

NC-213 PROGRESS REPORT FOR 2024

Title

Developing and Operationalizing Quality and Food Safety Management System at FMGSC to Address the Challenges Faced at US Feed Mills.

Investigators

Maier, D.E., Professor, Agricultural & Biosystems Engineering

Akoto, E.Y., Graduate Research Associate, Agricultural & Biosystems Engineering

Dickson, J.S., Professor, Animal Science and Inter-Departmental Program in Microbiology

Rosentrater, K., Professor, Agricultural & Biosystems Engineering

Greiner, L.L., Associate Professor, Animal Science

Mosher, G., Professor, Agricultural & Biosystems Engineering

IOWA STATE UNIVERSITY

Outputs/Research Updates

Achieving a high standard of food safety in animal food manufacturing facilities is needed by government regulations, international certifications, customer requirements, and companies' obligations to protect public health. In the United States, the Food and Drug Administration (FDA) requires feed mills to meet the Food Safety and Modernization Act (FSMA) rules based on the Code of Federal Regulations (CFR) 21 parts 507 and 225. Some feed mills implement multiple food safety management systems to achieve the feed safety standards different stakeholders require. These call for activities such as feed equipment cleaning to control micro-ingredients and/or medication carryover in finished feed, which can be challenging to implement. The objectives of this research are:

1. Identify and understand the challenges faced by some U.S. feed mills when implementing multiple food safety management systems (MFSMS).
2. Develop the Quality and Food Safety Management System at the ISU Kent Feed Mill and Grain Science Complex (FMGSC).
3. Implement the Quality and Food Safety Management System at the ISU Kent FMGSC.
4. Quantify feed/ingredient residue and validate equipment flushing as a cleanout procedure in the handling equipment of the ISU feed mill.

Outcomes/Impacts/Deliverables and updates of studies continued in 2024

Study 1: Identify and understand the challenges faced by some U.S. feed mills when implementing multiple food safety management systems (MFSMS)

A survey was administered to quality managers at U.S. feed mills, focused on the relationships between the general characteristics of feed mills and the implementation of FSMA and other private food safety systems while identifying the challenges associated with each system. We investigated the perception of QA managers with implementing other private food safety management systems and FSMA as MFSMS and aspects with similarities and the way forward to integrating these systems. Over half of the feed mills implement one additional FSMS to reassure their customers that they practice high food safety standards. Existing challenges include ineffective employee training, limited knowledge of regulatory requirements, and product defects. Perceived challenges are time-consuming, document duplication, repetition of monitoring and verification documents, and difficulty managing them. Possible solutions are the

integration of FSMA CGMPs and private FSMS prerequisite programs via standard operating procedures (SOPs) development using digital tools (cloud storage and hyperlinks). This study revealed challenges with managing MFSMS at U.S. feed mills. It is recommended that regulatory agencies collaborate with private FSMS entities to address and integrate these systems to ensure efficiency and effectiveness of food safety practices and protection of public health.

Study 2: Develop the Quality and Food Safety Management System at the ISU Kent Feed Mill and Grain Science Complex.

In this study, the main objective was sub-divided into four categories which included (i) developing a quality manual, (ii) developing standard operating procedures, (iii) using cloud-based storage systems for the real-time management of the documents, and (iv) registration of the ISU Kent FMGSC with the FDA as a food facility and licensed medicated feed manufacturing facility. The food safety plan was developed with a designated food safety team utilizing hazard analysis based on experience, illness data, scientific reports, and other available reports. A risk assessment table was created as a chart with columns focused on ingredients/processing stage, known or reasonably foreseeable animal food safety hazards (biological, chemical, and physical), severity of the animal food safety hazard, probability of the food safety hazard, and risk assessment as a product of the severity and probability of the hazard. Other sections of the document included a process flow diagram, validation and verification, recall plan, and reanalysis. The quality manual was developed using the AFIA Safe Feed Safe Food Guidance Document Version 7.0 with an emphasis on implementing CGMPs, internal audits, and referencing the food safety plan. The standard operating procedures (SOPs) were developed by subdividing them into sections focused on CGMPs and other sections in the food safety plan and quality manual. The food safety plan, quality manual, and SOPs were interconnected using hyperlinks in SharePoint cloud storage for convenient, real-time document access, and ease of SOP updates reflected in the other documents in which they are cited. Lastly, these documents were used during the FDA pre-license inspection, resulting in acquiring a medicated feed mill license, and FDA food facility registration in addition to the Commercial feed license from the Iowa Department of Agriculture and Land Stewardship.

Study 3: Implement the Quality and Food Safety Management System at the ISU Kent Feed Mill and Grain Science Complex.

The implementation of a quality and food safety management system at a food processing facility involves a series of steps such as developing training modules, creating an awareness campaign for food safety and product quality, management support, rolling out the training modules, record keeping of training, in addition to establishing quality control and assurance procedures for monitoring and verification purposes. The implementation process is also a step towards improving the food safety culture, and continuous review and modification of standard operating procedures to reflect the ‘actual operational practices by employees’ at the facility for addressing non-conformities and improving consistency. In this study, the main objective was subdivided into (i) developing a quality control and assurance program, (ii) developing and rolling out a training program, (iii) conducting internal audits, (iv) determining the impact of the employee on training food safety culture, and (v) capturing ‘actual operational practices’ through SOPs reviews by designated employees. In addition to using AFIA’s CGMPs onboarding training, a survey tool was created to capture employees’ perceptions of food safety culture (before starting work). The quality control and assurance program was designed to cover aspects

such as ingredient testing (e.g., moisture and mycotoxin analysis), process controls, complete feed testing, and routine environmental monitoring (*Salmonella spp.*). Also as part of onboarding and continuous training, thirteen training modules were created focused on ingredients inspection and receiving, operations, production and products holding and distribution, occupational safety and health, biosecurity procedures, housekeeping, non-conformance, corrective actions and customer reviews, preventive maintenance, quality control procedures, record keeping and traceability, training procedure, suppliers procedure and purchasing, internal audits and management review. The onboarding and continuous training modules were rolled out using the ISU CANVAS learning management system, where each employee was assigned to the onboarding module and designated modules associated with their area of work/responsibility, and the employees' knowledge levels of the material content were evaluated using designed quizzes, in addition to their supervisor's hands-on training. Fifteen individuals, including management, student employees, and graduate students, are enrolled in the CANVAS-based training program. The response rate has been 80% for the survey designed to determine an employees' perception of food safety culture at the ISU Kent FMGSC. The completion rate of training modules and associated quizzes has been low so far, with an average of 27%. Onboarding training has been highest at 33%. Both aspects have been brought to the attention of management and are being addressed. In 2024, two internal audits were conducted at FMGSC using the current good manufacturing (CGMP) self-audit tool. Communicating and reviewing the results of the first audit (compliance at 82.8%) resulted in a 6 percentage point increase in the second audit (compliance at 89.2%). The area that saw the most improvement between the audits was Plants and Grounds (507.17), while Personnel (507.14) with training has not changed which reflects the online training data. Considering the importance of the livability of SOPs for implementing quality and food safety management systems, supervisors in various departments such as procurement, receiving, production, and quality assurance, are reviewing and utilizing the SOPs. The study recommends that the ISU Kent FMGSC, similar to the trends observed in objective 1, must focus on improving completion rates of employees training towards implementing the internal quality and food safety management system. Also, internal audits will continue intermittently as they prove to be an effective tool for implementing and improving quality and food safety management systems.

Publications

Oral/Poster Presentation

- Akoto, Y. E. and Maier, D. E. 2023. Feed Mills' Challenges with Multiple Food Safety Management Systems (MFSMS). Advances in Food and Technology Poster Symposium. Iowa State University, April 21, Ames. IA.
- Akoto, Y. E. and Maier, D. E. 2023. A critical review of mechanisms of drug carryover and cleaning procedures in feed manufacturing as a function of drug properties and equipment design. ASABE Annu. Mtg Prog. Book, July 9-12, Omaha. NE.
- Cochran Fellow Training Course, Iowa State University Kent Feed Mill and Grain Science Complex (U.S.), U.S. Grains Council, September 18-22, 2023 (Akoto: 2 lectures, 1 hands-on training).
- Advanced Feed Manufacturing Industry Training Program-SSA DDGs Team, Iowa State University Kent Feed Mill and Grain Science Complex (U.S.), U.S. Grains Council, May 7-8, 2024 (Akoto: 2 lectures).
- Animal Industry Committee Meeting, Iowa State University Kent Feed Mill and Grain

Science Complex (U.S.), Agri-Business Association of Iowa, June 25, 2024 (Akoto: 1 lecture)

- Akoto, Y. E. and Maier, D. E. 2024. Feed Mills' Challenges with Multiple Food Safety Management Systems (MFSMS). ASABE Annu. Mtg Prog. Book, July 28-31, Anaheim, CA.
- Akoto, Y. E. and Maier, D. E. 2024. Feed Mills' Challenges with Multiple Food Safety Management Systems (MFSMS). Norman Borlaug Lecture Poster Competition. Iowa State University, October 28, Ames, IA.

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