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Development and Implementation of Hazard Analysis and Critical Control Point Plans by Several U.S. Feed Manufacturers

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ABSTRACT

The commitment to consumer food safety, global trade, and proposed new regulations by the U.S. Food and Drug Administration Center for Veterinary Medicine has led to increased adoption of hazard analysis and critical control point (HACCP) by the U.S. feed industry. A project supported by the U.S. Department of Agriculture Integrated Food Safety Initiate titled ''Development and Implementation of a Voluntary HACCP Program for the US Feed Industry'' enabled faculty from three land grant universities to assist individuals from 14 feed companies that collectively manufacture 15 million metric tons of feed in 100 facilities to develop HACCP plans. The process flow in these plans averaged 20 steps, and the most detailed plan included 60 process steps. Chemical hazards were more commonly identified in HACCP plans (average of four hazards per plan) than were biological hazards (average of one per plan). The most prevalent chemical hazards were cross-contamination of type A medicated articles and type B medicated feeds, aflatoxin, and wrong ingredient inclusion in feed. The most common biological hazard was mammalian protein contamination of feed ingredients and finished feed for cattle. An assessment of time and costs associated with developing HACCP plans revealed that approximately 29% of the companies needed additional personnel or additional equipment to implement a HACCP plan, and on average 268 additional person hours were needed to develop and implement a HACCP plan. Plan design, compliance monitoring, and record keeping were the three most time-consuming activities needed for developing and implementing a HACCP plan. The average cost of additional equipment needed to implement a HACCP plan was $250.

The interface between animal feed and animal health is a significant factor in a disease prevention and control framework *(13).* Animal feed hazards include those that impact animal health and those that pose a risk to human health. In the United States, the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) leads the regulatory oversight of the feed industry. In 2003, the CVM announced its plans to develop a comprehensive, risk-based animal feed safety system (AFSS) *(21).* The 1 March 2004 docket 2003N-0312 announcing the AFSS task force direction *(22)* indicates the CVM's intent to apply risk-based, preventive, and comprehensive animal feed control measures to protect animal and human health. These elements align with principles found in hazard analysis and critical control point (HACCP) plans. The AFSS preliminary hazard guide includes biological hazards reported by the Centers for Disease Control and Prevention and the General Accounting Office *(6, 10).*

The intergovernmental CODEX task force drafted a Code of Practice on Good Animal Feeding *(5).* The Code's seven sections include segments related to pathogen control and disease prevention, including traceability, health hazards associated with animal feeds, sanitation and pest control, hygiene during feeding, on-farm feed manufacturing, and sampling and analysis. The objective of the Code is to help ensure the safety of food through adherence to good animal feeding practices at the farm and good manufacturing practices during procurement, transportation, handling and storage, processing, and distribution of feed and feed ingredients. In the General Requirements section (p. 4), the Code states ''Where appropriate, good agricultural practices, good manufacturing practices (GMPs) and, where applicable, Hazard Analysis Critical Control Point (HACCP) principles should be followed to control hazards that may occur in food.''

U.S. pet food manufacturers exporting product directly to the European Union (EU) must comply with preinspection criteria outlined in Regulation EC no. 1774/2002 *(8)* that establishes requirements for importing into the EU animal by-products not intended for human consumption. To comply with this requirement, all U.S. facilities exporting pet food must be inspected and approved by the U.S. Animal and Plant Health Inspection Service. The EU requires pet food manufacturers to implement self-inspection programs similar to HACCP plans, although the EU does not specifically require a HACCP system.

The applicability of HACCP systems to the production and distribution of pet food came into focus during a class I recall of adulterated cat and dog food contaminated by plant protein (wheat gluten) containing melamine, ammeline, ammelide, and cyanuric acid. The FDA launched the voluntary recall on 16 March 2007, which included over

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TABLE 1. *Characteristics of HACCP plans developed for 14 feed-manufacturing facilities*[a]

Mill no.	Product type	Species	Process steps	Ingredients	Hazards			HACCP plan		Prerequisites	
					Chemical	Biological	CCPs	SOPs	SSOPs	SOPs	SSOPs
1	Biscuits	Dog	20	14	1	1	2	2	0	6	2
2	Mash	Swine	20	44	4	0	3	1	0	0	0
3	Mash pellet	Turkey, swine	60	56	6	1	6	4	0	1	0
4	Mash	All	14	38	4	2	5	0	0	1	0
5	Liquid	Ruminants	9		2	3	3	0	0	1	0
6	Mash pellet	All	18	36	2	3	3	1	0	7	0
7	Mash	Swine	15	29	6	0	4	0	0	0	0
8	Liquid	All	13	72	3	2	5	2	0	3	0
9	Mash	Beef cattle	13		3	1	4	2	0	10	1
10	Mash pellet	Swine	14	30	5	0	5	4	0	14	0
11	Mash	All	35		4	2	5	4	0	14	1
12	Mash	Layers	22	30	3	1	4	3	0	10	0
13	Supplement	Ruminants	13	69	4	2	5	7	0	6	0
14	Mash pellet	Broilers	14	23	4	0	4	4	0	1	0
Mean			20	40	4	1	4	2	0	5	0
SD			13	19	1.4	1.1	1.1	2.1	0	5.1	0.6

[a] CCPs, critical control points; SOPs, standard operating procedures; SSOPs, sanitary standard operating procedures.

5,000 products. Several HACCP principles could have impacted this incident, including conducting a hazard analysis during which the pet food manufacturer may have identified the need to implement an approved supplier program that would include onsite inspection of the facilities providing wheat gluten to avoid introduction of chemical hazards. The pet food company's palatability trial would likely have been identified during process flow development (a preliminary HACCP step), and corrective actions could have been implemented in the event of animal deaths during these trials. The company that manufactured the contaminated pet food contracted with other companies to procure wheat gluten and conduct palatability trials.

The U.S. feed industry manufactures approximately 145 million metric tons, and the market value for these products exceeds $30 billion annually. Although HACCP systems currently are not a regulatory standard for the U.S. feed industry, U.S. feed manufacturers have expressed a desire to assess the suitability of adopting a HACCP approach to ensure feed safety. To address this need, several universities, including Kansas State University, University of Nebraska, and Texas A&M University, assisted feed companies in developing HACCP plans.

Project objectives included assessing the applicability of HACCP principles and approaches at 14 feed-manufacturing facilities, developing model plans, and assessing the cost associated with developing and implementing HACCP plans in terms of both personnel time and addition of new equipment to test for or control hazards.

MATERIALS AND METHODS

The 14 feed mills that participated in this study were located in Iowa, Kansas, Missouri, Nebraska, and Oklahoma. The target animals served by these feed mills included broiler and layer chickens, turkeys, swine, beef cattle, and pets.

Procedures outlined by the National Advisory Committee on Microbiological Criteria for Foods *(12)* were followed in the development of the HACCP plans. These procedures included the preliminary steps of assembling a HACCP team, describing the feed and its distribution, identifying customers and intended use, and developing and verifying the flow diagram. HACCP coordinators for each feed mill participated in a Feed Industry HACCP Workshop that was accredited by the International HACCP Alliance (http://haccpalliance.org/). Feed mills received assistance in developing their HACCP plans, including review of their flow diagrams and completion of forms for the seven HACCP principles. The forms used were Hazard Analysis and Critical Control Point, Identifying Critical Limits, Monitoring and Corrective Action, Record Keeping and Verification, and the HACCP Plan Summary (www.feedhaccp.org). The process for the Hazard Analysis and Critical Control Point form included assigning significance to animal and human health hazards. Human health hazards were addressed as part of HACCP principle 2 (which is to determine critical control points), and animal health hazards were addressed in prerequisite programs. Multiple HACCP plans were developed for feed mills with separate production lines (e.g., lines for mash pellet feed and liquid feed).

In the spring of 2004, data were collected to assess the costs associated with the development and implementation of a HACCP plan. These data included plant capacity and the number of full-time and part-time employees. The additional personnel and equipment needed to develop and implement the HACCP plan were quantified. Personnel cost included additional person hours spent on plan design, training, compliance, laboratory analysis, plan review, and record keeping. Person hours spent on the HACCP plan included hours spent attending HACCP workshops and hours spent on plan development after the workshops. Person hours spent on HACCP training included hours spent by individuals conducting in-plant training of employees and hours spent by individuals attending in-plant training sessions.

RESULTS AND DISCUSSION

The 14 mills in this study were part of a group of approximately 100 facilities whose feed-manufacturing capacity exceeds 15 million metric tons per year (Table 1). Feed manufactured at these mills included mash, pellet, liq-

uid, and supplements for cattle, horses, turkeys, broilers, layers, and swine. One mill manufactured dog biscuits.

The process flows ranged from 9 to 60 process steps, with a mean (standard deviation [SD]) of 20 (13) steps. The number of feed ingredients reported on the ingredient description form ranged from 14 to 72, with a mean (SD) of 40 (19). Feed manufacturing is a batch process that includes ingredient receipt, storage, weighing (batching process step), mixing, and packaging in mash form or in some cases thermal processing to form pellets or extruded or baked products. The finished product must be labeled regardless of delivery container (e.g., bag or bulk). The feed industry is the principle consumer of coarse grains (*Zea mays* and *Sorghum bicolor*) and soybeans (*Glycine max*), and it serves as a principle market for recycled agricultural goods, including meat and bone meal, poultry meal, blood meal, and plate waste and coproducts such as corn gluten meal and whey. The Association of American Feed Control Officials ''Official Publication'' *(1)* contains definitions for 772 ingredients. Complete feed is manufactured to meet the animals' entire dietary requirement except for water. Consequently, many of the feed manufacturers' HACCP plans developed in this project possessed more process steps and ingredients than model plans developed for industries with mandated HACCP systems *(16).*

Chemical hazards were identified more often (average of four per plan) than biological hazards in the feed industry HACCP plans. The feed industry's emphasis on chemical hazards is partially related to the regulatory environment in which it operates. The CVM provides the federal regulatory oversight of the feed industry through current GMPs, which focus on the use of animal drugs in feed (21 CFR 225) *(23)* and mycotoxin action and advisory levels for aflatoxin (CPG 7126.3) *(24),* fumonisin (docket no. OOD-1277) *(20),* and deoxynivalenol *(4).* The most frequently identified chemical hazards in HACCP plans were cross-contamination by medicated feed, incorrect use of type A medicated articles and type B medicated feed, presence of aflatoxin, and incorrect weighing.

HACCP teams identified several manufacturing errors that could result in chemical hazards, including incorrect labeling and delivery of feed products. One hundred percent conformance with federal and state requirements is needed to correctly label and deliver all products; thus, the critical limit for these hazards was zero tolerance (Table 2).

Biological hazards occurred less frequently in HACCP plans (average of one per plan), and the principle biological hazard identified in these plans was animal protein prohibited in animal feed by the Food and Drug Administration, which prohibits feeding ruminant protein products to ruminants (21 CFR 589.2000) *(19).* In addition to three cases of bovine spongiform encephalopathy in cattle, three cases of the human disease, variant Creutzfeldt-Jakob disease, have been reported in the United States but were believed to have been contracted outside the country *(3).* HACCP coordinators included prohibited animal protein as a biological hazard because adherence to the ban on feeding mammalian protein to ruminants is one of the ''firewalls'' designed to prevent this disease in the United States. In the dog biscuit HACCP plan, the HACCP team identified *Salmonella* as a biological hazard. The decision to include *Salmonella* in this plan was justified based on product entry into homes and possible contact and consumption by humans. Animal feed and ingredients containing *Salmonella* are adulterated (as defined by the FDA in 21 CFR 500.35) and have been documented to cause salmonellosis in animals and humans *(6, 7).*

TABLE 2. *Hazards and their frequency and associated critical control points and limits identified in HACCP plans for 14 feed-manufacturing facilities*

Hazard	Frequency	Critical control point	Critical limit
Prohibited animal protein	9	Bulk receiving	Zero tolerance
	7	Bag receiving	Zero tolerance
	2	Rework	Zero tolerance
Aflatoxin	6	Bulk receiving	<100 ppb, 20 ppb
	1	Bag receiving	<100 ppb
Deoxynivalenol	1	Bulk receiving	<1 ppm
Pesticide residue	1	Bulk receiving	<FDA tolerance
Cross-contamination	1	Bag receiving	Zero tolerance
	14	Batching mixing	Flushing (5%), sequencing
	3	Shipping	Zero tolerance
	1	Rework	Zero tolerance
Wrong ingredient	1	Bulk receiving	Zero tolerance
	2	Bag receiving	Zero tolerance
	7	Batching mixing	Zero tolerance
Incorrect weight	2	Batching mixing	<2%
Salmonella	1	Oven	>160°F internal temp
Wrong delivery	3	Shipping	Zero tolerance
Wrong label	1	Receiving	Zero tolerance
	6	Warehouse	Zero tolerance

The most prevalent critical control points in HACCP plans included bulk receiving, mixer batching, receiving bagged ingredients, and bulk load out. The bulk receiving critical control point included control measures designed to prevent hazard introduction. Control measures for the prohibited animal protein included the use of approved suppliers, letters of guarantee, carrier wash out certificates, and physical inspection of the bulk containers. The critical limit for all these control measures was zero tolerance (Table 2). None of the feed companies possessed personnel capable of microscopically evaluating feed ingredients, and none utilized rapid tests to evaluate ingredients for the presence of prohibited animal protein. Critical limits for aflatoxin and deoxynivalenol conformed to the FDA guidelines for target species. All companies that identified mycotoxins as a chemical hazard conducted quantitative analyses to ensure that the toxins did not exceed their critical limit and to verify that suppliers were meeting contract specifications.

The most frequent critical control point involved the batching and mixing system. In 8 of the 14 HACCP plans, batching and mixing were treated as a single process step in the flow diagram. Of the 14 mills that participated in this study, only 4 had plans that did not include one or both of these process steps as a critical control point to ensure the

use of the correct ingredients and avoid cross-contamination. Control measures at the batching and mixing process step(s) included development of documentation systems to ensure that the batching operator weighed out the correct ingredients and proper sequencing and flushing practices were used at the mixer. One plan specified the amount of flush for the mixer (e.g., ground corn equivalent to 5% of the mixer capacity) and set a 2% difference between drug use records and weigh-back of the medicated article (type A) or feed (type B) at the end of the day as a critical limit. All other plans had a zero tolerance for not adhering to procedures outlined in the HACCP plan (Table 2).

The current GMPs specify that medicated feed manufacturers must use flushing, sequencing, or cleanout of the mixer to avoid cross-contamination of animal drugs between batches of manufactured feed (21 CFR 225.65, Equipment cleanout procedures) *(23).* Although the least common of these procedures is the cleaning out of mixers, studies document the impact of carryover between batches and resulting drug levels in the subsequent batches *(9, 11).* Compliance with GMP regulations represents a significant success in terms of reducing drug residues in food animal protein sources *(2, 18).*

The HACCP plans contained corrective action procedures and verification activities that are not typically found within feed company standard operating procedures (SOPs) designed to comply with current GMP regulations. SOPs were utilized in HACCP plans and prerequisite programs. The SOPs reported in Table 1 were collected from the Hazard Analysis form in the column titled ''Control Measures.'' Several plans included SOPs that would control multiple hazards at the same critical control point (e.g., hazards associated with bag and bulk receiving were handled with a single receiving SOP). Only one plan specified the use of a sanitary standard operating procedures. This involved using a sanitizing agent to clean the grinding equipment that ground raw meat used in manufacturing dog biscuits.

Despite a wide range of target animal species and feed types, plans contained common hazards, control measures, critical control points, and critical limits. Most control measures and critical limits involved adhering to SOPs that, if followed, would prevent or reduce to an acceptable level the hazard deemed significant to human health. FDA regulations exist for most of the identified hazards, including medicated articles and feeds, mycotoxins, ruminant protein, and *Salmonella.*

Table 3 summarizes the HACCP cost survey results. The average plant capacity of participating feed mills was approximately 38 tons per hour (range, 2 to 100 tons per hour). The feed mills had approximately 12 full-time and 2 part-time employees, and 4 of the 14 feed mills (29%) needed additional personnel to implement the HACCP plan.

Information on additional personnel was gathered by examining the additional person hours needed for plan design, training, compliance, laboratory analysis, plan review, and record keeping. On average, 268 additional person hours were needed to develop and implement a HACCP plan. This number differed considerably among the feed mills, ranging between 168 and 452 h. HACCP plan design, compliance monitoring, and record keeping were the three most time-consuming activities needed for developing and implementing a HACCP plan at the participating feed mills.

TABLE 3. *One-time and recurring costs of developing and implementing HACCP plans at 14 feed-manufacturing facilities*

Item	Mean	SD
Plant capacity (tons/h)	37.9	27.7
No. of full-time employees	11.8	12.5
No. of part-time employees	1.6	2.8
Additional help needed to implement plan (yes = 1; no = 0)	0.29	
Additional person hours		
Spent on HACCP plan design	72.9	37.3
Spent on HACCP training	24.4	22.2
Spent monitoring facilities for compliance with HACCP plan	70.9	59.4
Spent analyzing laboratory data related to HACCP plan	24.2	23.3
Spent reviewing HACCP	16.4	17.0
Spent keeping records associated with HACCP plan	59.5	53.3
Related to HACCP plan and training	268.3	102.0
Additional equipment		
Need to purchase new equipment to implement plan (yes = 1; no = 0)	0.29	
Cost of new equipment ($)	250	540

Most of the feed mills (10 of 14) did not need additional equipment to implement a HACCP plan. Feed mills that needed additional equipment (4 of 14 mills) listed thermometers, magnets, screens, and test kits as equipment needed.

Government agencies and feed manufacturers considering the development and implementation of a HACCP plan might be interested in the relationship between plant capacity and the additional person hours or equipment costs associated with the development and implementation of a such a plan. Plant capacity was positively correlated with total additional person hours and negatively correlated with additional equipment cost, although this correlation was not significant ($P = 0.14$).

The time required to develop and implement a HACCP plan, which averaged 269 h per facility, did not include the time invested by faculty in assisting companies by reviewing and directing their plans. Additionally, the time and cost data do not reflect the ongoing cost of HACCP maintenance and third-party verification, if companies choose to pursue certification.

The costs and benefits of complying with HACCP regulations were quantified shortly after promulgation in the United States *(17)* and more recently in the EU *(15).* The U.S. meat and poultry plants' food safety investments from 1996 to 2000 were approximately $380 million annually and $570 million in long-term investments to comply with U.S. Department of Agriculture (USDA) regulations. The industry investment was significantly greater than the U.S. Food Safety and Inspection Service estimate of $50 million per year. An Economic Research Service analysis indicated

that the total cost of regulatory implementation was less than 1% of the cost of meat and poultry products *(14)*. The time investment needed to develop and implement HACCP plans among participating feed mills represented 1% of the average total person hours of study participants. Romano et al. *(15)* reported that total costs to implement HACCP plans ranged between 0.5 and 3.0% among dairy and meat plants located in Italy, The Netherlands, and the United Kingdom.

Motivations for adopting HACCP plans involved a commitment to customer food safety, competitive positioning of products in the market, and perceptions that mandated HACCP or a requirement similar to HACCP is forthcoming.

In the present study, we successfully assisted feed companies to develop HACCP plans and documented hazards and critical control points identified by the feed industry. Although the inference space of this study is limited numerically and geographically, a trend emerged that reflected a greater concern for chemical hazards than for biological hazards (based on the number of occurrences). Many of the hazards identified in plans that required critical control points were supported by regulatory requirements found in the current GMP regulations for medicated feeds, action levels for aflatoxin, prohibited animal protein regulation, and *Salmonella* in animal feed regulation.

Adoption of HACCP systems does not appear overly burdensome for the U.S. feed industry. However, this conclusion must be tempered by the absence of a feed industry regulatory standard for HACCP plans, which would most probably increase cost of compliance. The results from this project provide the foundation upon which the feed industry could develop a voluntary HACCP standard in the United States that would facilitate third-party inspections and enable consistency among plans as U.S. feed manufacturers continue to adopt HACCP systems.

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