HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) AND REGULATORY REQUIREMENTS FOR FEED MILLS

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INTRODUCTION

In 2006, Mercer Milling Company decided to utilize new software capable of tracking lots in and out of the mill. As the company grew and the software produced more management data, the management group started to create a position for a quality assurance person. The main goals for this position in 2007 were to eliminate errors, reduce landfill costs, reduce labor, and to increase output. The position was announced mid-year of 2008 and the position was filled in the fall of 2008. The management group added the new Director of Quality Assurance to the management group. What was Mercer Milling Company’s first step in moving the business towards better quality? The first and most important step was supporting the idea of “quality” from the top of the business structure.

Since 2008, Mercer Milling Company has developed and implemented a series of policies, standard operating procedures, and critical control limits. William Colten, the owner, invested in educating the management group and the development of the hazard analysis at the mill. Rene Lavoie, the general manager, strongly supported the goal of developing programs that enabled Mercer Milling Company to obtain Restricted Use Protein Products (RUPP), Safe Feed Safe Food, and (Hazard Analysis Critical Control Points) HACCP certifications. The investment was validated by the third-party independent auditors from the Facility Certification Institute (FCI) and Office of the Texas State Chemist (OSTC).

Today, we continue to learn and implement additional improvements. Through this we have seen reductions in shrink, decreased errors, reductions in landfill cost, and reductions in labor costs. In addition, we have almost tripled the production output without significantly changing our production equipment. We have reduced our customer complaints, with very few end user issues. The top-down goal of increased quality has made it easier to meet all regulatory requirements, enhance our product quality, and ultimately serve our customers better.

REGULATIONS

HACCP and FSMA

The Food Safety Modernization Act (FSMA), which was signed into law on January 4, 2011, contains a number of rulemaking deadlines that the Food and Drug Administration (FDA) is required to meet. For the first time, FDA has a legislative mandate to require comprehensive, science-based preventive controls across the food
supply chain. This mandate includes preventive controls for food and feed facilities. It
requires food and feed facilities to implement a written preventive controls plan. This
involves: (1) identify and evaluate known or reasonably foreseeable hazards that may
be associated with the facility, (2) identify and evaluate hazards that may be
intentionally introduced, including by acts of terrorism, (3) develop a written analysis of
the hazards, (4) the preventive controls implemented are effectively and significantly
minimizing or preventing the occurrence of identified hazards, (5) there is documented,
periodic reanalysis of the plan, including maintaining routine records of the monitoring
and a requirement to reanalyze the program every three years. The FDA is not stating
that you must have a Hazard Analysis Critical Control Point (HACCP) plan, but the
definition of the “comprehensive, science-based preventative controls plan” sounds
identical to a HACCP plan (111th Congress Public Law 353).

How and who developed HACCP? The National Aeronautics and Space Act
(NASA) and Pillsbury Foods formed a work unit in the late 1950’s developing food for
the astronauts. They had to develop food that fit a number of specifications and had
strict microbiological requirements prescribed by NASA’s Dr. Lachance. Dr. Bauman
and others utilizing NASA’s engineering background, which mandated the use of critical
control points (CCPs), developed the start of HACCP in the food industry (Sperber and
Stier, 2009). Unfortunately, the use of HACCP in the food industry was not utilized until
a series of food contaminations and poisoning pushed the canned food industry to
adopting HACCP principles.

As of July 3, 2012, the FDA has missed the deadline to publish proposed rules for
FSMA and the expected date of release of the rules is after the November election
(AFIA FSMA Implementation Update 2012). There is expected to be a difference in the
requirements depending of large versus small mills. The definition of small facility at
this time in the bill states average sales are under $50,000.

RUPP Regulations in the Feed Industry

There are other regulations that are important to know in the feed industry. The
Restricted Use Protein Products (RUPP) 21 Code of Federal Regulation (CFR)
589.2001 enacted April 01, 2011. This regulation pertains to cattle materials prohibited
in animal food or feed to prevent the transmission of bovine spongiform
encephalopathy. The other RUPP regulation is 21 CFR 589.2000 which reviews animal
proteins prohibited in ruminant feed (21CFR589.2000-2001.)

Bioterrorism Act in the Feed Industry

The Public Health Security and Bioterrorism Preparedness and Response Act,
commonly known as The Bioterrorism Act of 2002, is designed to protect the United
States from bioterrorism and was a result of the September 11, 2001 terrorist attack of
the World Trade Center and Pentagon.
This law authorized the U.S. Department of Health and Human Services (HHS) to take action to protect the nation’s food supply against the threat of intentional contamination. The Food and Drug Administration (FDA), as the food regulatory arm of HHS, was responsible for developing and implementing food safety measures, including the following four major regulations. (1) Registration of Food Facilities: Domestic or foreign facilities that manufacture, process, pack, distribute, receive, or hold food for consumption by humans or animals in the U.S., (2) Prior Notice of Imported Food which began in 2003, FDA must receive advance notice of each shipment of food into the U.S., (3) Establishment and Maintenance of Records: Persons that manufacture, process, pack, transport, distribute, receive, hold, or import food will be required to create and maintain records FDA determines are needed to identify the immediate previous sources and the immediate subsequent recipients of food, (4) Administrative Detention that authorizes the FDA to administratively detain food if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals (107th Congress, 2001-2002, H.R.3448.ENR.).

CGMP’s and Animal Drug Availability Act

The medicated feed mill licensing requirements of the Animal Drug Availability Act of 1996 (ADAA), are found in 21CFR Part 515 (21 CFR 515). This regulation requires certain medicated feed mills to be licensed with FDA. Licensed facilities are allowed to manufacture animal feeds from Category II, Type A medicated articles. Mills that have a medicated feed mill license must adhere to the Current Good Manufacturing Practice (CGMP) regulations 21 CFD 225.120-225.202. There are nonbinding recommendations for CGMP’s for medicated feed manufacturers that are not required to be registered and licensed with the FDA. Although, it clearly states that the Federal Food, Drug and Cosmetic Act Section 501 (a) (2) (B) that a medicated feed containing an animal drug is adulterated if not produced in conformance with CGMPS. Therefore, all facilities should have a copy of the CGMP’s in the mill and understand the requirements they need to meet.

PEOPLE TO HELP YOU

There are many organizations available to help you gain the knowledge and training to develop a quality program that will meet regulations. Currently, three universities have programs in HACCP for the feed industry; Texas A & M, University of Nebraska Lincoln, and Kansas State University. In addition, the American Feed Industry Association is recommending the use of the Safe Feed/Safe Food Certification Program. This program has a website that provides information to help you start your program and suggests resources. It is strongly recommended that the lead quality person should have completed a course in HACCP. Finally, the cost of your quality program should be recovered in the savings generated by a good quality program within a short period of time.
REFERENCES


AFIA FSMA Implementation Update 2012.

RESOURCE MATERIALS

http://www.fda.gov/cvm

http://www.certifiedfacility.org/Links/index.cfm

http://www.fda.gov/cvm/guidance/guidance68.pdf

http://www.feedhaccp.org/

http://www.aafco.org/Publications/PublicationListing.aspx -- Guidance Material and Official Publication