DETAILED SUMMARY REPORT

on

ACTIVITIES AS A CONSULTANT TO ASSIST THE CVM/FDA ANIMAL FEED SAFETY SYSTEM (AFSS) TEAM, September 15, 2003 – March 31, 2004

and

STRENGTHS AND WEAKNESSES OF CURRENT MEASURES USED BY THE FDA IN ANIMAL FEED SAFETY AND NEEDED ENHANCEMENTS OR MODIFICATIONS

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CVM/FDA

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Objective: The overall objective of this six month, part-time consultancy was to provide technical assistance to The Center for Veterinary Medicine (CVM) in their study and evaluation of how to possibly develop a comprehensive, risk-based Animal Feed Safety System (AFSS) for minimizing the risks to the health of animals and people from hazards in the animal feed supply

Submitted: April 19, 2004

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I.

INTRODUCTION

PURPOSE STATEMENT AND FOCUS

The **purpose** of this six month part-time consultancy was to provide technical assistance to The Center for Veterinary Medicine's (CVM) Animal Feed Safety System (AFSS) Team for use in their on-going study and evaluation on possible development of a comprehensive, risk-based approach for minimizing the risks to the health of animals and people from hazards in the animal feed supply. This assistance was provided through various inputs to the AFSS Team over the period of the contract.

However, before further discussion, it seems appropriate and helpful to relate the description of the type of expertise the CVM/FDA was seeking as stated in the solicitation for technical assistance: individual who has in-depth knowledge of 1) the manufacture and distribution of animal feed, including ingredients, 2) the process control systems used by the industry and non-FDA government agencies, and 3) the regulations and programs employed by the FDA to ensure the safety of the products it regulates, with special emphasis on feed.

Technical assistance was provided to CVM/FDA through participation in the following activities:

1. The Animal Feed Safety System (AFSS) Public Meeting held on September 23-24, 2003

2. Participation in AFSS Team conference calls on a routine basis (usually weekly)

3. Submission of a written summary report of the Animal Feed Safety System (AFSS) Public Meeting

4. Participation in an AFSS Team Go-Away meeting on December 2-3, 2003, and presentation of the Public Meeting summary and update on activities and site visits

5. Planning and coordination of feed industry site visits that relate to both commercial and on-farm feed production

6. Preparation of a booklet on feed manufacturing and teaching a four-hour Feed Manufacturing Short Course to FDA personnel on March 22, 2004

7. Participation in a HACCP Training Workshop on March 23-25, 2004

8. Submission of this summary report

The **focus** of this technical assistance with the AFSS Team was to study the strengths and weaknesses of the current measures used by the FDA in Animal Feed Safety and thereby assist them in developing a comprehensive, risk-based approach for minimizing the risks to the health of animals and people from hazards in the animal feed supply. Specific informational items used to address the strengths and weaknesses of current measures in use today are embodied in the following topical summaries:

1. Census type information on the manufacture and distribution of animal feed by region, state, and specie across the U.S.

2. Evaluation and characterization of the process control systems used by the feed manufacturing industry and non-FDA government agencies across the U.S.

3. Study and evaluation of regulations and programs employed by the FDA to ensure the safety of the products it regulates with special emphasis on feed

4. Review of other measures used by industry and international organizations

II.

PLAN OF WORK, OUTLINE OF TYPES OF INFORMATION COLLECTED, AND SUMMARY OF ACTIVITIES AND COLLABORATION WITH THE AFSS TEAM

PLAN OF WORK

The overall plan of work included being involved with activities of the AFSS Team in their study and evaluation of the potential development of a comprehensive, risk-based Animal Feed Safety System (AFSS) and to assist in areas described in the purpose statement and focus; and to individually collect and compile information from literature searches, industry site visits, and organized events held by industry and/or state organizations. Two reports were required to be submitted to the AFSS Team. One, on the summary of the Animal Feed Safety System Public Meeting, and the other being this summary report on strengths and weaknesses of the current measures used by the FDA in Animal Feed Safety.

Below is a **chronological sequence of consultancy activities** for the period of September 15, 2003 through March 31, 2004.

- **September 15 – 22, 2003**

    1) Talked with Dr. George Graber, AFSS Team Leader, about the contract and studied confidential information he provided in the following three documents:

        a) Charter, Animal Feed Safety System (AFSS) Team

        b) Animal Feed Safety System (AFSS): Project Definition

        c) Concept Paper – Animal Feed Safety System (AFSS)

    2) Began a review and compilation of general information on animal feed safety issues and concerns in the U.S.

- **September 23 – 24, 2003**

    1) Participated in the AFSS Public Meeting at Herndon, VA

- **September 25 – October 31, 2003**

    1) Developed a detailed study plan to collect information from the feed manufacturing industry, and non-FDA government agencies across the U.S.

2) Participated in AFSS Team conference calls

3) Contacted four feed manufacturing companies about site visits

4) Participated in an AFSS Team Sub-Group conference call

5) Reviewed AFSS Public Meeting flip charts, scribes notes, and slides from presentations

- **November 1 – 30, 2003**

1) Studied transcripts of the AFSS Public Meeting

2) Wrote a summary report of the AFSS Public Meeting

3) Participated in AFSS Team conference calls

4) Conducted two feed industry site visits at companies on November 19 – 20 and discussed their quality control programs as related to feed safety

5) Prepared Power Point slides about the AFSS Public Meeting Report, and about on-going activities to present at the AFSS Team Go-Away meeting

6) Contacted other feed manufacturing companies, ingredient suppliers, and trade associations about site visits

- **December 1 – 31, 2003**

1) Attended the AFSS Team Go-Away meeting on December 2 – 3, and presented a summary report of the AFSS Public Meeting and on-going activities

2) Conduced three feed industry site visits at companies on December 17 – 18, and discussed their quality control programs as related to feed safety

3) Participated in AFSS Team conference calls

4) Contacted other feed manufacturing companies, ingredient suppliers, and trade associations about site visits

5) Collected information for use in preparing the detailed summary report

- **January 1 – 31, 2004**

    1) Conducted five feed industry site visits on January 6 – 8, and discussed their quality control programs as related to feed safety

    2) Coordinated the FDA Feed Manufacturing Short Course with Dennis McCurdy, and wrote a summary of topics to be presented

    3) Participated in AFSS Team conference calls

    4) Prepared information to use in the detailed summary report

    5) Coordinated other industry site visits

- **February 1 – 29, 2004**

    1) Prepared information for the FDA Feed Manufacturing Short Course

    2) Conducted one pet food industry site visit on February 18, and discussed their quality control program as related to pet food safety

    3) Participated in AFSS Team conference calls

    4) Coordinated other possible industry site visits

- **March 1 – 31, 2004**

    1) Conducted two feed industry site visits on March 3, and discussed their quality control programs as related to feed safety

    2) Prepared information for the FDA Feed Manufacturing Short Course

    3) Presented the four-hour FDA Feed Manufacturing Short Course on March 22

    4) Participated in AFSS Team conference calls

    5) Worked on writing the AFSS detailed summary report

    6) Participated in the FDA HACCP Training Workshop on March 23-25

OUTLINE OF TYPES OF INFORMATION COLLECTED

To address the subject areas described in the purpose statement and focus, different types of information were reviewed, collected, and some of it compiled for use in preparation of this report. Below is an outline summary of the major types of information studied.

- Literature searches on feed and/or food safety programs in the U.S.
- Literature searches on feed and/or food safety programs in other countries
- News releases on feed safety in trade magazines, Feedstuffs Newspaper, and other popular press sources
- American Feed Industry Association web site
- National Grain and Feed Association web site
- National Cattlemen Beef Association web site
- National Pork Producers web site
- USDA web site
- Personal communication with personnel from the USDA, state feed associations, feed industry leaders, and colleagues – all on a general and confidential basis related to feed safety
- HACCP programs for the food industry, and selected animal species
- CVM/FDA web site
- AAFCO web site
- AAFCO 2003 Official Publication
- Responses from personnel on industry site visits
- Transcripts and proceedings of the Animal Feed Safety System (AFSS) Public Meeting
- Notes and information discussed at the AFSS Team G0-Away conference

- Proceedings of the FDA Feed Manufacturing Short course

- Notes, group responses, and proceedings from the FDA HACCP Training Workshop

SUMMARY OF ACTIVITIES AND COLLABORATION WITH THE AFSS TEAM

Activities during this six month, part-time consultancy involved interaction with the AFSS Team Leader as needed on a daily basis, and with team members on a weekly basis through coordinated conference call work sessions and special functions. Feed safety activities were a high priority for all of the AFSS Team members and this helped stimulate new ideas and concepts that were continually discussed.

Throughout the duration of this six month period, correspondence and effective communication channels were always open and used through emails, conference calls, minutes of agenda items discussed, and proceedings of specific program events. Thus, overall collaboration by AFSS Team members was excellent and provided incentive to accomplish everything possible during this consultancy contract period.

Following is an outline summary of all major activities from September 15, 2003 through March 31, 2004.

1. **Animal Feed Safety System (AFSS) Public Meeting, September 23-24, 2003, Herndon, VA**

    a. **Purpose of public meeting:** To discuss the potential development of a comprehensive, risk-based Animal Feed Safety System (AFSS) describing how animal feeds (including ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and people consuming food products from animals

    The meeting featured stakeholder and government speakers discussing safety measures currently in use and others which could be adapted to the feed industry. In addition, the meeting included several facilitated breakout discussion groups

    b. **Agenda:** The program for the two day meeting consisted of introductory and opening remarks by CVM personnel, lecture type presentations from seven people, breakout study groups, and concluded with reports from breakout study groups. (Below is a retyped copy of the revised agenda.)

September 23

1:00 – 1:05 p.m.	Dr. George Graber, CVM – moderator
1:05 – 1:10 p.m.	Dr. Clifford Johnson, CVM – comments
1:10 – 1:30 p.m.	Dr. Stephen Sundlof, CVM – opening remarks
1:30 – 1:50 p.m.	Tim Costigan, Prince Agri Products – ingredient manufacturer, minerals
1:50 – 2:10 p.m.	Dave Harlan, Excel – ingredient manufacturer, rendering company
2:10 – 2:30 p.m.	Joe Garber, Wenger Feeds – feed manufacturer
2:30 – 2:50 p.m.	Break
2:50 – 3:10 p.m.	Mike Merkel, Doane Pet Care – pet feed company
3:10 – 3:30 p.m.	Mike Davidson, California Department of Food and Agriculture – State feed safety regulatory program
3:30 – 3:50 p.m.	Dennis Byrne, Herr Angus Farm
3:50 – 4:10 p.m.	Dr. Richard Wood, Food Animal Concerns Trust – consumer perspective
4:10 – 4:30 p.m.	Break
4:30 – 4:45 p.m.	Gloria Dunnavan – Explanation of Breakout Groups
4:45 – 5:30 p.m.	Meeting of Breakout Groups
6:00 – 8:00 p.m.	Reception

September 24

7:00 – 8:00 a.m.	Continental Breakfast
8:00 – 9:30 a.m.	Meeting of Breakout Groups
9:30 – 9:45 a.m.	Break
9:45 – 10:45 a.m.	Meeting of Breakout Groups, continued
10:45 – 11:00 a.m.	Break
11:00 a.m. – 12:00 noon	Reports by Breakout Groups
12:00 noon – 1:00 p.m.	Lunch (provided)
1:00 – 2:30 p.m.	Reports by Breakout Groups, continued
2:30 – 2:45 p.m.	Break
2:45 – 3:00 p.m.	Next Steps

c. **Attendance and participation:** Attendance was high and participation was good. This indicated great interest and importance in the topic for the meeting. Participants were from various segments of the overall feed industry in the U.S., state and federal agencies, universities, and the media.

d. **Presentations:** Seven (7) speakers representing feed industry businesses or state/federal agencies delivered twenty minute presentations in their respective areas. The speakers were:

- **Tim Costigan**, Prince Agri Products – ingredient manufacturer, minerals.
- **Dave Harlan**, Excel – ingredient manufacturer, rendering company.
- **Joe Garber**, Wenger Feeds – feed manufacturer
- **Mike Merkel**, Doane Pet Center – pet food company
- **Michael Davidson** - California Department of Food & Agriculture – State feed safety regulatory program
- **Dennis Byrne,** Herr Angus Farm
- **Richard Wood**, Food Animal Concerns Trust – Consumer perspective

e. **Breakout study groups:** Participants were placed in one of twelve (12) different breakout groups of approximate equal size and asked to discuss the concept of an Animal Feed Safety System by answering prepared questions. Each breakout group had a preselected group facilitator and a scribe. Information given to each participant stated the questions to consider; that the FDA is seeking information on the Animal Feed Safety System concept and would appreciate everyone's participation and ideas; and that each group should identify a spokesperson to give the group's report and someone to record the group's answers on a flipchart.

Questions were:

QUESTION # 1 – *What feed safety programs are operating today (industry and government) and can they be made available for review by the FDA?*

QUESTION # 2 – *What do you think are the basic elements of an Animal Feed Safety System?*

QUESTION # 3 – *What are the benefits of having a federal Animal Feed Safety System?*

The Notice of Meeting identified 7 items that FDA considered as possible elements of an Animal Feed Safety System. Please answer questions 4(a) through (h).

QUESTION # 4a – *How much of this are you doing as a firm right now?*

QUESTION # 4b – *Is it formal, i.e., written policy and procedures, or informal?*

QUESTION # 4c – *Would this involve training and what kind would be best and how often?*

QUESTION # 4d – *Would this involve the purchase and use of new equipment and/or software?*

QUESTION # 4e – *What kind of costs do you think this will entail?*

QUESTION # 4f – *What kind of assurances would you need to establish or demonstrate this is functional?*

QUESTION # 4g – *How do you envision risk being introduced into the AFSS? Should the risks be identified by industry or government or both?*

QUESTION # 4h – *Are current enforcement tools adequate?*

QUESTION # 5 – *In conclusion, are there any additional thoughts or comments this group would like to convey to FDA regarding an Animal Feed Safety System?*

f. **General conclusion statement:**

The Food and Drug Administration (FDA) public meeting conducted to discuss the potential development of a comprehensive, risk-based Animal Feed Safety System (AFSS) was highly successful in facilitating input from a rather broad based representation of people from the feed industry, and state and federal people. Many thoughtful ideas, suggestions, and recommendations were received and compiled by the FDA.

Although, as expected, not all ideas and opinions related to the need, direction, and how to establish a national feed safety system were in agreement, but most were supportive and felt the long-tem benefits would out weigh the negatives.

One of the most frequently voiced concerns centered around how to implement and maintain daily operations, on an equitable basis, across a level playing field through all segments of the U.S. animal feeding industries. If a system can be developed that will ensure uniformity, and is successful in identifying and reducing hazards in the U.S. food supply, it will be of great value to animal agriculture and agriculture in general.

Presentations were will prepared and delivered with enthusiasm and pride in light of the overall long-term history of safe animal feed in the U.S. Various presenters demonstrated the attributes and strengths of different components of state-of-the-art quality assurance concerns. While great progress has been achieved by some operations, none were quite at the level of the comprehensive risk-based Animal Feed Safety System being discussed at this meeting.

Results of the breakout study groups were great. The system of assigning groups and sequencing questions was well thought out and delivered the feedback needed. Different groups studied some questions more in depth than others and vice versa. Moreover, excellent and broad responses were received on all questions asked. Breakout group facilitators and scribes were invaluable in generating and capturing information from this part of the meeting.

Finally, overall interest, attendance, participation, and responses relative to discussion of the potential development of a comprehensive, risk-based Animal Feed Safety System (AFSS) were gratifying, and indicate a need to continue efforts in facilitating further broad-based discussions on a national basis. The vision for a system such as AFSS is notable and potential benefits are great.

2. **AFSS Team Go-Away Meeting**, December 2, 2003, Rockville, MD

   a. Meeting Agenda

AFSS TEAM GO-AWAY
December 2 & 3, 2003
MEETING AGENDA

Tuesday, December 2
Location: MPN4; Deli Conference Room

8:30 - 9:00	George Graber	Advancing the AFSS project
9:00 - 10:00	Reed Richardson	Summary of the September Public Meeting on the AFSS
9:30-10:00	10:00-10:15	BREAK
10:15 - 11:30	Group Discussion	Defining a "Comprehensive" AFSS
11:30-12:30	**LUNCH**	
12:30 - 2:00	Group Discussion	Basic Elements of an AFSS
2:00-2:15	**BREAK**	
2:15 - 3:15	Greg Claycamp	Risk Based Approaches for an AFSS
3:15 - 4:15	Randall Lovell	Assessing Animal and Public Health Risks
4:15-4:30	**BREAK**	
4:30 - 5:00	Group Discussion	AFSS Risks

Wednesday, December 3
Location: MPN4; Room 3555

8:30 - 9:30	Group Discussion	AFSS Risks (continued)
9:30 - 10:00	Group Discussion	Training for AFSS Team Members
10:00-10:30	**BREAK**	
10:30 - 12:00	Group Discussion	Obtaining Stakeholders-Input
12:00 - 1:00	**LUNCH**	
1:00 - 1:30	John Lienesch	Economic Impact of AFSS
1:30 - 2:00	David Mednick	Legal Aspects of AFSS
2:00 - 3:00	Next Steps and Wrap Up	George Graber

b. This AFSS Team Go-Away meeting allowed time for the team to work together under the opening challenge of "Advancing the AFSS Project". The meeting was held midway through the six month period and was very beneficial in helping to start pulling concepts and ideas together toward a common goal and

potential end point, and provided focus and direction for staying on the right course.

3. **AFSS Team Conference Calls**: Conference calls were scheduled for Wednesdays and held on a routine basis from 2:30 to 4:00 (Eastern), and were effective in keeping Team members informed about the progress others were making in different areas and on new agenda items.

   a. **Example agenda**:

Animal Feed Safety System Team Meeting

1/14/04
2:30 to 4:00
Call-in Number
Password:
CVM Conference Room

Meeting called by:
George Graber

Type of meeting:
Weekly Team Meeting

Timekeeper: Dennis McCurdy

Attendees: AFSS Team

----- Agenda Topics -----

Update	George Graber	5 minutes
ORA "U" Update	Dennis McCurdy	5
Update on Feed Mill Visits	Reed Richardson	10
Comments to Risk-based Sub-committee's Report	Karen/Team	10
List of Hazards	Karen/Team	10
Draft Definition: Risk-based	Henry Ekperigin	5
Other Business	George/Team	5
Action Items	Jackie Pace	5

Other Information

4. **FDA Feed Manufacturing Short Course**, March 22, 2004, Rockville, MD

   a. **Objective:** Review the fundamental aspects of feed manufacturing in order to familiarize AFSS Team members of conditions, procedures, limitations, and constraints that may be helpful in addressing feed safety in the U.S.

   b. **Introduction:** The animal feed industry (commercial and on-farm) is a vital component of the overall network of activities in the production of animals for food and other purposes. Feed manufacturing is one of the major links in the efficient production of all food producing animals. More that 120 countries around the world are manufacturing feeds, with the U.S. being the largest in size and complexity.

      Feeds are formulated more scientifically and accurately than they can be manufactured in most cases. However, the feed industry in the U.S. and some other countries is closing the gap in manufacturing knowledge and new advances are continually being brought to the industry. In the U.S., improvements in procedures and technology used in the economic and safe production of feeds require a coordinated effort from equipment manufactures, formula feed producers, universities, and other agencies.

   c. **Course focus:** Quality control in the production of feeds

   d. **Feature sections:**

      - Feed manufacturing facility design and production capabilities
      - Inventory control
      - Quality control
      - Manufacturing steps
      - Micro ingredient inclusion process
      - Factors that contribute to variation of nutrients and feed additives

   e. **Wrap-up and conclusion:**

Feed manufacturing is an integral part of agriculture in the U. S. It plays a key role in adding value to many plant crops that are produced primarily for animal feed, and many secondary byproducts from food processing and industrial uses. Thus, it is an understatement to say it provides a very important service to the general populace of the nation that many people take for granted.

Along with the great value the feed manufacturing industry provides, comes with it the high responsibility to be diligent in addressing high quality standards in the production of nutritious and safe feeds for all animals. Feed manufacturing is a rather broad discipline-based industry requiring expertise in several areas such as nutrition, engineering, management, accounting, marketing, sales, government relations, and others.

A short course such as this one just allows for a brief review and discussion of some of the topics involved and, hopefully, has provided some insight into quality aspects being addressed at hundreds of locations on a daily basis. Follow-up information may be found from the references provided or from other sources available.

5. **FDA HAACP Workshop**, March 23-25, 2004, Rockville, MD

   a. **Purpose:** Train the AFSS Team and FDA personnel on the concepts and principles of the Hazard Analysis and Critical Control Point (HACCP) system for prevention of problems related to chemical, biological, and physicals hazards that could be carried from animal feeds through animals to human food.

   b. **Summary:** This was a two and one-half day workshop coordinated by representatives from Kansas State University. The workshop was very beneficial in being able to understand how a HACCP program complements other quality assurance steps and procedures covered under Current Good Manufacturing Practices and standard operating procedures. Below is a copy of the HACCP Workshop agenda which includes HACCP principles by title, followed by an excerpt from a publication about the HACCP concept. The publication is titled “HACCP – A Systematic Approach to Food Safety”.

FDA HACCP Workshop Agenda

March 23	Topic
8:30 a.m.	Registration
	Welcome and introductions

	HACCP: A Tool That Will Enhance Food Safety
	Prerequisites for Feed Mills (CGMPs, SOPs, CFRs)
	Break
	Overview of HACCP Principles & Initial Steps in Developing a HACCP Plan
	Case Study Example
	Working Groups: Defining Your Product and Flow Diagram
Noon	*Lunch*
	Continue Working Groups: Defining Your Product & Flow Diagram
	Discussion of Working Group Results
	Break
	Physical and Chemical Safety Hazards in a Feed Mill
	Pathogen Reduction and Biological Food Safety Hazards
5:00 p.m.	*Adjourn*

<u>March 24</u>

8:00 a.m.	HACCP Principle 1: Hazard Analysis and Risk Assessment
	Case Study Example
	Working Groups: Hazard Analysis
	Break
	Discussion of Working Group Results
	HACCP Principle 2: Identifying Critical Control Points (CCPs)
	Case Study Example
	Working Groups: Identifying Critical Control Points
Noon	*Lunch*
	Discussion of Working Group Results
	HACCP Principles 3-5: Establishing Critical Limits, Monitoring Activities, and Corrective Actions
	Case Study Example
	Break
	Working Groups: Critical Limits, Monitoring and Corrective Action Procedures
	HACCP Case Study Example
5:00 p.m.	*Adjourn*

<u>March 25</u>

8:00 a.m.	HACCP Principle 6: Establishing Verification Procedures
	HACCP Principle 7: Establishing Recordkeeping Procedures
	Case Study Example
	Summarize HACCP Plan
	Break
	Discussion of Working Group Results
	Recalls: Class 1 and Class 2
	Integrating HACCP with SOPs and GMPs (Group Discussion)
Noon	*Adjourn*

HACCP CONCEPT

The **H**azard **A**nalysis and **C**ritical Control **P**oint (HACCP) system is a management system focused on prevention of problems in order to assure the production of food products that are safe to consume. It is based on a common-sense application of technical and scientific principles to the food production process from field to table. The principles of HACCP are applicable to all phases of food production, including basic agriculture, food preparation and handling, food processing, food service, distribution systems and consumer handling and use.

The most basic concept underlying HACCP is that of prevention rather than inspection. A food grower, processor, handler, distributor or consumer should have sufficient information concerning the food and the related procedures they are using, so they will be able to identify where and how a food safety problem may occur. If the "where" and "how" are known, prevention becomes easy and obvious, and finished product inspection and testing becomes superfluous. A HACCP program deals with control of factors affecting the ingredients, product and process. The objective is to make *the* product *safe to consume, and to be* able to prove it. The where and how are the HA (hazard analysis) part of HACCP. The proof of the control of processes and conditions is the CCP (Critical Control Point) part. Flowing from this basic concept, HACCP is simply a methodical and systematic application of the appropriate science and technology to plan, control and document the safe production of foods.

By definition, the HACCP concept covers all types of potential food safety hazards—biological, chemical and physical—whether they are naturally occurring in the food, contributed by the environment or generated by a mistake in the manufacturing process. While chemical hazards are still feared by many consumers and physical hazards are the most commonly identified by consumers, microbiological hazards are the most serious from a public health perspective. For this reason, while HACCP systems address all three types of hazards, a majority of the emphasis is placed on microbiological issues. For example, a piece of metal (physical hazard) in a food product may result in a chipped tooth for one consumer, but contamination of a batch of milk with *Salmonella* may affect hundreds or even thousands of consumers.

III.

INDUSTRY SITE VISITS

Thirteen (13) industry site visits were conducted at organizations representing both large and small commercial feed manufacturers, pet food manufacturers, poultry producers, grain processors, automated micro ingredient providers, and cattle feeders, to gain on-site feedback and an appreciation of industry attitude

toward animal feed safety concerns in the U.S. Locations visited in the order conducted, and contact representative(s) were:

1. United Feeds, Inc., Sheridan, IN – Kerry Krom

2. ADM Alliance Nutrition, Inc., Quincy, IL – Randy Sample, Kim Humphry

3. Land O'Lakes, Inc., Shoreview, MN – Keith Pike

4. Cargill, Inc., Minneapolis, MN – Sue Carlson, Jeff Threlkeld, Charlie Engrem

5. Ridley, Inc., Mankato, MN – Bruce Johnson, Mike Stott

6. Bagdad Roller Mills, Bagdad, KY – William Tucker

7. Producers Feeds, Louisville, KY – Brent Williams

8. Odom's Livestock Supply, Inc., Mayfield, KY – Joe Odom

9. Medallion Feeds, Mayfield, KY – Lisa Barlow

10. Cagle's Keystone Foods, LLC, Franklin, KY – Richard Morrison

11. Doane Pet Care Company, Temple, TX – John Sarcopski, Thomas Smolen

12. Micro Beef Technologies, Amarillo, TX – Duane Lomax

13. Texas Cattle Feeders Association, Amarillo, TX – Ross Wilson

Upon arrival at all locations, it was explained to contact representatives the purpose of the site visit and that any comments they made would not be directly connected with their organization in any subsequent reporting to CVM/FDA. In all visits, representatives were cordial and expressed interest in the topic of the meeting. After introductions, a one page sheet with information shown below was given to industry representatives participating in the meeting. A secrecy agreement was signed at one site before discussions proceeded.

FEED INDUSTRY SITE VISITS

Conducted by

C. Reed Richardson, Consultant for the FDA Center for Veterinary Medicine (CVM) on The Animal Feed Safety System (AFSS)

MY ROLE: ASSIST THE AFSS TEAM IN:

1. Summarizing the manufacture and distribution of animal feed (including ingredients) by region, state, and specie across the U.S.

2. Evaluating and characterizing the process control systems used by the feed manufacturing industry and non-FDA government agencies across the U.S.

3. Studying and evaluating the regulations and programs employed by the FDA to ensure the safety of the products it regulates with special emphasis on feed.

Duration of site visits ranged from one to two hours, depending on whether a walk through tour of facilities was involved. Prepared questions were not asked in a routine sequence, but instead discussions mostly followed the direction of their points of interest about animal feed safety concerns. However, sometime throughout the visit, representatives at all sites were asked to respond to the same fundamental questions and concepts related to animal feed safety. Summary responses to these questions and concepts are reflected in the pooled comments below.

SUMMARY COMMENTS FROM INDUSTRY SITE VISITS

Question – Does your company/organization have a quality assurance program that addresses animal feed safety? Responses:

1) No policies for microbiological testing

2) Working on HACCP certification

3) Have certification programs in all plants

4) Went with ISO certification and now working toward HACCP approval

5) Using only non-GMO corn

6) View feed safety as a high priority

7) Test for pesticides in the birds marketed

Question – What do you think is the most effective way to address animal feed safety concerns across the nation? Responses:

1) Should cover medicated and non-medicated facilities

2) Should be more aligned with the small feed producers where the problem areas exist

3) See feed manufacturing plants becoming specialized and feed safety should cover all types

Question – Does your company/organization have a policy for chemical testing of feeds? Responses:

1) Pull random samples and send to commercial licensed labs

2) Working toward this at all plants

3) Certification programs in all plants

Question – Does your company/organization have a policy for microbiological testing of feeds? Responses:

1) No

2) Working toward HACCP certification in all plants

3) Certification programs in all plants

4) Some steps are being taken

Question – Does your company/organization have a policy for detection of physical hazards in feeds? Responses:

1) "Yes" was the response at all sites visited

Question – What priority and emphasis does your company/organization place on traceability of feedstuffs you acquire? Responses:

1) High priority and will have policies in place within a year for all products

2) Not a priority yet

3) High priority and have traceability

4) One buyer for all ingredients, with specifications required

Question – Does your company/organization use ISO certification and/or HACCP certification in its overall quality assurance program? Responses:

1) Use ISO

2) Working on HACCP certification

3) No

4) The feed industry should decide on what the critical control points are that could develop in unsafe feeds

5) Yes

Question – What are your thoughts about feed sampling procedures used in the industry and should they be standardized? Responses:

1) The methods and procedures are working

2) Random sampling is used

3) Sampling at site of supplier before loading

4) Deal only with reputable suppliers

5) Use only approved suppliers

6) Routine sampling of every load

Question – How could an animal feed safety system be designed to include both commercial and on-farm feed production? Responses:

1) Industry needs to be highly involved in developing a feed safety system that will cover all feed producers

2) Need to tie the efforts of AAFCO together with the efforts of FDA

Question – What steps need to be followed, at this time, to minimize the risks to the health of animals and people from hazards in the animal feed supply? Responses:

1) Continue to work toward certification of all feed producers

2) Follow through with AFSS study and keep industry involved in the process

Question – How can the ideas, opinions and issues from all the stakeholders in animal feeding in the U.S. be pulled together under one umbrella of an animal feed safety system? Responses:

1) Industry must be highly involved

2) Steps taken in the AFSS Public Meeting were in the right direction

3) Continue to get feedback from all stakeholders

Question – Do you have any additional comments or concerns about animal feed safety as related to your company/organization? Responses:

1) Concern is that if a FDA Feed Safety System is established, some companies will be expected to meet higher standards than others

2) Concern about how to implement and maintain daily operations, on an equitable basis, across a level playing field through all segments of the U.S. animal feeding industries

3) AFSS must address the entire feed industry and not just the medicated feed facilities

4) Will see a move by the U.S. feed industry toward HACCP

5) Not all states do the same inspections now. For example, only about half of the 50 states do BSE inspections

The feed manufacturing industry in the U.S. is composed of a wide variety of feed producers including large companies, cooperatives, and small businesses who collectively manufacture feed for all species of animals. Even though all manufacturers have the same overall general purpose in the production of nutritious and safe feed for animals, they do have different programs and procedures for addressing quality assurance and may have different inherent capabilities. Thus, overall similarities in programs across the industry are greater than the differences; however, significant differences do exist.

The most prominent difference in quality assurance programs is between medicated and non-medicated facilities. Since management at medicated facilities already have in place programs and day-to-day SOP's to comply with CGMP requirements, it will enable them to adapt feed safety procedures more rapidly.

The other prominent difference in quality assurance programs is between manufactured complete feeds produced by a business and on-farm production of diets, rations and supplements of various types. This on-farm production is much more difficult to characterize and to make summary comparisons on how, what,

and where in reference to procedures, type of formulation (if any), and location – all which may have direct relationships to safety and traceability. On-farm feed production appears to mostly fit in one of the following three categories:

1) feeding ingredients grown on the farm or bought, without any grinding or mixing;
2) feeding ingredients grown on the farm or bought, plus adding a supplement mixed on the farm; or
3) feeding ingredients grown on the farm or bought, plus adding a supplement purchased from a feed manufacturing business.

Categories 2) and 3) could constitute diets formulated to meet requirements, but this may or may not be the case across the U.S. Instead of formulation, a set amount of supplement (usually protein, minerals and/or vitamins) may be offered daily or twice a week, with the energy source (roughage or higher energy feedstuffs such as grain) provided in a separate feeding allotment. Category 1) is commonly not formulated to meet requirements.

IV.

SUMMARY OF FINDINGS ON STRENGTHS AND WEAKNESSES OF THE CURRENT MEASURES USED BY THE FDA, STATE REGULATORY AGENCIES, INDUSTRY, AND INTERNATIONAL ORGANIZATIONS

Attempting to summarize the strengths and weaknesses across federal, state, industry, and international programs related to feed safety was a daunting task and is potentially flawed by possible omissions and misinterpretations. However, a workable comparison of strengths and weaknesses is possible based on information available relating to on-going practices and policies to monitor quality standards.

Much has been written about the value of quality/safety based policies such as CGMP's, ISO's, HACCP, and other related programs. Moreover, it is not the intent here to review and/or compare these programs, but to concisely compare and differentiate the functional uses of quality assurance programs across federal, state, industry, and international programs. Before addressing this appraisal of strengths and weaknesses of current measures in use, it is important to emphasize that the U.S. has a highly effective system of feed manufacturing and feed distribution necessary for use in meeting the proper nourishment of animals, and the Nation enjoys a long history of safe animal feeds.

Based on all sources of information studied during this consultancy contract (as summarized earlier in this report) and knowledge of the subject in other ways through university teaching and research – strengths and weaknesses will be

compared followed by some ideas for possible enhancements and/or modifications necessary for AFSS. Quality assurance programs related to feed manufacturing, animal food products, and animals enterprises in general have been updated in recent months to address specific hazards in the animal feed supply. The following three subsections of information are presented for use in addressing comments that follow on strengths, weaknesses, enhancements, and/or modifications.

CENSUS TYPE INFORMATION ON THE MANUFACTURE AND DISTRIBUTION OF ANIMAL FEED BY REGION, STATE, AND SPECIE ACROSS THE U.S.

1. Manufactured feed production in the U.S. and consumption by specie

Total annual production of manufactured feed in the U.S. is approximately 160 million tons. This number does not include on-farm feed production or roughage utilization.

Manufactured feed consumption by specie

Specie	U.S. (million tons)	Rank	% of Total
Poultry	53	1	32.8
Swine	40	2	24.7
Dairy	36	3	22.3
Beef	31	4	19.2
Sheep	0.9	5	0.6
Catfish	0.6	6	0.4
Horses[a]	-	-	-
Pets[a]	-	-	-

[a]Because of packaging type and size of many products, data on overall tons manufactured are unavailable.

2. Number of approved medicated feed mill licenses by state and total estimated number of feed mills by state

	Medicated licenses	Feed mills
• Alabama	24	107
• Alaska	-	-
• Arizona	3	23
• Arkansas	38	73
• California	46	141
• Colorado	33	106
• Connecticut	2	15

• Delaware	6	14
• Florida	13	100
• Georgia	59	188
• Hawaii	-	-
• Idaho	19	94
• Illinois	36	476
• Indiana	33	465
• Iowa	111	729
• Kansas	78	513
• Kentucky	16	173
• Louisiana	10	61
• Maine	2	2
• Maryland	9	75
• Massachusetts	3	3
• Michigan	14	270
• Minnesota	74	453
• Mississippi	23	89
• Missouri	46	381
• Montana	16	61
• Nebraska	68	368
• Nevada	-	-
• New Hampshire	1	1
• New Jersey	1	16
• New Mexico	4	34
• New York	10	228
• North Carolina	59	218
• North Dakota	11	85
• Ohio	32	394
• Oklahoma	31	158
• Oregon	10	60
• Pennsylvania	32	310
• Rhode Island	-	-
• South Carolina	8	66
• South Dakota	17	199
• Tennessee	12	100
• Texas	100	509
• Utah	7	51
• Vermont	3	19
• Virginia	19	135
• Washington	22	47
• West Virginia	2	26
• Wisconsin	35	623
• Wyoming	2	16

3. Animal numbers in the U.S., Canada, and Mexico and feed potential

a. Poultry numbers and feed potential

REGION: STATE	Layers (thousand)	Broilers[1] (thousand)	Turkeys (thousand)	Total feed potential (thousand tons)
NORTH ATLANTIC:				
Connecticut	3,106	-	7	125
Maine	4,146	-	-	166
Massachusetts	269	-	68	14
New Hampshire	159	-	5	7
New Jersey	1,994	-	34	81
New York	3,887	2,400	520	193
Pennsylvania	23,641	133,200	9,900	2,098
Rhode Island	-	-	-	-
Vermont	197	-	46	10
TOTAL	37,399	135,600	10,580	2,694
NORTH CENTRAL:				
Illinois	3,431	-	2,900	278
Indiana	22,435	-	13,000	1,528
Iowa	36,980	-	6,800	1,809
Kansas	-	-	-	-
Michigan	6,686	-	4,800	500
Minnesota	11,729	44,200	44,000	2,826
Missouri	6,923	-	25,500	1,514
Nebraska	11,591	3,700	-	482
North Dakota	-	-	1,900	92
Ohio	30,479	39,000	5,400	1,678
South Dakota	2,335	-	4,800	326
Wisconsin	4,272	33,800	-	342
TOTAL	136,861	120,700	109,100	11,375
SOUTH ATLANTIC:				
Delaware	1,315	257,400	3	1,353
Florida	10,631	114,700	-	1,004
Georgia	20,452	1,290,500	-	7,335
Maryland	3,197	292,900	435	1,628
North Carolina	11,045	735,200	45,500	6,361
South Carolina	5,372	192,900	9,900	1,669
Virginia	3,134	265,500	20,000	2,436
West Virginia	1,219	89,700	3,600	676
TOTAL	56,365	3,238,800	79,438	22,463
SOUTH CENTRAL:				
Alabama	10,173	1,051,300	-	5,716
Arkansas	14,829	1,186,300	29,500	8,015
Kentucky	3,932	269,900	-	1,520
Louisiana	1,982	-	-	79
Mississippi	6,795	769,500	-	4,158
Oklahoma	4,173	232,800	-	1,343
Tennessee	1,354	186,400	-	995
Texas	18,608	588,100	-	3,714
TOTAL	61,846	4,284,300	29,500	25,540
WEST:				
Alaska	-	-	-	-

Arizona	-	-	-	-
California	23,652	-	17,700	1,805
Colorado	3,736	-	-	149
Hawaii	539	880	-	26
Idaho	886	-	-	35
Montana	341	-	-	14
Nevada	-	-	-	-
New Mexico	-	-	-	-
Oregon	2,750	-	-	110
Utah	3,342	-	-	134
Washington	5,166	-	-	207
Wyoming	12	-	-	0
TOTAL	40,424	880	17,700	2,480
OTHER STATES	4,312[2]	809,900[3]	26,111[4]	5,529
USA TOTAL	337,207	8,590,180	272,429	70,081

[1]Includes Alaska, Arizona, Nevada, New Mexico, North Dakota, and Rhode Island.
[2]Includes California, Indiana, Iowa, Louisiana, Missouri, Oregon, and Washington.
[3]Excludes states producing less than 500,000 birds.
[4]Includes Colorado, Georgia, Iowa, Kansas, Minnesota, Nebraska, Oklahoma, Oregon, Texas, Utah, and Wisconsin.
Adapted from Feed Management, October, 2003. Source: NASS, UDSDA

b. Swine numbers and feed potential

REGION: STATE	Operations	Sows (thousand)	Pigs fed (thousand)	Total feed potential (thousand tons)
NORTH ATLANTIC:				
Connecticut	220	1	6	3
Maine	400	2	13	7
Massachusetts	400	3	21	10
New Hampshire	270	1	8	4
New Jersey	300	2	18	8
New York	1,300	15	125	58
Pennsylvania	2,900	213	1,879	870
Rhode Island	50	1	5	2
Vermont	300	1	5	2
TOTAL	6,140	237	2,079	965
NORTH CENTRAL:				
Illinois	4,600	850	7,332	3,415
Indiana	3,400	610	5,331	2,475
Iowa	10,000	1,740	14,940	6,968
Kansas	1,500	320	2,773	1,290
Michigan	2,300	196	1,764	813
Minnesota	6,200	1,060	9,409	4,350
Missouri	2,800	695	6,169	2,852
Nebraska	2,900	675	6,050	2,790
North Dakota	600	52	438	205
Ohio	4,500	297	2,647	1,222
South Dakota	1,500	269	2,400	1,108
Wisconsin	2,300	110	937	438
TOTAL	42,600	6,874	60,190	27,926
SOUTH ATLANTIC:				

Delaware	130	8	56	28
Florida	1,400	14	98	48
Georgia	1,000	100	883	409
Maryland	510	9	70	34
North Carolina	3,200	2,175	19,576	9,017
South Carolina	600	57	511	236
Virginia	1,100	59	539	247
West Virginia	1,100	2	18	8
TOTAL	9,040	2,424	21,751	10,027
SOUTH CENTRAL:				
Alabama	300	24	217	100
Arkansas	1,000	200	1,902	864
Kentucky	1,200	90	772	360
Louisiana	580	5	32	16
Mississippi	1,500	59	498	233
Oklahoma	2,600	670	5,980	2,761
Tennessee	1,300	53	441	207
Texas	3,800	184	1,640	757
TOTAL	12,280	1,284	11,482	5,298
WEST:				
Alaska	40	0	2	1
Arizona	180	33	261	125
California	750	33	286	133
Colorado	390	304	2,573	1,205
Hawaii	230	5	32	16
Idaho	400	6	42	20
Montana	500	38	348	160
Nevada	100	1	7	3
New Mexico	400	0	3	1
Oregon	1,000	6	54	25
Utah	400	137	1,242	571
Washington	750	5	42	20
Wyoming	150	42	365	170
TOTAL	5,290	610	5,257	2,449
USA TOTAL	75,350	11,429	100,758	46,665

Adapted from Feed Management, October, 2003. Source: NASS, USDA

c. Dairy numbers and feed potential

REGION: STATE	Cows (thousand)	Calves to 6 mos. (thousand)	Replacement heifers (thousand)	Total feed potential (thousand tons)
NORTH ATLANTIC:				
Connecticut	23	11	11	85
Maine	36	19	19	126
Massachusetts	20	10	10	68
New Hampshire	17	8	8	60
New Jersey	13	6	6	42
New York	680	333	325	2,210
Pennsylvania	590	287	280	2,169
Rhode Island	1	1	1	4
Vermont	153	60	59	511
TOTAL	1,533	737	719	5,275
NORTH CENTRAL:				
Illinois	114	51	50	402

Indiana	145	56	55	511
Iowa	208	103	100	734
Kansas	105	51	50	425
Michigan	301	138	135	1,174
Minnesota	480	302	295	1,848
Missouri	134	56	55	503
Nebraska	66	21	20	224
North Dakota	37	13	13	125
Ohio	260	113	110	942
South Dakota	94	31	30	318
Wisconsin	1,265	666	650	4,934
TOTAL	3,209	1,602	1,563	12,139
SOUTH ATLANTIC:				
Delaware	9	3	3	28
Florida	147	41	40	724
Georgia	85	30	29	391
Maryland	80	33	32	257
North Carolina	63	29	28	242
South Carolina	20	8	8	85
Virginia	118	49	48	392
West Virginia	15	7	7	47
TOTAL	537	200	195	2,166
SOUTH CENTRAL:				
Alabama	19	7	7	72
Arkansas	31	10	10	114
Kentucky	120	46	45	408
Louisiana	49	10	10	182
Mississippi	33	15	15	126
Oklahoma	88	31	30	347
Tennessee	84	41	40	303
Texas	311	113	110	1,392
TOTAL	735	274	267	2,944
WEST:				
Alaska	1	1	1	5
Arizona	150	36	35	611
California	1,680	810	790	7,075
Colorado	98	39	38	424
Hawaii	6	3	3	3
Idaho	390	195	190	1,874
Montana	18	11	11	69
Nevada	25	11	11	109
New Mexico	310	72	70	1,598
Oregon	117	62	60	473
Utah	91	46	45	337
Washington	247	108	105	1,032
Wyoming	4	1	1	11
TOTAL	3,137	1,394	1,360	13,621
USA TOTAL	9,152	4,206	4,104	36,146

Adapted from Feed Management, October, 2003. Source: NASS, USDA

d. Beef numbers and feed potential

REGION: STATE	Operations	Cows (thousand)	Replacement heifers (thousand)	Feedlot cattle (thousand)[1]	Total feed potential (thousand tons)
NORTH ATLANTIC:					
Connecticut	800	6	1	-	1
Maine	1,000	10	5	-	1
Massachusetts	700	5	1	-	1
New Hampshire	530	4	2	-	0
New Jersey	900	9	3	-	1
New York	6,000	80	25	-	9
Pennsylvania	11,200	150	45	-	16
Rhode Island	140	2	0	-	0
Vermont	1,000	10	4	-	1
TOTAL	22,270	276	85	-	30
NORTH CENTRAL:					
Illinois	15,800	426	60	-	42
Indiana	12,000	230	41	-	23
Iowa	26,000	992	130	712	1,238
Kansas	28,000	1,525	250	5,495	8,961
Michigan	7,000	89	35	-	10
Minnesota	15,500	400	100	-	42
Missouri	58,000	2,116	305	-	209
Nebraska	22,000	1,934	280	4,610	7,581
North Dakota	11,800	973	155	-	97
Ohio	16,000	260	70	-	28
South Dakota	16,800	1,686	290	422	846
Wisconsin	12,000	235	65	-	25
TOTAL	240,900	10,866	1,781	11,239	19,101
SOUTH ATLANTIC:					
Delaware	230	4	1	-	0
Florida	16,500	953	130	-	94
Georgia	20,000	625	90	-	62
Maryland	2,700	41	11	-	4
North Carolina	21,000	417	73	-	42
South Carolina	10,000	210	38	-	21
Virginia	22,000	682	120	-	69
West Virginia	11,000	195	35	-	20
TOTAL	103,430	3,127	498	-	311
SOUTH CENTRAL:					
Alabama	25,000	761	118	-	76
Arkansas	27,000	949	180	-	96
Kentucky	39,000	1,120	175	-	111
Louisiana	13,000	471	86	-	48
Mississippi	21,000	557	95	-	56
Oklahoma	50,000	2,042	380	770	1,441
Tennessee	44,000	1,106	200	-	112
Texas	133,000	5,489	760	5,980	10,126
TOTAL	352,000	12,495	1,994	6,750	12,064
WEST:					
Alaska	80	4	1	-	0
Arizona	2,000	165	34	341	564
California	12,500	740	130	671	1,150
Colorado	10,500	702	102	2,470	4,029

Hawaii	700	79	12	-	8
Idaho	7,600	490	90	728	1,216
Montana	11,400	1,402	380	-	149
Nevada	1,400	245	46	-	25
New Mexico	6,800	470	90	177	331
Oregon	12,600	593	115	-	60
Utah	5,600	339	75	-	35
Washington	10,100	248	55	508	840
Wyoming	5,200	706	120	-	71
TOTAL	86,480	6,183	1,250	4,895	8,478
OTHER STATES				755	1,210
USA TOTAL	805,080	32,947	5,608	23,639	41,195

[1] 1,000+ capacity feedlots
Adapted from Feed Management, October, 2003. Source: NASS, USDA

e. Sheep numbers and feed potential

REGION: STATE	Ewes (thousand)	Lambs (thousand)	Total feed potential (thousand tons)
NORTH ATLANTIC:			
New England[1]	32	27	5
New Jersey	-	-	-
New York	40	32	6
Pennsylvania	55	52	10
TOTAL	127	110	21
NORTH CENTRAL:			
Illinois	42	45	9
Indiana	34	36	7
Iowa	135	218	40
Kansas	47	61	11
Michigan	41	33	6
Minnesota	85	132	24
Missouri	48	50	9
Nebraska	56	100	18
North Dakota	77	85	16
Ohio	97	106	20
South Dakota	265	308	58
Wisconsin	52	55	10
TOTAL	979	1,227	229
SOUTH ATLANTIC:			
Delaware	-	-	-
Florida	-	-	-
Georgia	-	-	-
Maryland	-	-	-
North Carolina	-	-	-
South Carolina	-	-	-
Virginia	38	40	7
West Virginia	23	25	5
TOTAL	61	65	12
SOUTH CENTRAL:			
Alabama	-	-	-
Arkansas	-	-	-
Kentucky	-	-	-
Louisiana	-	-	-
Mississippi	-	-	-

Oklahoma	41	34	6
Tennessee	-	-	-
Texas	680	495	97
TOTAL	721	529	103
WEST:			
Alaska	-	-	-
Arizona	56	88	16
California	295	517	95
Colorado	155	880	156
Hawaii	-	-	-
Idaho	184	204	38
Montana	213	247	46
Nevada	65	48	9
New Mexico	140	93	18
Oregon	125	172	32
Utah	250	237	45
Washington	34	50	9
Wyoming	295	284	54
TOTAL	1,812	2,820	521
OTHER STATES[2]	89	60	12
USA TOTAL	3,789	4,810	899

[1]Includes Connecticut, Maine, Massachusetts, Rhode Island, and Vermont.
[2]Includes Alabama, Alaska, Arkansas, Delaware, Florida, Georgia, Hawaii, Kentucky, Louisiana, Maryland, Mississippi, New Jersey, North Carolina, South Carolina, and Tennessee.
Adapted from Feed Management, October, 2003. Source: NASS, USDA

f. Cat fish live weight and feed potential

STATE	Operations	All food size fish (thousand pounds)	Total feed potential (tons)
Alabama	231	142,000	142,360
Arkansas	155	97,000	99,280
California	38	3,900	3,974
Florida	34	1,300	1,333
Georgia	43	1,670	1,770
Illinois	12	200	212
Kentucky	60	1,470	1,475
Louisiana	57	26,600	26,600
Mississippi	405	392,000	405,480
Missouri	31	765	765
North Carolina	46	4,900	4,960
South Carolina	13	988	1,018
Texas	30	950	973
Other states	*	*	2,194
USA total	1,155	673,743	692,394

*Included in other states to avoid disclosure of individual operation.
Adapted from Feed Management, October, 2003. Source: NASS, USDA

g. Petfood sales in dollars

Type	U.S. Dollars (millions)
Dry dog food	5,201

Canned dog food	1,380
Semi-moist dog food	1,475
Dog treats	80
Total dog food	8,136
Dry cat food	2,344
Canned cat food	1,652
Semi-moist cat food	53
Cat treats	167
Total cat food	4,216
Total dog and cat food	12,352

Adapted from Feed Management, October, 2003. Source: Davenport & Company

Petfood sales by retail outlet

Outlet	U.S. Dollars (millions)
Grocery store	4,620
Mass market	3,055
Pet specialty store	2,490
Farm/feed store	903
Vet/kennel	754
Other	530
Total dog and cat food	12,352

Adapted from Feed Management, October, 2003. Source: Davenport & Company

h. Canadian food animal numbers

LOCATION	Poultry (thousand)	Swine (thousand)	Dairy (thousand)	Beef (thousand)
Newfoundland	9,086	5	6	1
Prince Edward Island	2,374	234	21	43
Nova Scotia	23,146	238	35	41
New Brunswick	17,328	228	28	36
Quebec	174,833	7,556	549	374
Ontario	210,833	7,890	567	979
Manitoba	30,729	6,575	62	879
Saskatchewan	23,075	2,023	43	1,661
Alberta	58,367	4,178	128	4,113
British Columbia	122,006	325	112	436
Canada total	667,771	29,252	1,551	8,563

Adapted from Feed Management, October 2003. Sources: Livestock Statistics, Statistics Canada, catalogue number 23-603; Chicken Farmers of Canada, 2002; Canadian Egg Marketing Agency, 2002; Canadian Turkey Marketing Agency, 2002.

i. Mexican livestock production

Specie	Thousand metric tons
Broilers	1,928
Eggs	1,892
Swine	1,058
Beef cattle	1,445
Goats	39
Sheep	36
Milk (thousand liters)	9,472

Adapted from Feed Management, October 2003. Source: Mexican Ministry of Agriculture (Secretaria de Agricultura, Ganaderia y Desarollo Rural).

EVALUATION AND CHARACTERIZATION OF THE PROCESS CONTROL SYSTEMS USED BY THE FEED MANUFACTURING INDUSTRY AND NON-FDA GOVERNMENT AGENCIES ACROSS THE U.S.

Process control systems used by the feed manufacturing industry and non-FDA government agencies have similar features and are developed to meet expectations for quality assurance. Verification of process control is an important aspect of all quality assurance programs, in all types of feed production facilities.

1. Flow diagrams for different processes

   In developing process control systems, one of the first steps is to develop flow diagrams for the various systems that are involved in the overall operation. The following considerations should be part of flow diagram development.

   a. Identify the purpose of the flow diagram

      - Who will be using it
      - What should be included in the flow
      - Should bin volumes, flow rates, machine capacities, motor sizes, etc. be included
      - Include only that information required for the intended purpose

   b. Break the process down into individual systems with specific functions which are clearly identified in the processing steps.

      - Block diagrams such as the one in Figure M-1 may be useful in making this identification

- The block diagram should cover the whole process from receiving to finished product storage and shipping

c. Develop a master flow diagram for the complete manufacturing process

d. Include provisions in the flow diagrams for timely flow revisions

- Most feed manufacturing processes are dynamic and the flow is constantly changing.

The following table (M-1) and figures (M2A, M2B, M2C, M3A, M3B, and M4) give information and systems used in the block process flow diagram in Figure M-1.

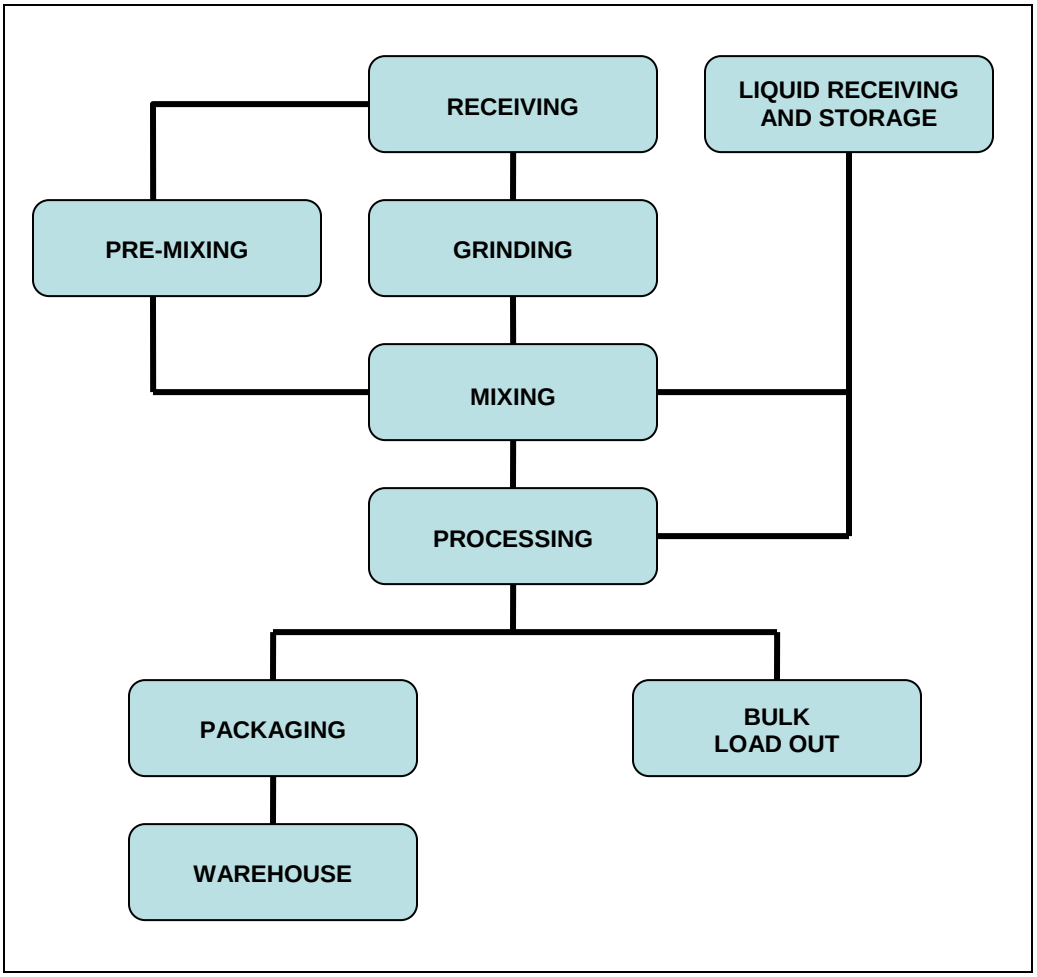

Figure M-1. Block process flow diagram.

Table M-1
General Rules for Constructing Process Flow Diagrams

- Try to limit crossing of lines as much as possible.
- Where crossing of lines is necessary, do not use "loops" around other lines.
- Always show end points of gravity and pneumatic conveying lines with sharp arrowheads.
- If the same piece of equipment is used repeatedly in a flow, try to keep all pieces the same size.
- If a conveying line must run through a piece of equipment, bin, etc., show the line to the equipment leaving a small space and continue in line, leaving a small space on the other side of the equipment or draw a continuous line through the equipment.
- Try to keep all lines as horizontal and vertical as possible; avoid use of diagonal lines.
- Gravity lines should never be shown running up the page. Gravity lines meet and change directions at sharp angles, they do not curve.
- Try to use uniform spacing between conveying lines.
- Pneumatic and suction lines meet and change directions with some curvature. They do not meet or change direction at sharp angles.
- A flow diagram is never drawn to any type of scale; however, it is centered on the entire page with equipment sized relative to each other.
- Keep labeling to a minimum. Let the symbol do the "communicating" as much as possible. However, label equipment sequentially using numbers or letters (i.e., l,2,3,...or A,B,C,...) when more than one piece of identical equipment exists on the same floor.
- Where lettering is used, keep it as uniform on the page as possible. Light lines can be used as a guide, if necessary.
- Order is very important to a flow diagram. For example, several discharges from a screw conveyor should always be shown in the order that exists in the actual flow.
- Always lay work out on a scratch paper before doing the final flow diagram on drafting vellum or on the computer. Try several combinations before settling on the final approach.
- Title blocks should be dated, and the use of sequential revision numbers is recommended.

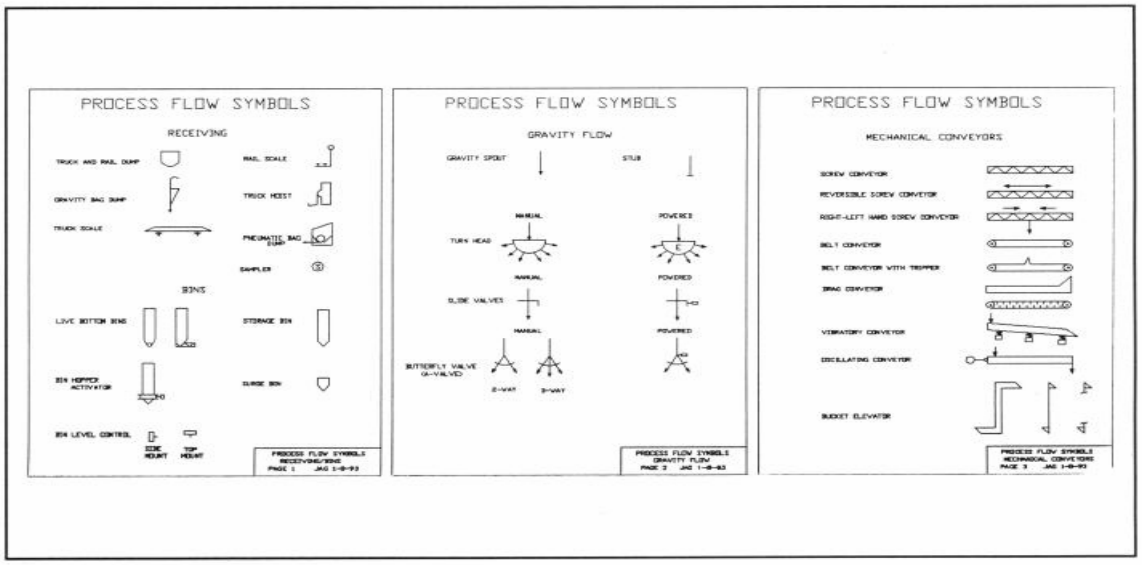

Figure M2A — Process Flow Symbols.

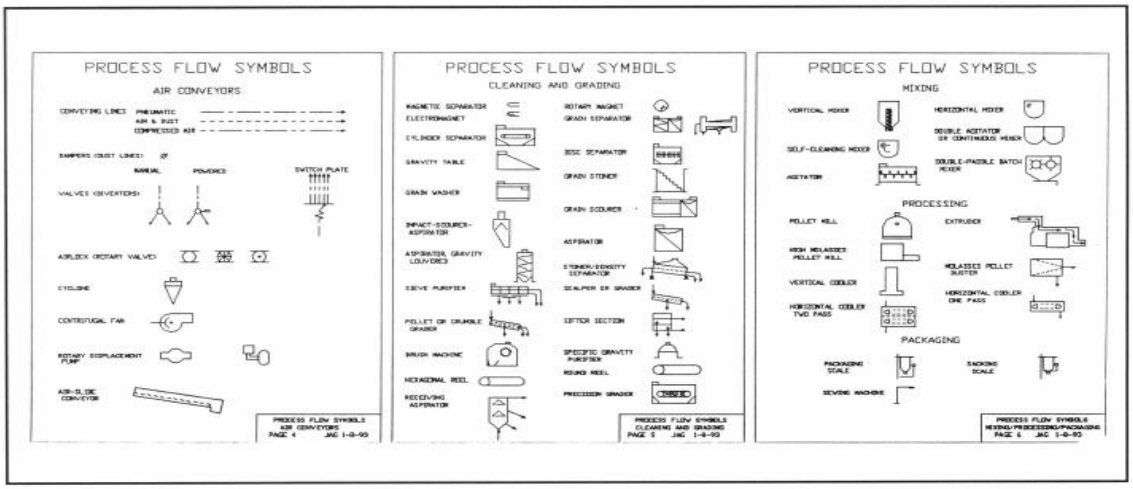

Figure M2B — Process Flow Symbols.

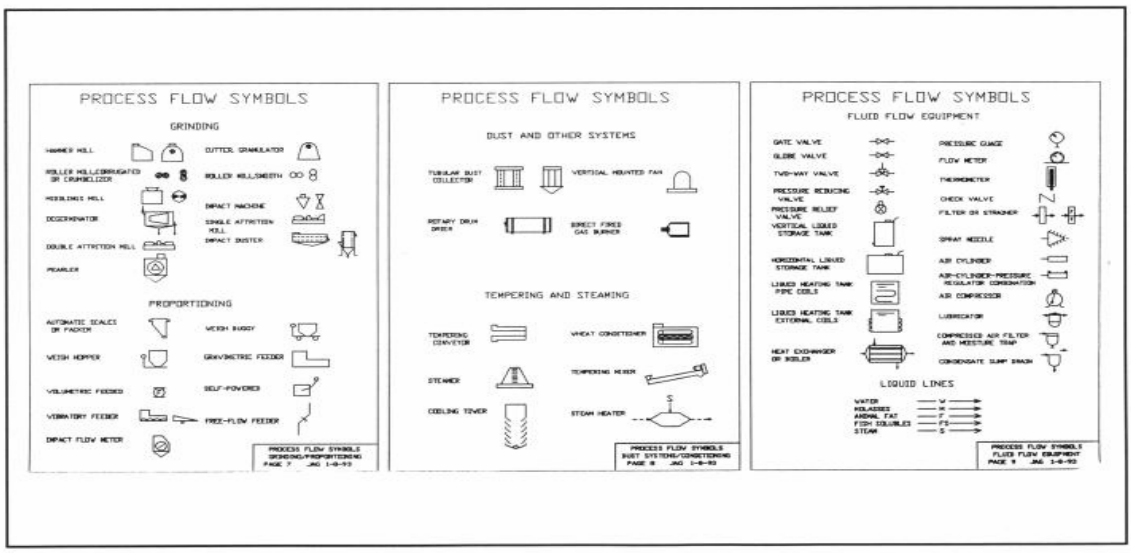

Figure M2C — Process Flow Symbols.

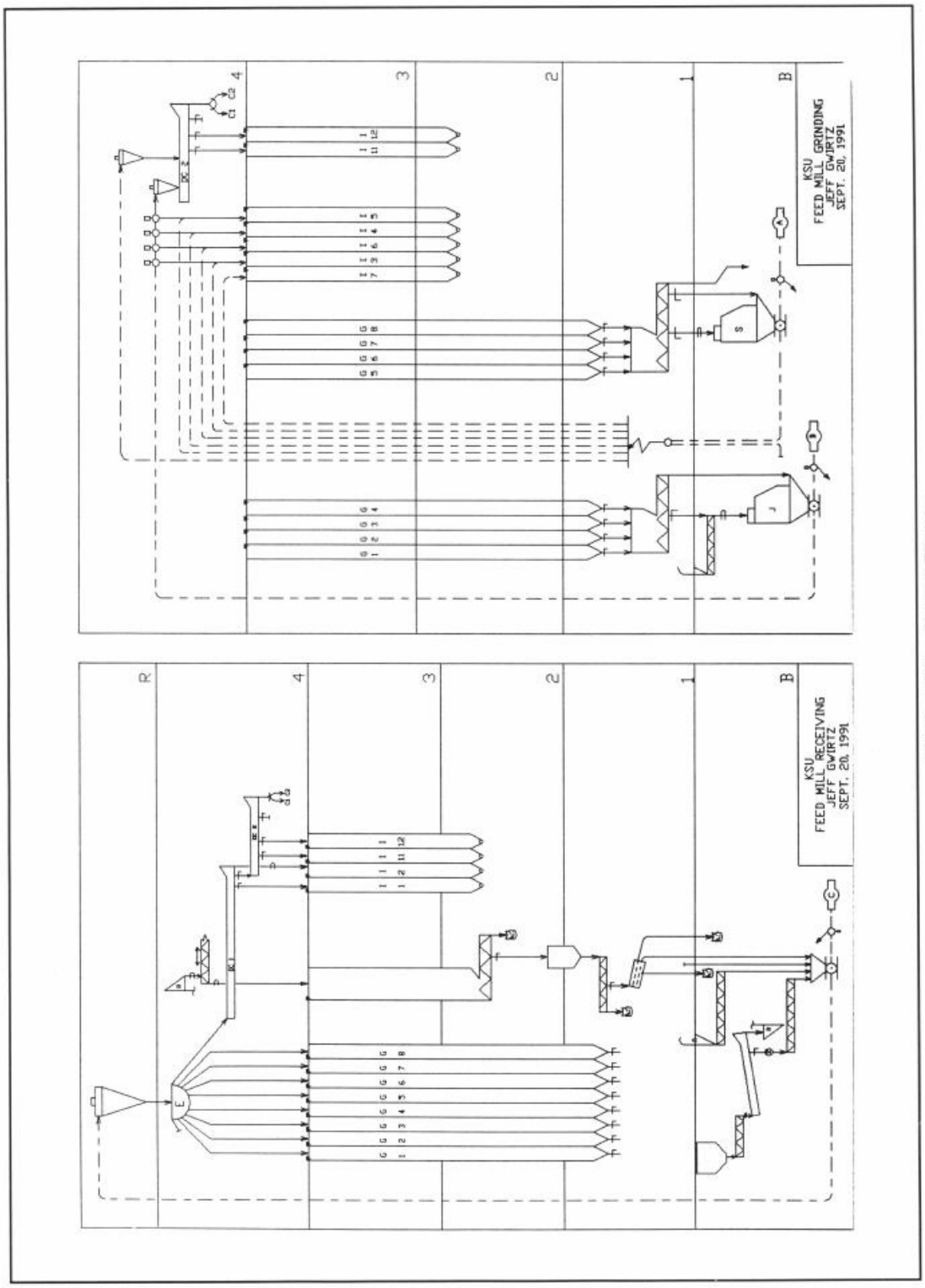

Figure M3A — Process Diagram.

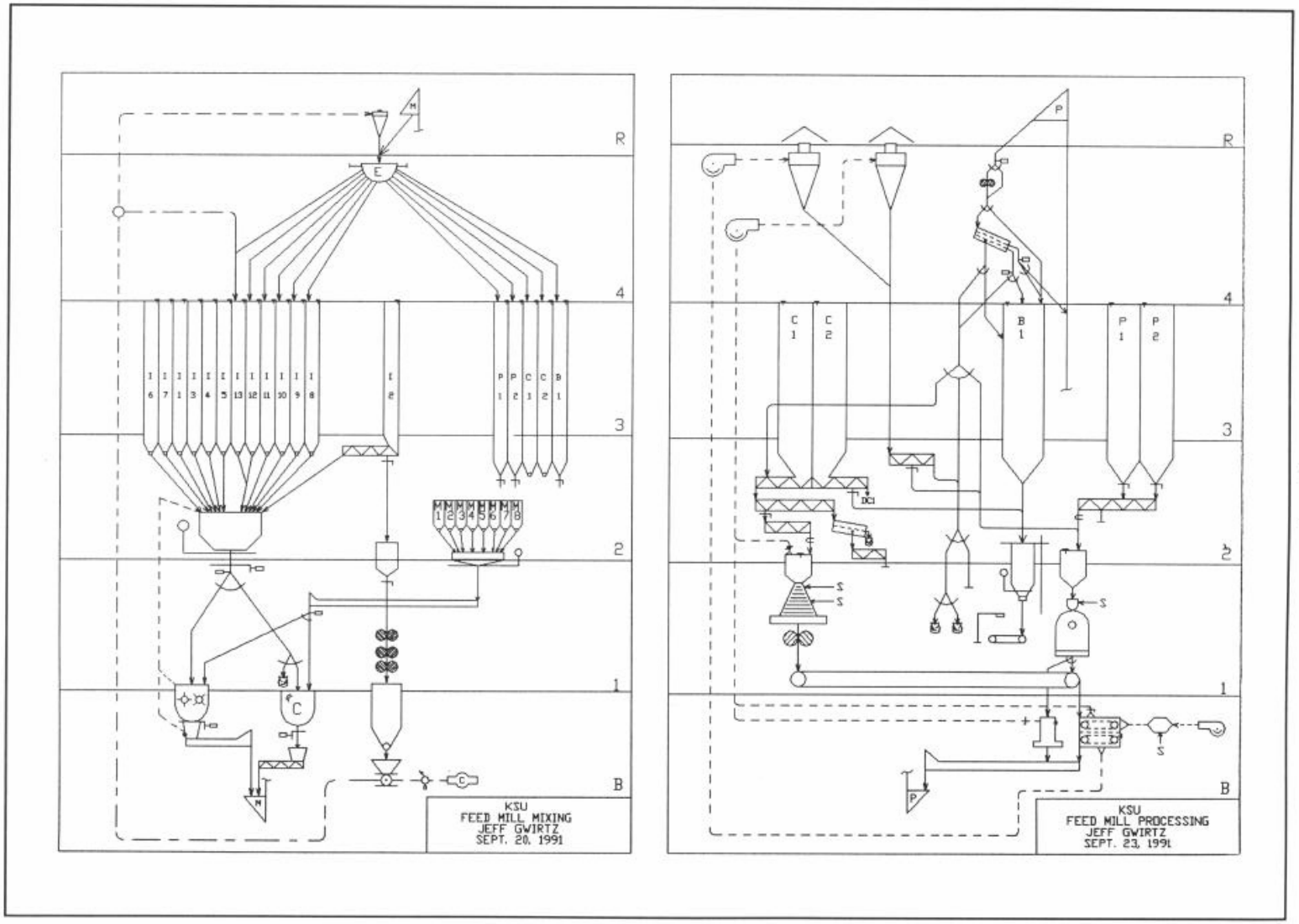

Figure M3B— Process flow diagrams.

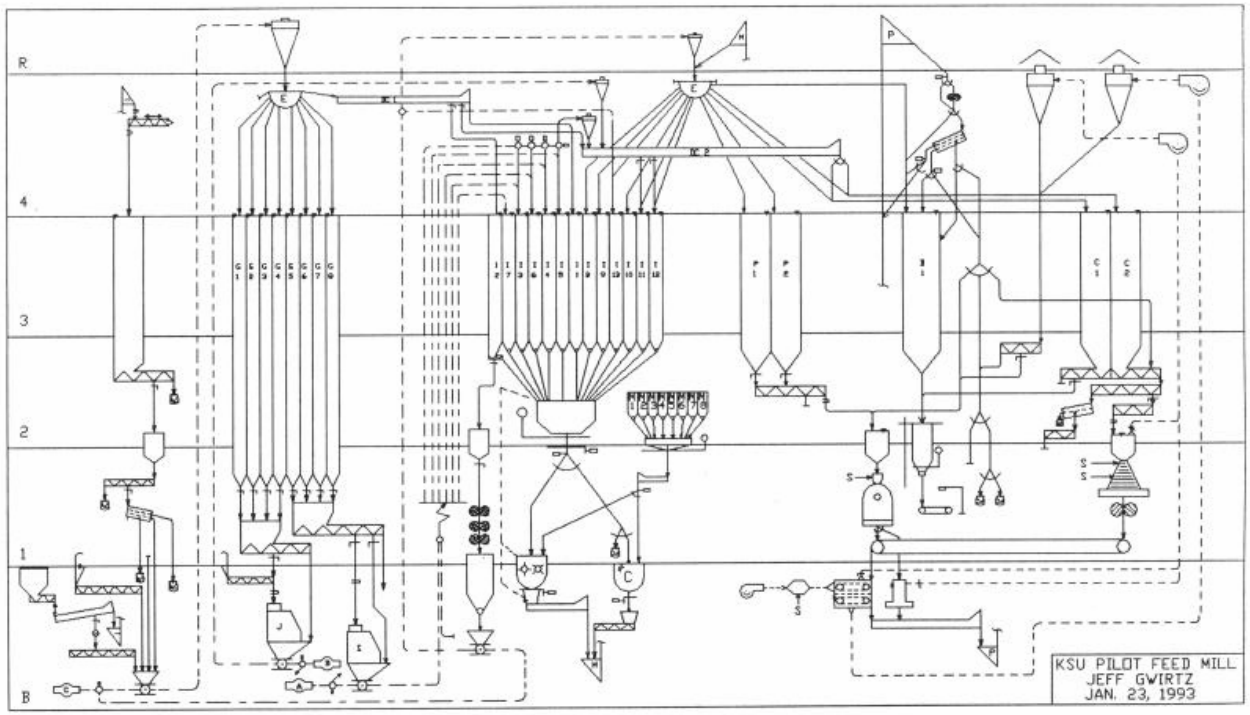

Figure M4 — Process flow diagram.

STRENGTHS AND WEAKNESSES OF THE CURRENT FEDERAL, STATE, INDUSTRY, AND INTERNATIONAL PROGRAMS

The United States, as well as other countries worldwide, are active in improving the quality and safety aspects of human food. Furthermore, animals provide an important role in producing meat, milk and eggs for human consumption and this source of food can have safety considerations that may be linked to feed quality. Federal, state, industry, and international programs are being developed and modified simultaneously and all share some common dimensions, but also differ in specific features.

1. Strengths of FDA and state programs

    a. Current Good Manufacturing Practices (CGMP's) are highly affective in regulating the use of medicated feeds and other key quality aspects of feed manufacturing processes in feed plants across the U.S.

    b. Although CGMP's do not cover all aspects of chemical, biological, and physical hazards that could potentially be in feeds, they provide the backbone to build an Animal Feed Safety System

    c. State feed programs function cooperatively with federal programs and this complimentary effort is a key strength for the U.S. as a whole

    d. Both federal and state programs are supported by the availability of research, teaching, and extension information from the USDA and Universities across the Nation

    e. Proven record of manufacturing and distribution of medicated feeds

2. Strengths of industry programs

    a. Support from regional, state, and national commodity groups and organizations which drive the feed industry and develop programs to answer specific problems

    b. Backed by strong memberships that promote economic and/or safety incentives

    c. Leadership and committees to address research and rapid dissemination of information to the general memberships and the populace

d. Some feed manufacturing plants are starting to use HACCP and are reporting beneficial effects

3. Strengths of international programs

    a. May have less restrictions than the U.S. in addressing specific concerns

    b. May be at a higher priority level than in the U.S.

    c. May have a larger funding base for programs

    d. In the process of finalizing CODEX regulations that go down to the farm level, and have traceability as a component

4. Weaknesses of FDA and state programs

    a. Enforcement is centered around, but not restricted to, commercial medicated feed facilities. Need to develop a more inclusive system that relates to all sectors of the U.S. animal feed industry

    b. No highly visible model safety programs for non-medicated feed facilities

    c. No highly visible model safety programs for on-farm feed production

    d. Need improvement in uniformity of sampling procedures and techniques to detect hazards in feed ingredients and mixed feeds

    e. No quality standards for some feed ingredients

    f. Lack of a list of safe feed ingredients for different species

    g. Lack of feed safety guidelines that are widely disseminated to all feed producers

    h. Need for broader and more frequent educational exposure to new safety developments

    i. Sampling procedures are not standardized and this is a problem in detecting aflatoxins

5. Weaknesses of industry program

    a. Not all feed manufacturers are members of state or national organizations and don't get information in a routine and timely manner

    b. Not all states have the same major animal enterprises and needs, and thus relate to industry organizations differently

    c. Emphasis of feed safety is not at the same priority level as CGMP's

    d. Different programs seem to be going in somewhat different routes and may be confusing, such as ISO, HACCP, others

    e. Mixed signals from industry about the ability to establish feed safety rules that fit all situations

    f. Lack of dedicated equipment to prevent cross contamination

    g. Lack of a system to preserve the identity and source of ingredients in storage

6. Weaknesses of international programs

    a. Lack of research

    b. Not science based in some cases

    c. May be used to facilitate trade with the U.S.

STUDY AND EVALUATION OF REGULATIONS AND PROGRAMS EMPLOYED BY THE FDA TO ENSURE THE SAFETY OF THE PRODUCTS IT REGULATES WITH SPECIAL EMPHASIS ON FEED, AND ENHANCEMENTS OR MODIFICATIONS CONSIDERED NECESSARY FOR THE ANIMAL FEED SAFETY SYSTEM (AFSS)

The Food and Drug Administration (FDA)/Center for Veterinary Medicine (CVM) regulations of animal feed have focused on areas that have played an important role in human health and food safety. These regulations are covered under medicated GMP's which control potentially unsafe residues in edible animal tissue, and the BSE feed ban to prevent the spread of BSE cattle and the potential for variant CJD in humans.

However, there is no umbrella federal regulatory program in place for assuring that all animal feedstuffs and mixed feeds are controlled by a risk-based approach for minimizing the risks to the health of animals and people from hazards in the animal products consumed.

The Animal Feed Safety System (AFSS) being studied by the FDA could provide an umbrella for a risk-based, preventive, animal feed/food safety system that would identify and minimize problems associated with animal feed before they result in adverse health consequences to animals or potential risks to human health. Agriculture has been a main support for the U.S. and it is imperative to accurately appraise the strengths and weaknesses of existing programs in order to make appropriate enhancements and/or modifications as related to animal feed safety and human health.

Effective quality control programs have been developed and are being practiced under CGMP's, but with feed safety, the focus and emphasis is centered on prevention which brings a new and fundamentally different dimension to feed quality assurance programs. In short, this means that all processes involved in receiving, processing, mixing, manufacturing, storage, and delivery of ingredients and mixed feeds must be conducted on a minute-by-minute basis under a state of control, with verification of control measures.

Overall possible enhancements and/or modifications of current measures used by the CVM/FDA are unclear in final definition, but should allow for the inclusion of "system models" for both food producing animal enterprises and the pet food industry. Some enhancements or modifications may include, but are not limited to, the following considerations:

- One, development of safety programs to match the type of feed production methods and inherent capabilities of facilities. For example, management of commercial feed facilities may be able to verify control measures through different steps than on-farm feed producers or ingredient processors. Thus, flexibility seems to be both desirable and needed in program development.

- Two, work toward development of diagnostic tests specifically for safety measures of chemical, biological, and physical hazards in the feed supply.

- Three, work toward developing a system to identify and track bulk ingredients in process flow by source

- Four, study and evaluate the potential of using quarantine procedures for incoming bagged and bulk ingredients and products until safety has been verified

- Five, develop standard sampling methods for ingredients and mixed feeds

- Six, assist in the development of software programs to facilitate analysis of safety data

- Seven, the paradigm for quality assurance in feed production needs to be modified to embrace all elements of quality control and feed safety

- Eight, the intent and scope of individual feed producers need to be considered, much like violations and overall past performance is considered in CGMP's

- Nine, broaden the coverage of FDA programs to include all sectors of the animal feed industry

V.

GENERAL CONCLUSION STATEMENT

The importance of feed safety in the production of animals for food and other purposes in the U.S. is invaluable. This feed safety aspect of the overall animal food production system in the Nation is presently a high priority and has possible long-term implications. Thus, it is a critical and sensitive time for the U.S. feed manufacturers and animal enterprise groups to focus on ways to do a better job to ensure feed/food safety.

The general populace in the U.S. is more interested in the future than the past as related to the safety of meat, milk, and eggs. Furthermore, there appears to be no sharp disagreement in the U.S. feed industry toward the study and possible implementation of a feed safety system. However, to move in a somewhat different priority mindset toward a "keep-the-feed-safe system" will require careful evaluation of strengths and weaknesses of current practices in place across commercial and on-farm feed producers.

The six month consultancy period of working closely with the AFSS Team, and conducting industry site visits provided a broad base of exposure and appreciation for the complexity and challenge of possible development of an Animal Feed Safety System in the U.S. Moreover, much has been discussed and learned and no strong opposition has been voiced against this national feed safety study. In contrast, segments of the overall animal and feed industries in the U.S. have expressed support for the AFSS concept, but have concerns about how to uniformly address feed safety across all commercial and on-farm

situations, and how such an effort would compliment what is already being practiced through CGMP's, ISO certifications, and HACCP principles.

Complex systems such as feed manufacturing are sometimes controversial and require careful consideration, involvement of all interested parties, and accurate recognition and appraisal of all the major factors involved, before the most plausible way to mold existing practices to encompass new developments and needs can be decided. Feed/food safety brings a significant new challenge to feed manufacturing in the U.S.; but, with continued open discussions and participation from all parties directly involved, a consensus on the best approach to develop a national feed safety system can be reached. Finally, it is clear, from all information collected during this consultancy period, that an Animal Feed Safety System (AFSS) is worthy of further study and evaluation and, if developed, will provide long-term benefits to the general populace of the U.S. through continued safe domestic feed/food and possibly improved competitiveness in foreign markets.

VI.

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