others, "Cost Model for In-Plant Operations," Proceedings of the 1956 Midwest Feed Production School (Kansas City, Missouri: Midwest Feed Manufacturers Association, 1956), p. 1.

¹³H. B. Pfof, "Feed Mixing," Feed Manufacturing Technology, tech. ed. H. B. Pfof (Chicago: American Feed Manufacturers Association, 1970), p. 77.

weighing bulk and trace ingredients, opening and dumping bagged ingredients and the actual weighing of the feed including additions of liquids through liquid blenders. Also included is all work connected with making premixes. Finally, the movement of all mixed feed into holding bins is included in this center. The Cost Center ends after the mix is placed in holding bins at the next Cost Center.¹⁴

Vosloh used essentially the same definition for the mixing center in his study on standards for costs, labor and equipment in two models of mixing centers with capacities of 80 tons and 200 tons per shift per day.¹⁵

A modification of this definition of the mixing cost center was made for purposes of this report by excluding the preparation of premixes.

Objectives of the Study and Source of Data

The primary objective of this study was to investigate the effect that the good manufacturing practice regulations of the Federal Food, Drug and Cosmetic Act had on the efficiency of the mixing cost center of a feed manufacturing plant.

Operating procedures of the mixing cost center, good manufacturing practice regulations and published literature on feed mixing were used in this investigation. Mixing cost

¹⁴Witherspoon and others, op. cit., p. 4.

¹⁵Carl J. Vosloh, Jr., Labor and Capital for Mixing Formula Feeds, U.S. Department of Agriculture, Marketing Research Report No. 564 (Washington: U.S. Government Printing Office, October 1962), p. 2.

center production records and operating practices and procedures obtained in a case study from a Midwest feed manufacturer were also analyzed.¹⁶ The time period covered by this study was January 1, 1969 through December 31, 1969.

A secondary objective was to improve the understanding of federal regulations applicable to the feed industry.

¹⁶The cooperating feed manufacturer requested anonymity.

ANALYSIS OF THE MIXING COST CENTER OPERATION

The hypothesis was made in this study that the good manufacturing practice regulations did decrease the efficiency of the mixing cost center. This assumption was logical since the regulations did apply to the mixing operation and an increase in regulation is generally thought to be accompanied by greater restriction of operating freedom and hence higher cost per unit of output.

The influence of good manufacturing practice regulations on the mixing cost center efficiency was evaluated by analyzing the operating functions of the cost center and determining the general impact of the regulations on these functions. A case study of the mixing cost center production records of a cooperating feed manufacturer was also used as a method of evaluation and will be discussed later in this report.

The operation of the mixing cost center must be known before determining how mixing efficiency was affected by the good manufacturing practice regulations. Efficiency of the mixing cost center is defined here as the ratio of mixed feed output to the input of factors of production. Vosloh described the operating duties of employees in the mixing center as follows:

Workers in the mixing center spend most of their time in this area. They typically perform the following duties in an 8-hour shift:

1. Weigh and mix the proper bulk ingredients listed on the formula sheet and add proper amounts of bagged ingredients that are to be added to each batch. In doing this the workers will:
 - a. Check the scale and other equipment before starting each batch.
 - b. Assemble all bagged ingredients, including pre-mixes, listed on the formula sheet.
 - c. Compare the cumulative weight shown on the formula sheet after adding each ingredient, and compare the total weight of the batch with the formula sheet before emptying the scale. Several lots of material will be dumped into the hopper scale to make up the batch. After all bagged ingredients plus microingredients have been dumped, the batch is ready to be mixed.
2. Start, stop, and operate the mixer. The following steps usually are taken:
 - a. Check the flow of materials into and out of the mixer.
 - b. Schedule the dumping of mixed feed into the surge bins, dumping of ingredients from hopper scale, and the preparation for another weighing of a new batch so that changeover time is kept to a minimum.
 - c. Check hopper scale, mixer, and surge bin before dumping so that contamination will be minimized.
 - d. Add liquids to mixed feed, as required on the formula sheet.
3. Operate the scalper and finished feed blender for a uniform product free of lumps, string, and other foreign matter.
4. Other duties required of the workers include:
 - a. Take quality control and other precautionary steps to assure production of a quality product.
 - b. Perform maintenance jobs as assigned.
 - c. Perform some housekeeping functions.¹

Rempe outlines similar operating duties for mixing personnel in his article on weighing and mixing

¹Carl J. Vosloh, Jr., Labor and Capital for Mixing Formula Feeds, U.S. Department of Agriculture, Marketing Research Report No. 564 (Washington: U.S. Government Printing Office, October, 1962), pp. 6-7.

operations.²

A study of the operating duties of the mixing center employees and the good manufacturing practice regulations was combined with a literature review to determine the impact of these regulations on the efficiency of the mixing cost center.

Research concerning the effect of good manufacturing practice regulations on the efficiency of the mixing cost center were not found in the literature review, but several authors did report information on product control in the mixing center which was useful to the objectives of this study.

Murray discussed the design and construction of buildings and equipment used in the manufacture of feeds. He reports that buildings and equipment must be designed and constructed in a manner which will: (1) prevent contamination of the feed, (2) assist mill cleanliness and maintenance, and (3) allow the mill to meet variable production demand.³

Wietlake reported that manufacturers of all animal feeds must provide for personnel training, production records,

²J. E. Rempe, "Weighing and Mixing Operations," Feed Manufacturing Technology, tech. ed. H. B. Pfost (Chicago: American Feed Manufacturers Association, 1970), pp. 382-384.

³Phil C. Murray, "Obtaining and Maintaining Quality-Mill Design," Feed Manufacturing Technology, tech. ed. Harry B. Pfost (Chicago: American Feed Manufacturers Association, 1970), pp. 315-316.

inventory records, accurate identification and labeling of finished product, mill cleanliness, visual and chemical analysis of feeds and feed components, and methods for recall of feed which does not meet specifications.⁴

Pierce stated that a feed manufacturer's first consideration of quality should be control of ingredients. Control of ingredients must be insured by the following methods: (1) A sampling and analysis schedule for all feed components to assure that they meet predetermined specifications, (2) maintenance of adequate storage and handling to prevent loss of quality, and (3) provide methods for proper identification of all bins and containers used for holding feed components.⁵

All three of these authors expressed the above opinions without reference to the good manufacturing practice regulations. This implied that they were discussing essential manufacturing methods and practices required of all feed manufacturers. These methods and practices are not different from the good manufacturing practice regulations except for the enforcement provisions of the Federal Food, Drug and Cosmetic Act.

⁴Allen W. Wietlake, "Obtaining and Maintaining Quality-Packaging and Handling," Feed Manufacturing Technology, tech. ed. Harry B. Pfost (Chicago: American Feed Manufacturers Association, 1970), pp. 310-315.

⁵James G. Pierce, "Obtaining and Maintaining Quality-Ingredients," Feed Manufacturing Technology, tech. ed. Harry B. Pfost (Chicago: American Feed Manufacturers Association, 1970), pp. 302-306.

Wilcox was emphatic that the regulations were not overly restrictive to feed manufacturers. He summarized his article on good manufacturing practices in mixing feed with the following statement:

The manufacturing practices that are required by the regulations should be a part of everyday good business practice for a firm that wants to produce and sell a quality product and to make a profit in the process. In this context the adoption of the entire GMPR should not require many changes in most feed mixing enterprises. For the few that will need to repair, remodel or alter buildings, equipment, records, working practices, and habits, the changes should result in more consistent product quality and improved customer relations. Doing a better job should result in more business and an improved economic situation for the firm. The Good Manufacturing Practices are, in the main, good business practices for all who manufacture feeds.⁶

An analysis of the operating duties of the mixing center employees and the good manufacturing practice regulations indicated that the employee duties were not significantly affected by the regulations except for a part of one section. The one exception was the requirement for adequate cleaning of the mixing equipment after the manufacture of medicated feed. This requirement would alter mixing center employee duties since additional work and time would be involved.

It was concluded at this point in the study that the sections of the regulations pertaining to buildings, equipment, personnel, formula and production records, components,

⁶Robert A. Wilcox, Good Manufacturing Practices in Mixing Feeds (MF-161, Manhattan, Kansas: Kansas State University Extension Service, August, 1966), p. 11.

packaging and labeling, laboratory controls, distribution records and complaint files would not affect the efficiency of the mixing cost center. The required practices contained in these sections would be necessary to the successful operation of any mixing center regardless of regulatory requirements.

An additional conclusion was made that the requirements for cleaning of the mixing equipment, contained in the section on production and control procedures, were restrictive to the operation of the mixing cost center. A case study was made of a feed mill operation for a one-year period to more carefully identify the restrictive factors and relate them to the efficiency of that operation. The remainder of this report presents the results of this study.

Selection of the Case Study Mill

A case study approach was used in this study to expand the investigation of the influence of good manufacturing practice regulations on the efficiency of the mixing cost center.

The selection of the case mill was critical and was carefully made since information would be supplied by only the selected mill. A number of Midwest feed manufacturers were contacted during the planning stages of this study to determine the suitability of their mixing operation for use in this study.

Several criteria had to be met by the case study mill

to accomplish the primary objective of the study. The criteria were: (1) The mill had to be registered as a drug establishment with the Food and Drug Administration and be engaged in interstate commerce. (2) Production had to include a variety of medicated feeds. (3) Complete production records of the mixing cost center were required. (4) Production volume had to be large enough to provide sufficient data for analysis. (5) Management had to be willing to provide production records of the mixing cost center and company procedures on compliance with good manufacturing practice regulations.

It was also desirable, although not a criteria, that the case study mill had experienced an inspection by the Food and Drug Administration prior to the time period used for the study. Proper compliance with the good manufacturing practice regulations would have been indicated if such an inspection had been made and no violations found. This would have also indicated that the mixing cost center practices were acceptable with respect to the sections of the regulations dealing with buildings and equipment.

The selected mill had successfully passed a Food and Drug Administration inspection prior to the time period used for the study. All other required criteria were also met.

The flow diagram in Figure 1 illustrates the production flow of the case study mixing center. Bulk ingredients and processed grain are moved by screw conveyors or gravity to the hopper scale for formulation by weight.

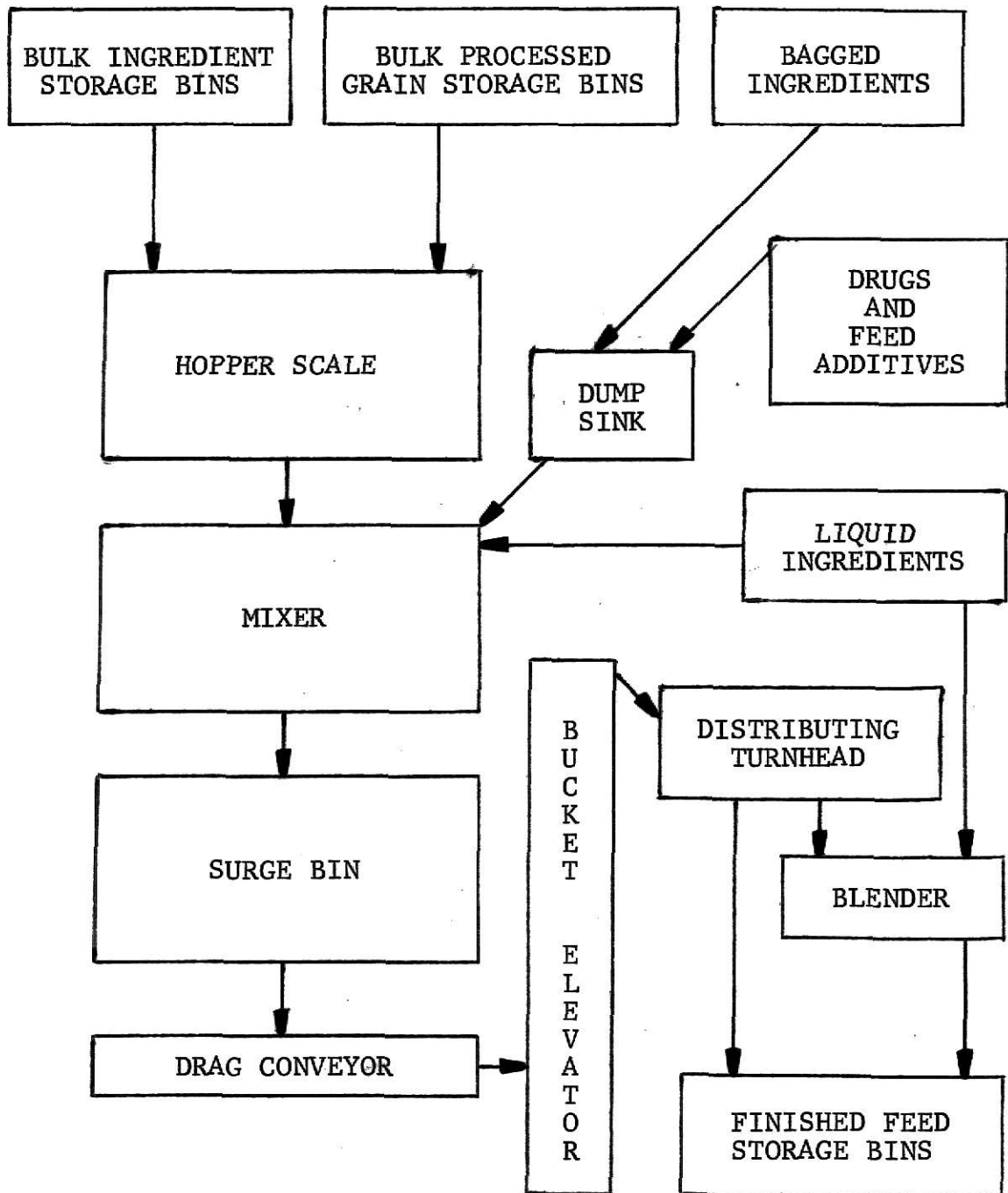


Figure 1. Flow diagram of the case study mixing center

Weighed materials move by gravity through an air operated slide gate into the mixer. Bagged ingredients, drugs and other feed additives are deposited in the mixer through the dump sink for mixing with processed grain and ingredients. Liquids may also be added at the mixer. After the contents of the mixer are blended, they move by gravity through an air operated slide gate into the surge bin. Materials are moved out of the surge bin by a drag conveyor to a bucket elevator. The bucket elevator conveys material to a distributing turnhead. The materials are then conveyed to a continuous blender where additional liquids are added to the ration or they may be conveyed directly to finished feed storage bins.

The conclusion developed earlier in this report that the section on production and control procedures of the good manufacturing practice regulations would restrict the mixing center was also true for the case study mixing center. The specific part of this section which was restrictive to the case study mixing center was the required cleaning of all mixing equipment that had been in contact with medicated feed prior to the manufacture of a different medicated feed or a non-medicated feed. Mixing equipment of the case study mill was not cleaned following manufacture of medicated feed prior to the adoption of the good manufacturing practice regulations.

The method used to comply with the requirement for cleaning of mixing equipment was a flushing procedure. This

procedure specified that 400 pounds of soybean meal or ground corn be weighed in the hopper scale. It was transferred to the mixer and the mixer was operated for a normal three minute mixing time. After mixing, the contents of the mixer was passed through the remainder of the mixing system and collected in marked containers for use in later production of like medicated feed.

Analysis of the Case Study Mixing Cost Center

The term "efficiency" used here means the relationship of output to input. Plant production efficiency refers to the ratio of plant production output to the input of factors of production.

There are several terms used to describe or measure efficiency of a production unit. The measurement of efficiency commonly used in the feed industry is cost per unit of output, which is expressed in terms of cost per ton. This concept of efficiency was used in this study of mixing cost center efficiency.

Vosloh, in a study dealing with the costs of mixing formula feed, outlined the costs of mixing.⁷ These costs were: (1) production labor, (2) supervision labor, (3) equipment depreciation, (4) interest on investment, (5) electricity, (6) maintenance labor, and (7) fuel required

⁷Carl J. Vosloh, Jr., Labor and Capital for Mixing Formula Feeds, U.S. Department of Agriculture Marketing Research Report No. 564, (Washington, D.C.: U.S. Government Printing Office, October, 1962), pp. 14-19.

for steam. These kinds of costs correspond closely with the kind of costs of the case study mixing cost center.

In economics, the term "cost" generally means the outlay of funds for productive services. Costs can be divided into fixed costs and variable costs.

Fixed costs are costs which do not vary as output varies. Fixed costs of the mixing cost center of this study were: (1) taxes, (2) insurance, (3) interest on investment, and (4) depreciation. These four fixed costs of the mixing cost center were included as a part of the total mill fixed costs but they could have been prorated and assigned to the mixing cost center.

Fixed costs of the case study mixing cost center would have been increased if capital improvements had been made to the mixing center equipment or structure to comply with the good manufacturing practice regulations. Capital improvements were not made in the mixing cost center for the specific purpose of complying with these regulations.⁸ It was determined that the fixed costs composed of taxes, insurance, interest on investment and depreciation were not altered due to the compliance requirements of the good manufacturing practice regulations.

Variable costs are costs which change as output changes. Variable costs of the mixing cost center in this

⁸Interview with the general manager of the case study mill.

study were: (1) labor, (2) maintenance, (3) electricity, and (4) fuel.

An analysis of the mixing cost center production records was used to study the effect of good manufacturing practice regulations on the variable costs of the mixing cost center. Materials used in the analysis of the production records were: (1) practices and procedures of the case study mill, and (2) the 1969 Feed Additive Compendium to assist in determining when clean out of the mixing system was required.⁹

Mixing cost center production records for each production day from January 1, 1969 to December 31, 1969 were analyzed. These daily production records were completed by the mixer operator. The name of the feed manufactured, including code for name and level of medication, was recorded. Production was recorded in the sequence in which each feed was manufactured. Additional information included on this record was: (1) destination bin used, (2) number of tons manufactured during each production run, and (3) texture of feed produced.

Table 1 is a summary of the production statistics that were calculated from the mixing cost center production records. All calculations based on production records were

⁹"Additives and Their Uses," 1969 Feed Additive Compendium (Minneapolis, Minnesota: Miller Publishing Company, 1969), pp. 99-371.

rounded to the nearest whole number since data was reported in whole numbers.

Table 1

Summary of the Mixing Cost Center Production Records,
January 1, 1969 through December 31, 1969^a

Number of production days	252
Total production	21,294 tons
Total number of formula changes	4,016
Average daily production	84 tons
Average daily number of formula changes . . .	16
Average production per formula change	5 tons
Total required mixing system flushes	1,839
Average daily required mixing system flushes .	7
Percent of runs requiring mixing equipment flush	46

^aAll calculations rounded to the nearest whole number.

The number of production days, total production and total number of formula changes were compiled directly from the mixing cost center production records. The mixing cost center operated 252 days and 4,016 formula changes were used to produce 21,294 tons of feed.

Average daily production and average daily number of formula changes were calculated by dividing total production and total number of formula changes respectively by the number of production days. Each days production averaged

84 tons and an average of 16 formula changes were made.

Average production per formula change was calculated by dividing total production by the total number of formula changes. The average production per formula was five tons.

Total required mixing system flushes was arrived at by analyzing the production records. A mixing equipment flush was required when the production record indicated that a medicated feed had been manufactured and was followed by a non-medicated feed or a feed containing a different medication. This situation occurred 1,839 times during the production period studied.

Average daily required mixing system flushes was calculated by dividing the total required mixing system flushes by the number of production days. Percent of runs requiring mixing equipment flush is the ratio of total required mixing system flushes to the total number of formula changes expressed as a percentage. The number of required mixing flushes necessary to comply with good manufacturing practice regulations were significant in number. Flushes were required, on the average, seven times per day or approximately forty-six percent of the formula changes required flushing procedures.

The capacity of the mixing cost center was limited by the amount of time required to collect ingredients in the hopper scale and charge the mixer with hand dump items. This time varied according to the formula and the physical

characteristics of the ingredients. It was estimated that average collection and charge time was six minutes per three ton batch. Based on this time factor, theoretical production capacity of the mixing cost center was calculated to be 240 tons per eight hour shift.¹⁰

The flushing procedure used by the case study mixing center to clean the mixing system determined the amount of lost production time. It was calculated that the time required for one flushing would closely approximate the time required to mix a three ton batch of feed. While collection and charge time was less for flushing than for mixing three tons of feed, extra time was needed for additional equipment set up and proper handling of the flush material. For this study, six minutes was used as the time required for each batch used in compliance with flushing procedures.

The mixing cost center averaged seven mixing system flushes per eight hour production day. At six minutes per flush, a total of 42 minutes of feed production time was used for flushing each day. During the year, there were 1839 flushes at six minutes each or approximately 184 hours was used for flushing. This is equivalent to four weeks and three days, based on a 40 hour standard work week. This time

¹⁰ Minimum required mixing time was three minutes, but mixing time was not a limiting factor on the production capacity of the mixing cost center. The surge bin allowed the mixed feed to be unloaded from the mixer at the end of the required mixing time. Unloading could be done in a shorter time than materials could be accumulated for the next batch. Therefore, the mixer was normally empty before the next charge was weighed and ready for transfer to the mixer.

was charged to compliance with the good manufacturing practice regulations.

During this 42 minutes, a maximum of seven batches or 21 tons of animal feed could have been mixed. Assuming a theoretical mixing cost center capacity of three tons per six minutes or 240 tons per eight hour shift, a change in production capacity due to flushing was computed. This computation revealed that the production capacity of the mixing cost center was decreased by two and five-eighths tons per hour. The percentage decrease in capacity was 8.75 percent.

An alternative computation of the effect on production capacity of the case study mixing cost center was made using information from a Midwest Feed Manufacturers Association study.¹¹ In the time standards developed for their mixing cost center models, five minutes was allotted for each formula change. A complete description of the factors used in arriving at this allowance were not reported but the good manufacturing practice regulations had not been adopted at the time of this report. It was rationalized that this five minute allowance would be applicable to any formula change. Additional time would be needed for procedures deemed necessary by the manufacturer for compliance

¹¹J. R. Witherspoon and others, "Cost Models For In-Plant Operations," Proceedings of the 1956 Midwest Feed Production School (Kansas City, Missouri: Midwest Feed Manufacturers Association, 1956), pp. 39-50.

with good manufacturing practice regulations.

Theoretical capacity of a mixing cost center would be reduced under the assumption that five minutes was required for each formula change. Average theoretical capacity of the case study mixing cost center was reduced from 240 tons per eight hour shift to 200 tons, since an average of 16 formula changes were made each day. The change in the case study mixing cost center production capacity resulting from mixing system flushes was still two and five-eighths tons per hour, but capacity was decreased by 10.5 percent.

The effect of the mixing system flushing procedure on the variable costs of the case study mixing center was calculated in the following manner. Expenditures for electricity and maintenance were not significantly increased since the mixing equipment was operating at only 6.7 percent of full load during flushing. Fuel costs were not affected since fuel was used in the mixing center only for heating liquid ingredients and these ingredients were not used in the flushing procedure. The average daily labor cost attributed to required mixing system flushing was \$4.28. This computation was based on the 42 minutes used each day for flushing of the mixing system, a mixing center labor force of two people, and a \$3.06 per hour wage rate.¹² The labor cost per ton was increased, based on an average daily

¹²Wage rate information was supplied by the case study mill. This rate includes employee fringe benefits.

production of 84 tons, by five cents.

The effect of mixing equipment flushing on the efficiency of the case study mixing cost center was also investigated through the use of marginal analysis.

Marginal analysis of production consists of the examination of the rate of change of production outcomes corresponding to changes in production variables. The concepts of marginal analysis used in this study were: (1) The marginal cost which is defined as the change in total cost corresponding to a unit change in output.¹³ (2) The marginal physical product which is defined as the rate of change of output corresponding to a unit change of an input variable.¹⁴

The case study mixing center did not experience any increase of fixed costs due to mixing system flushing. The only significant change in variable costs was an increase in labor costs resulting from additional labor requirements for flushing. This increase in labor cost resulted in an increased marginal cost since the change in total cost was greater than the corresponding unit change in output of feed than would have been the case if flushing had not been done. Marginal cost is equal to the slope of the total variable cost curve and the total cost curve, therefore, total costs

¹³H. H. Liebhafsky, The Nature of Price Theory (Homewood, Illinois: The Dorsey Press, Inc., 1963), p. 163.

¹⁴Ibid., pp. 123-124.

for a given output of feed were greater when flushing was required.

The marginal physical product of labor was decreased by flushing since an increase in feed output required a greater corresponding increase in labor than when flushing was not used during production.

Decreased capacity of the mixing cost center, due to flushing requirements, would be particularly critical when the production requirements for animal feed, formula changes and flushing of the mixing system exceed the normal work day mixing capacity. This situation could require additional expenditures for production inputs such as overtime labor, increased mill operating time, and equipment investment.

The case study mixing cost center had an effective mixing capacity of 200 tons per eight hour shift. Average daily production, after allowing for 112 minutes lost production time for formula changes and flushes, required a mixing capacity equivalent to 140 tons. This was 70 percent of the effective eight hour mixing capacity. These computations indicate that the mixing cost center was able to meet the average daily production requirements during an eight hour shift.

Even though the mixing center could satisfy the average daily production demand, increases in daily production, number of formula changes, and required mixing system flushes over the daily averages could still result in mixing inefficiency.

A statistical analysis of the data on daily production, number of formula changes and required mixing system flushes was made to investigate the variability of these three daily requirements of the mixing cost center used in this study.

The data pertaining to the variability of daily production, daily number of formula changes and daily required system flushes is in Table 2.

Table 2

Summary of the Variability of Daily Production, Daily Formula Changes and Daily Required Mixing System Flushes, January 1, 1969 through December 31, 1969^a

Population Analized	$\bar{O}$	CV
Daily Production (tons)	23	27%
Daily Number Formula Changes	4	25%
Daily Required Mixing System Flushes .	3	43%

^aAll calculations of the variability statistics rounded to the nearest whole number.

The following formula was used to calculate the standard deviations.¹⁵

$$\text{Standard Deviation} = \bar{O} = \sqrt{\frac{\sum X^2 - \frac{(\sum X)^2}{N}}{N}}$$

¹⁵H. C. Fryer, Elements of Statistics (New York: John Wiley and Sons, 1954), pp. 12-17.

The following formulae were used in calculating the coefficients of variation, expressed as percentages.¹⁶

$$\text{Arithmetic Mean} = \mu = \frac{\sum X}{N}$$

$$\text{Coefficient of Variation} = CV = \frac{\sigma}{\mu} \times 100$$

The variation in daily production was pronounced, as evidenced by a standard deviation of 23 tons and a coefficient of variation of 27 percent.

The number of daily formula changes was also quite variable from day to day since the standard deviation was four changes and a coefficient of variation of 25 percent.

The most variable production requirement was the daily number of required mixing system flushes since the standard deviation was three flushes and a coefficient of 43 percent.

The eight hour effective production capacity of the case study mixing center was not exceeded despite the large variability in the daily requirements for production, number of formula changes and mixing system flushes. An examination of the daily production records disclosed that the combination of these three production requirements was never so large that the demand could not be met with existing eight hour mixing capacity. This indicates that large variability in daily production requirements does not necessarily result

¹⁶Ibid., pp. 40-42.

in a decrease in mixing efficiency so large that overtime labor, extended mill operating time or additional equipment is required by the case mill.

It would be a serious error to assume that these findings would necessarily be true for mixing cost centers of other mills. Other mixing centers cannot be expected to have the same eight hour mixing capacity or like demands for amounts and types of feed. The excess capacity of the mixing center enabled the case study mill to meet the daily mixing requirements through an increase of labor input without increasing the mixing center size.

Conditions can exist in a feed manufacturing plant where the production demands of the mixing cost center can be satisfied only through the use of overtime labor and extended mill operating time or by an increased investment in mixing equipment. These two methods for increasing mixing capacity are commonly used in the feed industry, but management must recognize a special problem associated with the use of additions to equipment investment to expand mixing capacity. This method of increasing mixing capacity is complicated by the fact that inputs of mixing equipment are not available in minute divisible units. The inputs of mixing equipment such as mixers, scale hoppers, surge bins, conveyors, elevators and holding bins must be added in indivisible units. Additional units will maintain or improve efficiency of the mixing center only when they are operated at or near their most efficient capacity. Decisions to

invest in additional mixing equipment to enlarge mixing capacity should be justified by an increased demand or an anticipated increase in demand for mixed feed that is large enough to permit utilization of the added capacity at peak efficiency.

Inputs of overtime labor and mill operating time can be added in divisible units and can be employed with a rather wide degree of flexibility. Overtime labor and extra mill operating time should be used to meet temporary demands for mixed feed which cannot be met with existing eight hour mixing capacity. The use of this method for expanding mixing capacity can be utilized to meet increasing demand for mixed feed until a second shift or equipment investment becomes a more economical alternative.

Comments on Production Scheduling and Future Research

This study has shown that mixing capacity and efficiency of the mixing cost center are directly affected by the number of times that the mixing system is cleaned and the frequency of formula change. It is rationalized from this evidence that production scheduling performs a key role in the determination of mixing efficiency.

The mechanics of preparing a production schedule to assure maximum efficiency of the mixing cost center is a complex problem. The production schedule is complicated by the following factors: (1) customer demand for feed at

specified times, (2) capacities and production schedules of the other mill cost centers, (3) mill capacity for finished feed storage, and (4) capacity and schedules of delivery vehicles.

It is essential that all of these factors be considered in scheduling, but the actual sequence of production runs also affects mixing efficiency. Customer orders for feed should be combined, prior to placement on the mixing production schedule, to reduce the number of production runs of like formulations or medication.

The methods used in analyzing the operation of the case study mixing cost center could be employed in an expanded research project. Information from a representative sample of all feed mills in the United States that are required to comply with the good manufacturing practice regulations would be the basis of such a project. Data similar to the information provided by the case study mill of this report should be obtained from the industry sample.¹⁷ The data could then be analyzed by methods used in this report to determine the effect of the good manufacturing practice regulations on the mixing efficiency of the total feed industry.

The results of such a research study would be especially valuable to the improvement of the working

¹⁷A questionnaire could be developed to obtain the same information which was obtained by the production record analysis used in this case study.

relationship between regulatory agencies and feed manufacturers. The effects on mixing efficiency resulting from government regulations would be based on total industry data and this knowledge should reduce the amount of misunderstanding that often exists about restrictive regulations.

This type of research could also provide the impetus for research and development of improved clean out features for mixing system equipment. This would be particularly true if conclusions of the research study did indicate that the costs associated with mixing system clean out were significant.

SUMMARY AND CONCLUSIONS

The production of animal feeds has become a very complex manufacturing process. Nutritional improvements of livestock rations have been continually incorporated into animal feeds. The demand for these more nutritious diets has required the feed industry to manufacture feeds containing large and diverse combinations of ingredients, vitamins, minerals, drugs, and other feed additives.

Governmental regulatory agencies have been given increased authority over the proper use and handling of drugs in the manufacture of medicated feeds. The influence of federal regulations on the formula feed industry became significant when the Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act were adopted in 1962. Feed manufacturing plants and their mill operations were brought under more direct federal control by the good manufacturing practice regulations enacted on May 11, 1965.

This trend towards governmental regulation of feed manufacturing is expected to continue, therefore feed mill managers must improve their knowledge of the regulations. They must also increase their understanding of the economic implications that these regulations can have on the manufacturing of animal feeds.

This study was primarily concerned with the good

manufacturing practice regulations of the Federal Food, Drug and Cosmetic Act. This study was designed to investigate the influence that compliance with these good manufacturing practices had on the efficiency of the mixing cost center. The mixing cost center was selected for study because mixing is the most important operation in feed manufacturing.

The good manufacturing practice regulations, operating duties of the mixing cost center employees and literature on the operation of the mixing center were analyzed to determine the influence of good manufacturing practice regulations on the efficiency of the mixing cost center. It was concluded that the requirements for cleaning of mixing equipment was the only section of the regulations that would restrict the operation of the mixing cost center.

A case study of a cooperating feed manufacturers' mixing cost center production records was used to determine how the good manufacturing practice regulations affected mixing efficiency. The case study mixing center's labor costs were increased by five cents per ton and effective mixing capacity was decreased by 10.5 percent. These changes in labor costs and mixing capacity were a result of the mixing system cleaning procedure used to comply with good manufacturing practice regulations during the manufacture of medicated feeds.

A statistical analysis of the daily production records indicated that daily requirements for production

tonnage, number of formula changes and mixing system flushes were highly variable during the study period. The case study mixing center was still able to meet mixing demand during a normal eight hour work day.

The method of study used to investigate the effects of good manufacturing practice regulations on efficiency of a single cost center could prove to be a useful tool for management. This approach could assist in the identification of specific problem areas in a mill operation and possibly indicate the nature of the corrective action required.

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THE EFFECTS OF GOOD MANUFACTURING PRACTICE REGULATIONS
ON THE EFFICIENCY OF THE MIXING COST CENTER

by

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The primary objective of this study was to investigate the effects that the good manufacturing practice regulations of the Federal Food, Drug and Cosmetic Act have on the efficiency of the mixing cost center of feed manufacturing plants.

The mixing cost center was selected for study because mixing is the most important operation in feed manufacturing. Selection of this cost center was also made because all feed manufactured must pass through this cost center.

It was concluded that the requirements for cleaning of mixing equipment used in the production of medicated feeds was the only section of the good manufacturing practice regulations that would restrict the operation of the mixing cost center.

A case study approach of a cooperating feed manufacturer's records was used to determine how the regulations affected mixing efficiency. Mixing cost center daily production records for the production year of January 1, 1969 through December 31, 1969 were used for this study. The cooperating feed manufacturer also provided mill operating procedures which outlined the mixing system clean out procedures. The case study mill was using a flushing procedure to clean out the mixing system. Mill procedures were used in conjunction with information from the 1969 Feed Additive Compendium to establish the number of times that a mixing system flush was required during the mixing center production schedules.

The influence of the federal good manufacturing

practice regulations was evaluated by the change in effective mill capacity and mixing efficiency. The case study mixing center had an effective mixing capacity of 200 tons per eight hour day. It was determined that an average of 42 minutes of production time was lost per day because of the seven required mixing system flushes. Using a three ton batch size and a six minute production time per batch, the mixing cost center could have manufactured 21 tons of animal feed during this 42 minute time period. This loss of production represented a 10.5 percent decrease in the effective capacity of the mixing cost center. Labor costs of the mixing cost center were increased five cents per ton.

The case study mixing cost center was able to meet the average daily production requirements during a single eight hour shift even when following the procedures for flushing used to comply with good manufacturing practice regulations. This was possible because the effective eight hour mixing capacity exceeded the average daily production requirements by 30 percent.

Production requirements larger than average could have reduced the ability of the mixing cost center to complete production during a single eight hour shift. A statistical analysis of daily production records was made to investigate the variability of daily production requirements. This analysis revealed that daily requirements for production tonnage, number of formula changes and mixing system flushes were highly variable during the study period. Despite this

variability, the mixing center was able to meet production demand for every day of the study period.

A secondary objective of this study was to improve the understanding of federal government regulations applicable to the feed industry. Information on the history and development of federal regulations pertaining to the manufacture of animal feeds is included in this report.