

Evaluation of health concerns at a pet food manufacturing facility - Missouri

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The cover photo is a close-up image of sorbent tubes, which are used by the HHE Program to measure airborne exposures. This photo is an artistic representation that may not be related to this Health Hazard Evaluation.

Highlights of this Evaluation

In September 2012, the National Institute for Occupational Safety and Health received a confidential health hazard evaluation request from employees of a pet food manufacturing plant in Missouri. The requesters expressed concerns about vomiting, seizures, and breathing difficulties, as well as problems with their kidneys and livers, possibly related to substances used in the manufacture of pet food and dog biscuits and/or possible phosphine exposure, which is a fumigant applied to bulk materials prior to arriving at the facility. In December 2012, we conducted a walk-through site visit. We planned a return medical survey for August 2013 to assess the respiratory health of workers because of our concerns for possible occupational lung disease. The survey was cancelled due to plant closure.

What NIOSH Did

- We interviewed several employees and facility representatives by telephone.
- We spoke to Occupational Safety and Health Administration personnel including a compliance officer who had taken phosphine measurements at the plant.
- We reviewed documents including a facility map; a report from the Occupational Safety and Health Administration on phosphine monitoring conducted at the facility; consultant reports on phosphine; company material safety data sheets, absentee records, quality control procedures for receiving bulk ingredients, mold sampling results, and the plant phosphine monitoring log.
- We conducted in-person interviews on- and off-site with employees from departments throughout the facility to understand any health and safety concerns.
- We monitored air concentrations of total volatile organic compounds in real-time to identify potential future sampling locations and sources.
- We collected air samples for volatile organic compounds in multiple areas of the facility.
- We collected bulk samples for headspace analysis of volatile organic compounds.
- We monitored particle concentrations in real-time to identify source locations and potential for emission from processes.

We investigated concerns of work-related respiratory and gastrointestinal illness potentially secondary to phosphine or organic dust exposure. Interviews with employees, review of medical records, and limited sampling indicated that work-related illness could not be excluded, and a medical survey was needed to further investigate the presence of work-related risks. The plant closed before medical testing could be carried out, but we nonetheless recommend medical surveillance or studies in similar plants, as well as careful assessment of the potential hazards of phosphine and flavoring use. Dust generated during the manufacture of pet food may also be hazardous due to microbial components, and this should be evaluated in more detail.

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- We collected three tape-lift surface samples for mold in two areas of the facility.

What NIOSH Found

- Facility management was cooperative and shared information about the evaluation with the workforce.
- The facility had many controls and protocols in place to limit employee exposure to phosphine.
- In the mill rooms, we observed airborne dust when the operator manually weighed/added components into the mixers.
- On the micro-ingredient deck in the pet food mill room, we observed airborne dust when bags of ingredients were manually added to bins.
- At the pet food coating station, we observed airborne dust when dry ingredients were added to the process.
- During cleaning and maintenance of the care & treat mill room and pet food mill room, we observed airborne dust when compressed air and/or sweeping were used to clean up powdered ingredients. We also observed the use of the central house vacuum system for cleaning and maintenance of many dusty tasks.
- Some employees were concerned with the response time for confirmatory phosphine sampling by supervisory personnel after a real-time monitor alarm.
- Some employees had concerns about health, especially those who worked in the mill room. Health concerns included respiratory illness, gastrointestinal illness, and allergy symptoms.
- We found that one of the ingredients used at the facility that we sampled had the potential to release diacetyl and 2,3-pentanedione into the air under certain circumstances.
- Absentee records for 2012 showed that short-term absenteeism in workers potentially exposed to grain dust or phosphine was not significantly increased.
- Company mold sampling results showed airborne mold concentrations exceeded the measurement range of the sampler on multiple days and at various locations.

We make the following recommendations (with the understanding that this pet food manufacturing facility has closed) so that this guidance will be available to other pet food manufacturing facilities, and this facility, should it be reopened.

What the Employer Can Do

- Continue aeration and clearance of fumigated railcars away from building intakes and enclosed or semi-enclosed spaces.
- Convene a health and safety committee to incorporate employee input into ways of safely assessing airborne phosphine concentrations in the summer and autumn months

when bulk materials are more likely to be received under fumigation.

- Continue voluntary use of N95 respirators.
- Train employees how to effectively put on and take off respirators.
- Ensure that N95 respirators in various sizes are readily available in each mill room, at the coating station, and elsewhere around the plant as needed. They should be stored in a convenient, clean location, and protected from settled dust.
- Perform air sampling when flavorings are in use to determine if protection (such as improved ventilation or respirators) may be necessary.
- Consider medical surveillance for excess pulmonary function decline, and evaluate possible work-related distribution of abnormalities.

What Employees Can Do

- Avoid cleaning with compressed air as much as possible. Instead, use the central vacuum system and wet methods whenever possible.
- Use N95 respirators when performing tasks that generate dust.
- Report respiratory symptoms or other health symptoms to your personal healthcare provider and, as instructed by your employer, to a designated individual at your workplace.

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Abbreviations

cc	Cubic centimeter
CFR	Code of Federal Regulations
CT	Computed tomography
C&T	Care and Treats
EPA	U.S. Environmental Protection Agency
FMLA	Family Medical Leave Act
GC/MS	Gas chromatograph/mass spectrometer
LHCP	Licensed healthcare provider
m ³	Cubic meter
mg/m ³	Milligrams per cubic meter
MSDS	Material safety data sheet
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PEL	Permissible exposure limit
ppb	Parts per billion
PPE	Personal protective equipment
ppm	Parts per million
QC	Quality control
STEL	Short-term exposure limit
VOC	Volatile organic compound

The recommendations in this report are made on the basis of the findings at the workplace evaluated and may not be applicable to other workplaces.

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Introduction

In September 2012, the National Institute for Occupational Safety and Health (NIOSH) received a confidential health hazard evaluation request from employees of a pet food manufacturing plant in Missouri. The requesters expressed concerns about vomiting, seizures, and breathing difficulties, as well as problems with their kidneys, livers, and lungs possibly related to substances used in the manufacture of pet food and dog biscuits and/or possible phosphine exposure, which is a fumigant applied to bulk materials prior to arriving at the facility. We conducted a walk-through site visit in December 2012. In February 2013, we sent the company and confidential requesters two interim letters with preliminary results from our walk-through site visit.

Background

The Occupational Safety and Health Administration (OSHA) conducted sampling for phosphine, a fumigant, in response to an employee concern in July 2012. Results for 6-hour phosphine monitoring of six employees during the day of their visit were below detection limits. Additional phosphine monitoring by a company-hired consultant confirmed that phosphine air concentrations were below detection limits on a single day of sampling in August 2012. During our early conversations with the company and requesters, we were told that a number of employees were involved in litigation with the company because of the same health concerns that prompted the OSHA investigation and the NIOSH health hazard evaluation request.

Process Description

The facility produced dry dog and cat food and care and treats (C&T), also known as biscuits, in an approximately 307,000 square-foot building constructed in 1954 and upgraded in 1987. The current owners purchased the facility in 2006. In December 2012, the facility had approximately 120 associates, 25 temporary workers, and 20 managers and administrative personnel. This process description section describes the processes as of December 2012.

Bulk Materials

The facility received bulk ingredients such as soy, corn, wheat, and dry meat & bone meal by railcar and truck. Railcar and truck receiving areas were located next to the dry product mill room.

Fumigation is the process of introducing a pesticide into a space containing bulk material. The pesticide reacts with air and moisture to form a gas, which kills insects and rodents. Aluminum phosphide pellets, foil packets, or strips can be used, depending on the type of bulk material; each produces phosphine gas. While aluminum phosphide foil packets and strips must be removed from the container after it is determined that the phosphine gas has dropped below a threshold level, pellets are not removed and may leave an inert, grey residue

on the bulk material after the reaction has gone to completion. Occasionally, due to low temperatures or poor aeration, the reaction may not complete, and some of the residue may contain active materials that may start reacting once a container is opened for use. Railcars may be legally transported while under fumigation after they are sealed and labeled with placards, but trucks cannot. Trucks containing bulk materials must complete the fumigation process and be cleared at the point of loading before traveling. We were informed by workers that trucks occasionally arrived at the facility while undergoing fumigation and were turned away per company policy. With railcars, the phosphine fumigation process was initiated by contractors at the primary bulk material loading location upstream of the processing facility. They were subsequently cleared prior to being unloaded, as described below.

After railcars arrived at the pet food facility, a contracted pest management operator performed air sampling to confirm that phosphine gas concentration had dropped below a 0.3 parts per million (ppm) threshold. If the phosphine gas concentration within the railcar had dropped below 0.3 ppm, the placards were removed, and the railcar was cleared for further processing. If the phosphine concentration was not below the 0.3 ppm threshold, the railcar was aerated at a distance from the facility and retested at a later time. A few workers reported that some railcars in the past had been cleared and the placards removed without air sampling to determine if the phosphine gas concentration had dropped below 0.3 ppm, which is against company policy. Once a railcar was cleared, quality control (QC) technicians collected samples of bulk material for testing (described in section below). After passing QC testing, the bulk material was unloaded from the bottom of the truck or railcar into a grated conveyor system that transferred it to storage silos.

QC personnel, unloaders, and dry food mill operators wore real-time portable phosphine monitors (Draeger 7000) with two alarm threshold levels. The first level was set at 0.2 ppm to serve as a warning, and the other was set at 0.3 ppm. The QC personnel started wearing the real-time monitors in the early 2000s when collecting grain samples for QC testing after several trucks arrived at the facility while still “under gas.” As mentioned previously, trucks should not be fumigated in transit by law, and this is also against company policy. The unloaders started wearing the real-time monitors in mid-2011 when they took over the sampling function of QC personnel. The mill room operators also started wearing the real-time monitors for the same reason.

If a phosphine monitor alarmed, the workers were instructed to leave the area and contact supervisory personnel who would then return to conduct air sampling with colorimetric tubes (Draeger tubes) and hand pumps to verify phosphine levels. The tubes were direct-reading measuring devices that were specific for phosphine and changed color to indicate the presence of airborne phosphine.

Dry Dog and Cat Food

Dry products operated on a schedule of three shifts per day, five days a week.

A conveyor system automatically transported bulk material (i.e., corn, wheat, flour) from

storage silos into a mixer in the mill room. A mill room operator manually scooped specific powdered ingredients (e.g., dyes, red iron oxide) onto a weighing balance and then dumped the ingredients by hand directly into the mixer according to a recipe; this process was called “hand-adds” by operators. The mixer spanned two floors: the basement and the first floor. The hand-add station, weighing balance, and mill operator control room were located on the first floor. The basement contained the mixer body and the conveyor system to the hammermills (i.e., grinders). Workers rarely entered the basement area, generally only to perform maintenance and cleaning. Additional powdered ingredients (e.g., potassium chloride, Dog Trace, Cat Trace, dried brewer’s yeast) which were stored in the micro-ingredient deck in the mill room were added by a screw conveyor system. Throughout the day, the mill room operator opened large bags of ingredients and manually emptied them into bins on the micro-ingredient deck that fed the screw conveyor.

After all ingredients were added to the mixer, the mixture was transferred to a hammermill and ground into a fine powder. The powdered mixture was pneumatically conveyed to a bag house and then transferred to the extrusion room. The bag house required periodic cleaning and maintenance as needed. An extrusion operator controlled machines that added moisture and heat to the product which was then extruded and cut with blades into final pellet form. The heat in the extrusion process performed the crucial role of eliminating *Salmonella* and other potentially harmful bacteria from the product. The product was then placed on a conveyor belt and sprayed with a coat of palatability enhancers (i.e., flavorings and liquid fats). Finally, the product was dried in an oven and transported to short-term storage silos. The finished product was then packaged, palletized, and stored in the warehouse where it was held for three days for QC testing.

Care and Treats

C&T products operated on a schedule of two shifts per day, four days a week.

Similar to the dry food product area, a conveyor system also automatically transported bulk material (e.g., wheat and meat & bone) from silos into a mixer in the C&T mill room. A mill room operator manually scooped powdered ingredients (e.g., Dog Trace, Cat Trace, dyes) onto a balance and then “hand-added” the ingredients into the mixer which also spanned two floors. The first floor contained the hand-add station and the balance; and the basement contained the mixer body and the conveyor system to hammermills (grinders). The ground mixture was transported to a ribbon mixer and combined with water. The biscuit processing operator controlled the ribbon mixer and manually added ingredients (e.g., chicken meal, beef meal, vitamins, and flavor enhancers) to the wet, dough-like substance. The dough was then pressed into shapes using roller dies and baked at high temperatures in an oven. The final product was packaged and stored in the finished product warehouse where it was held for three days for QC testing. If the recipe required, care and treat products could be coated with flavors in a basting process that would occur after baking. This process was not running at the time of the NIOSH site visit; the company reported that this process only occurs approximately four days per month.

Quality Control

QC personnel took samples of incoming bulk products (including corn, brewer's rice, wheat, fats, and oils) to test for such things as aflatoxin, vomitoxin, salmonella, molds, insects, rodent activity, and foreign or extraneous materials. For railcars, the QC technician climbed a ladder onto the roof of a railcar (while wearing fall protection equipment). The QC worker performed a visual and odor check to look for wet, moldy, off-odor, or infested product prior to accepting the load. If fumigant was suspected or detected by their monitor, the worker stopped and followed fumigant protocols. If there were no fumigant concerns, the QC technician inserted a probe into the bulk material to collect samples of product from different areas of the railcar. For bagged materials such as flavorings and pre-blends, a subset of bags was selected for QC testing. QC technicians also performed hourly checks of finished products for blends, weights, metal detection, and *Salmonella* and aflatoxin testing.

Improvements

The company installed a central vacuum system throughout the plant in 2010. In September 2012, a central vacuum drop was located near the balance at the hand-add station in the pet food mill room.

Cleaning

Employees used the central vacuum system to remove accumulated dust. To prevent airborne dust generation, the use of compressed air was limited to areas that could not be reached by vacuuming. At the end of a shift, staff used brooms to sweep waste product into central piles. Once a week, the second shift performed a more extensive cleaning of the facility.

Personal Protective Equipment

Employees were required to follow "Good Manufacturing Practices" in all production areas, which included specific attention to personal hygiene, hair covering, and work practices to prevent product contamination. Employees in the production areas wore company-provided uniforms and were required to wear steel-toed shoes, hearing protection, and safety glasses. Jewelry was not allowed in the production area. Latex gloves were worn in areas such as the micro-ingredient deck and packaging. Face shields, rubber gloves, and rubberized fabric suits were used for certain cleaning and maintenance procedures, such as cleaning and degreasing the extruders. The company did not have a formal respiratory protection program; however, they provided N95 respirators for voluntary use. The company did not maintain a roster of N95 users. We did not observe any workers wearing N95 respirators during our visit.

Methods

Prior to our visit in December 2012, we interviewed eight current and former workers via telephone about their work experiences at the facility. We asked them if they had any health concerns, and reviewed medical records for seven workers.

We conducted a walk-through site visit of the facility from December 17–19, 2012. During our walk-through site visit, we held an opening meeting with representatives of management and associates, toured the facility, talked with current and former employees on and offsite, and met with the company’s occupational medicine provider. We also obtained the following documents: 1) a copy of the company presentation given at the opening meeting; 2) the facility’s Good Manufacturing Practices requirements booklet, which we read and signed prior to the tour; 3) standard operating procedure for managing rail cars that arrive with pesticide placarding and responding to alarms issued by gas monitors; 4) selected material safety data sheets (MSDSs); 5) hazard communication tables from their MSDS binders; 6) micro-ingredient tracking logs; 7) log of rail cars under fumigation; and 8) phosphine gas detector data collection sheets.

During the site visit, we conducted brief, informal interviews about work history and health concerns with 31 employees (23 on-site, eight off-site) from the different departments and work areas in the facility. Although we attempted to select employees randomly from departmental lists, some employees refused interviews, others volunteered as a convenience sample during co-scheduled urine drug testing, and some interviews were conducted in groups of up to four, without individual privacy. Thus, we did not assume that the interviewees were a random sample of either the workforce or of specific departments or work areas.

Workers were asked about their job history at the plant. They were also asked about any health problems they had, and any comments about health and safety at the plant. We used this information in concert with the information from telephone interviews to assess possible clustering of symptoms. During the interviews, we provided an informational handout about the NIOSH walk-through site visit of the facility. We also had pamphlets available on the NIOSH health hazard evaluation program [CDC 2009]. Company lawyers and management expressed concern for biased information from litigants. In response, we excluded the responses from the eight litigants (whose names were provided by the company) from our evaluation of clustering of symptoms by work areas.

During our walk-through site visit, we employed limited sampling techniques to assess exposure potential to volatile organic compounds (VOCs), bulk ingredients, and dust. We also collected a few samples to assess potential surface mold contamination. We sampled for VOCs in aggregate to determine if this agent could be of potential concern and to determine source locations. We collected samples of bulk ingredients for subsequent laboratory headspace testing for alpha-diketones as these agents have been known to cause respiratory diseases. We sampled airborne dust and for possible surface mold since requesters had expressed a concern about these agents. We intended to sample for phosphine using real-time monitors, but the monitors were damaged during shipment. The purpose of the sampling was to assess the hazard potential in terms of types and potential emission of agents in the work environment. The sampling was not designed for compliance monitoring or comparison with occupational exposure limits. It was intended to inform decisions regarding possible future, comprehensive industrial hygiene sampling.

Real-time Volatile Organic Compound Measurements

We used ppbRae Plus (Rae Systems, Inc.) real-time photoionization detectors with 10.6 electron volt lamps to monitor total VOC concentrations throughout the facility.

Evacuated Canisters

We collected six instantaneous, whole-air samples using evacuated 450 cubic centimeter (cc) canisters for VOC analysis. The air samples were collected at several locations throughout the plant and analyzed using an Entech 7100 preconcentrator attached to a 5890/5973 Agilent gas chromatograph/mass spectrometer (GC/MS) system pursuant to a recently published method validation study [LeBouf et al. 2012] with the following modifications: 1) diacetyl (2,3-butanedione), 2,3-pentanedione, and 2,3-hexanedione were added, and 2) qualitatively-identified compounds were compared to National Institute for Standards and Technology 2008 Mass Spectral Library and reported if the quality factor was greater than or equal to 75%. The concentrations were reported in parts per billion (ppb). At present, the canister method is partially validated and is being reviewed for incorporation into the NIOSH Manual of Analytical Methods. The canister sampling was conducted to screen for VOCs that may be related to requesters' respiratory health concerns with a particular emphasis on flavoring-related compounds listed in the modifications above. No comparisons can be drawn with applicable regulatory exposure limits since the samples were collected instantaneously. Subsequent to results reported in the interim letter, we identified an issue with the calibration procedure for diacetyl during method validation of the canister analysis protocol. A correction factor was applied to all diacetyl results to account for the difference between sampling and calibration procedures. The previously reported results have been corrected by multiplying by a factor of 0.79.

Headspace Volatile Organic Compound Analysis of Bulk Process Ingredients

We collected small quantities of bulk ingredients in containers for subsequent laboratory analysis to investigate the VOC emission potential of the material via headspace analysis.

We collected and analyzed samples of liquid apple and hickory flavor and powdered Dog Trace, Ped Min PMX, Cat Trace, Ped Vit PMX, Dried Brewer's Yeast and Molasses, Optimizer DC426, Palatability Enhancer, Natural Pork Sausage Flavor, Bacon Fat, Beef Meal, Chicken Meal, Turkey Meal, Peanut Flour, Gold Fat, Cinnamon Flavor Powder, and Caramel Color Powder.

We placed 1 cc (for the liquids) or between 0.2 and 1 gram (for the powder) of bulk material into a sealed 40 cc amber volatile organic analysis vial where it stood for approximately 24 hours at room temperature (70°F). We then transferred 1 to 2 cc of headspace air to a 450 cc canister and pressurized it to approximately 1.5 times atmospheric pressure. We injected 200 cc from the pressurized canister onto the preconcentrator/GC/MS system. We calculated the concentration [in ppm] of analytes in the headspace based on an internal standard method. We also subjected some products (Dog Trace, Dried Brewer's Yeast and Molasses, Natural Pork Sausage Flavor, Beef Meal, Chicken Meal, and Cinnamon Flavor Powder) to a wet

method. We added 1 cc of water to an aliquot of the bulk product in a volatile organic analysis vial and heated it to 122°F for one hour. The rest of the transfer and analysis steps were the same as the dry preparation method described above. The same correction factor as above was applied to all diacetyl headspace results to account for the difference between sampling and calibration procedures.

Real-time Particle Monitoring

We used DustTrak DRX (TSI, Inc.) real-time instruments to monitor dust concentrations throughout the facility.

Mold Tape-lift Samples

We collected two tape-lift samples from C&T mill room basement and one from the pet food mill room basement. The surface samples were collected on wall locations that were discolored and visually identified as possible mold contamination. We observed the samples with a bright field technique under an optical microscope (Nikon Eclipse 600) to evaluate presence of fungal spores or mycelia. This limited sampling cannot be construed as a full investigation of possible mold contamination in the plant.

Closing Meeting

At the end of the site visit, we held a closing meeting with representatives of management and associates. We summarized our activities during the site visit and provided copies of a NIOSH informational handout about the site visit, NIOSH pamphlet on the health hazard program [CDC 2009], NIOSH flavorings alert [CDC 2003] along with a NIOSH publication on preventing phosphine poisoning and explosions during fumigation [CDC 1999]. We requested mold air sampling results as well absentee records by department and job title.

Absentee Records

After the site visit, the company provided us with requested absentee records by department and job title for 2012. Our motivation for looking at population-based absenteeism data was to investigate whether absenteeism was increased in a group of employees potentially exposed to phosphine and/or grain dust and extend impressions from our small sample of interviews.

We eliminated anyone who worked less than 200 hours during the year (about 5 weeks), which included several people who received a pay check but did not work. We also eliminated two individuals whose Family and Medical Leave Act (FMLA) time off exceeded the time they worked during 2012. We created two variables: total short-term time off, which included short-term (one day) plus doctor's note (two to three days) absence; and total hours worked, which included regular time, overtime, and missed punch hours. We did not include FMLA time off. We created a ratio of short-term absenteeism to total hours for each person. We analyzed these data using a one-sided Wilcoxon-Mann-Whitney test because the Shapiro-Wilk test indicated the data were not normally distributed. The Wilcoxon-Mann-Whitney test was used to see if absenteeism was increased when the data were grouped by job title in

two ways: potential for phosphine exposure (yes, no); potential for grain dust exposure (yes, no). Potential for phosphine exposure group had 17 out of 136 employees and consisted of the following job titles: mill room operator (pet food area only), relief operator (pet food area only), unloader, QC technician, and quality technician. Potential for grain dust exposure group had 31 out of 136 employees and consisted of the following job titles: mill room operator (pet food and C&T areas), relief operator (pet food and C&T areas), QC technician, quality technician, and Maintenance A and B. These groupings were developed based on information obtained from our interviews with employees and our tour of the plant.

Results

Workplace Observations

Throughout our visit, we found managers and employees friendly and welcoming. We found most of the plant clean and organized. In the C&T and pet food mill rooms, we observed settled dust in the hand-add area near the mixer, in the mill room basements, and on the micro-ingredient deck in the pet food area. We noted that fugitive airborne dust was potentially created during 1) the addition of ingredients by hand (hand-adds) into mixers; 2) manually dumping bags of ingredients into bins on the micro-ingredient deck in the pet food mill room; 3) cleaning in the mill rooms; 4) automatic ingredient transfer from silos to the mixer; 5) hammermill operation and maintenance; and 6) dumping of ingredients from railcars to the automated transfer system.

Many employees informed us that plant cleanliness improved under the current ownership. They reported that under the previous ownership, employees stood in ankle-deep dust while working in the mill rooms. Improvements made by the current owner included the installation of a central vacuum system throughout the plant. We were also informed that plans were under way for capital process improvements for the mill room and grain elevators, but these plans are irrelevant given the recent decision to close the plant.

Medical Record Review

We reviewed medical records from seven current or former employees at the plant who released their records to NIOSH. All seven of these people had respiratory complaints, including persistent cough or shortness of breath. They were referred to pulmonologists and subsequently had a variety of conditions diagnosed, including restrictive lung disease and asthma. Some were sent to specialists for further evaluation, and these evaluations are ongoing.

One worker has nearly completed the health evaluation process and has given permission to discuss the details. This person first noted illness about four months after beginning work in the mill room. Symptoms consisted of fatigue, shortness of breath, persistent cough, dizziness, and wheezing. This worker subsequently went to an emergency room and was diagnosed (per worker report) with pneumonia or bronchitis. These records were not available. Despite treatment, the worker noted no improvement. Over the next year, symptoms continued to

progress, and the employee was evaluated for potential infectious causes without success. In the first half of 2012, this worker was evaluated seven times for chest pain or shortness of breath, with no cause identified. At the last of these evaluations, the chest x-ray showed abnormal thickening of the lining of the lungs, and a possible nodule, so the employee was referred for further evaluation, including a computed tomography (CT) scan of the chest. At this time, the employee was told to use a respirator at work but reported that the request was denied by the company.

Further workup revealed a severely restrictive pattern on spirometry. A restrictive abnormality indicates that the amount of air exhaled from the lungs is smaller than normal. This can occur in people with stiff lungs, such as found with pulmonary inflammation or fibrosis (lung scarring); people with weak respiratory muscles; or in people who are considerably overweight. It can also be seen in people who have other severe lung abnormalities.

The worker was given inhalers and was referred for lung biopsy and evaluation at a national referral center. The worker underwent repeat pulmonary function testing and CT scan in April 2013, at which point the employee had not been working for over six months. Though fatigue and nausea had improved, the employee still felt short of breath. Improved, but still abnormal, spirometry was observed at that time, and methacholine challenge demonstrated some mild nonspecific bronchial hyperreactivity, which improved with medication. Repeat CT showed diffuse bronchial wall thickening, ground glass opacities, and air trapping. Pathology of the biopsy showed non-necrotizing granulomas, air spaces with foamy macrophages, and focal constrictive changes around some bronchioles (airways). The biopsy was felt to be consistent with hypersensitivity pneumonitis, which has been related to organic dust exposure. The breathing tests indicated asthma or an asthma-like condition, and bronchodilators were recommended. On December 24, 2013, the physician indicated there was reasonable medical probability that the worker's respiratory condition was due to his workplace exposures at the pet food manufacturing facility.

This physician evaluated another worker (not described in detail here) from the same pet food manufacturing facility. The physician indicated that this worker's lung disease was reasonably attributable to the workplace. This worker also had a lung biopsy consistent with hypersensitivity pneumonitis.

Employee Health Concerns

Employee Phone Interviews

The most common concerns from the phone interviews prior to the site visit were worsening breathing and gastrointestinal symptoms. Workers stated that while working in the mill room, they and other workers frequently became nauseous and even vomited. Workers also complained of accompanying headaches and dizziness. In some cases, these symptoms persisted as chronic abdominal pain or diarrhea. Workers related this to unloading and mill room processing of railcars or trucks of grain and meat & bones that had been fumigated

with phosphine but were inadequately aerated after fumigation. They attributed their symptoms to phosphine because they smelled garlic, which is the characteristic odor of phosphine, and handheld phosphine monitors alarmed at the time of symptom onset. Some expressed considerable dissatisfaction about the absence of available respiratory protection for phosphine which some symptomatic employees had been advised to request by their physicians.

Generally, they described their pulmonary symptoms as repeated respiratory illnesses, increasing shortness of breath, and less ability to perform daily activities. Several people reported abnormal lung function tests or radiologic images and were referred for further care.

Employee Interviews During Site Visit

Approximately two-thirds of the workers interviewed reported symptoms they felt were work-related. Some reported respiratory symptoms (cough, sneezing) around mill room dust or ingredients (such as flour, potassium, sodium metabisulfate, Cat Trace, or gravy powder). Some workers reported that ingredients irritated their eyes or nose, worsened their allergies, or that they coughed up colored sputum or had nasal secretions that appeared to have dye colors used in manufacturing. We also heard the term “bag house flu,” described as a flu-like illness with achiness and sore throat, which some workers experienced when working in the bag house, and for which they occasionally pretreated themselves with over-the-counter medicine such as Advil[®] or Nyquil[®]. A few workers mentioned work-related symptoms of fatigue, tiredness, light-headedness, dizziness, headache, stomach ache, nausea, and/or vomiting associated with being in the mill room or in the railcar/truck unloading area. The majority of the workers attributed these symptoms to phosphine, as workers felt symptoms were more common in the summer months and after the opening of railcars that had been fumigated. One worker reported that the mill room dust caused a skin rash. Those we interviewed were generally aware of the availability of disposable, particulate respirators (N95 respirators) for voluntary use, although few reported using these respirators. Some workers reported that the company did not provide a copy of Appendix D of the OSHA Respiratory Protection Standard. The company reported that they covered Appendix D and informed workers about available voluntary respiratory protection during annual training sessions. Phosphine-specific respirators were not available.

Analysis of Information from Employee Interviews

We looked at self-reported work location and symptoms among the workers we interviewed by phone or during our site visit. In all, we spoke to 35 different workers, some multiple times. Eight workers were interviewed by phone, 23 were interviewed at the plant, and eight were interviewed at an off-site location. We excluded the eight litigants as requested by the company, leaving 27 interviews which were analyzed for job history and symptoms. Of the 27 interviewees, 18 of the workers had performed duties in the mill rooms or ever held a job that required frequent, but intermittent, entrance into the mill rooms (including quality and maintenance personnel). The remaining nine had never worked in the mill room.

Pulmonary, allergy, and gastrointestinal symptoms were common in people who had ever worked in the mill room. Of those who were currently or had been employed in the mill room, 55% described respiratory symptoms such as cough and wheeze. Additionally, 50% of ever mill room workers described allergies, and 27% of this same group identified gastrointestinal symptoms such as pain, nausea, and vomiting. Prevalences of these symptoms in workers outside the mill room were 11%, 33%, and 0% respectively. Neurologic symptoms, cancer, and urinary tract symptoms did not appear to be more likely in one group or the other, though in some cases, numbers were quite small, making it difficult to evaluate. No tests of significance were performed due to the limitations of the interviews, which were not considered representative.

MSDS Review

A number of MSDSs for ingredients including Dog Trace, Cat Trace, Milled Wheat Products, and several dye products recommend the use of respiratory protection during the generation of dust. OSHA permissible exposure limits (PELs) for such particulates may not exist, in which case they are considered by OSHA to be “Particulate Not Otherwise Regulated” with a total dust limit of 15 milligrams per cubic meter (mg/m³) [Code of Federal Regulations (CFR) , Title 29, Part 1910, Section 1910.1000 (29 CFR 1910.1000)]. The OSHA PEL for grain dust (including wheat and barley) has a slightly lower limit of 10 mg/m³ [29 CFR 1910.1000]. Respiratory protection for nonspecific particles is not required when time-weighted average concentrations are below these limits, but the MSDSs recommend respiratory protection for employees that want to protect themselves from potential hazards associated with these particles.

Review of Company Phosphine Monitor Data

We reviewed the company’s phosphine gas monitor data collection sheets from August 4 to December 17, 2012. The personal phosphine monitors were set to alert at threshold levels of 0.2 ppm and 0.3 ppm (which corresponds to the time-weighted average OSHA PEL). The Draeger tubes can detect up to a concentration of 1.0 ppm. While these are instantaneous measurements and cannot be used for compliance assessments against the OSHA PEL or the NIOSH Short-Term Exposure Limit (STEL) of 1.0 ppm, the exposure limits provide a benchmark for comparison. For some days, there were no entries on the log sheets. On August 4, 2012, there were three monitor measurements (0.18 ppm, 0.33 ppm, and 0.18 ppm) within 30 minutes at the pet food mixer that were each confirmed by Draeger tube results of 0.1 ppm, indicating the presence of phosphine. From August 4 to October 29, 2012, personal phosphine monitor measurements ranged between 0 and 5.85 ppm. On two days, there was a personal monitoring reading of 5.85 ppm around the auger. One of the confirmatory Draeger tube measurements for these instances was 0. For the other 5.85 ppm alert, the Draeger tube measurement was not recorded; there was a comment on the log sheet that it took the supervisor 15 minutes to collect the confirmatory measurement. The majority of personal monitor alert readings from August 4 to October 29 were below 0.6 ppm and occurred around the pet food mixer. Confirmatory Draeger tube measurements ranged from 0 to 1.0+ ppm; the majority of measurements were below 0.06 ppm. The 1.0+ Draeger tube

measurement occurred when a railcar was opened for sampling; the personal monitor reading was 0.56 ppm. From October 31 to December 17, 2012, the logs indicated that there were no personal phosphine monitor alerts.

Review of Company Absentee Data

No statistically significant difference was observed in fraction time off between groups classified with potential phosphine exposure [average (min – max) = 0.0061 (0 – 0.0396)] and unexposed groups [0.0046 (0 – 0.0331)] (p=0.50).

No statistically significant difference was observed in fraction time off between groups classified with potential grain dust exposure [0.0056 (0 – 0.0396)] and unexposed groups [0.0045 (0 – 0.0331)] (p=0.43).

Review of Company Mold Sampling Results

Sampling was performed using Sampl'air[®] Lite (AES-Chemunex Inc., Princeton, NJ) onto dichloran glycerol 18 (DG18) agar media plates. Results were reported in terms of colony forming units per 100 liters. We converted these results into a more conventional form of colony forming units per cubic meter (m³) by multiplying the value by a conversion factor of 10 (1000 liters = 1 m³). Reports were provided for February 3, 2012 to December 3, 2012 with two to four reports per month for a total of 29 reports. All sampling for a given report was conducted on the same day. No details regarding time of day were given. There were 13 locations that were consistently sampled at the same location in each report. Results were between 20 and >12,590 colony forming units /m³. A seasonal trend was noted with lower counts during the winter months compared to the summer months, which had the highest counts. Results showed airborne mold concentrations exceeded the measurement range of the sampler on four days for a total of 26 out of 377 samples (6.9%). Among the four days, every location sampled had at least one result that exceeded the measurement range.

NIOSH Industrial Hygiene Results

Volatile Organic Compounds

Real-time Sampling

We observed an increase in VOC concentrations around alcohol-based hand sanitation stations located between raw and processed product areas.

Evacuated Canisters

We identified ethanol, acetone, and isopropyl alcohol in all six samples (Table 1). The alcohols (i.e., ethanol and isopropyl alcohol) were presumably due to hand sanitizing stations used in the plant to reduce cross-contamination between raw and finished product areas. Diacetyl was found at low concentrations in the dry product coating (1.8 ppb) and drying (1.5 ppb) areas of the facility; both values are between the detection limit and the quantitation limit.

In C&T, we sampled a chicken meal ingredient bin used for hand-adding dry ingredients,

which resulted in 3.1 ppb diacetyl and 6.2 ppb 2,3-pentanedione. We did not detect 2,3-hexanedione in any of the samples. We qualitatively identified a number of aldehydes (e.g., 2-methylpropanal, 3-methylbutanal, 2-methylbutanal, pentanal, hexanal, and heptanal) in the dry product coating and drying and the C&T processing hand-add ingredient bins.

Headspace Analysis of Bulk Materials

We identified diacetyl (78 ppm) and 2,3-pentanedione (19 ppm) in the headspace of liquid hickory flavor; we did not detect 2,3-hexanedione. We did not detect diacetyl, 2,3-pentanedione, or 2,3-hexanedione in any of the other bulk ingredients.

Real-time Particle Monitoring

Automated release of raw materials from the hopper into the mixer (pet food mill room) and transfer of bagged ingredients into bins (micro-ingredient deck) were associated with dust emissions. In the unloading bays, release of raw materials from trucks into the floor grates was associated with dust emissions.

Mold Tape-lift Samples

We did not observe fungal spores or mycelia on the three surface samples.

Update Since Site Visit

In response to inquiry, we received the following information by telephone and letter from the company and legal representatives. The company reported it continued to encourage the use of the central vacuum system instead of blowing with compressed air when possible to clean up dust. Management provided additional N95 respirators in cabinets near the mill room and coating stations. They placed a laminated NIOSH document demonstrating how to put on and take off the N95 respirators by the N95 cabinets. Company health and safety staff conducted training sessions on the use of N95 respirators. Management contacted the hickory flavoring manufacturer to inquire about the presence of diacetyl and 2,3-pentanedione in the flavoring product. The manufacturer stated that they did not add diacetyl or 2,3-pentanedione to the flavoring, and these chemicals were not on the MSDS. Management placed colorimetric tubes (Draeger tubes) with hand pumps near the pet food mill control room. In the summer of 2013, the company closed. The dry food products department was shut down on June 21, 2013, and the care and treats department was shut down on August 9, 2013.

Discussion

One of the workers' concerns was for suspected work-related health effects from phosphine. Intermittent phosphine exposures may have been present, as documented in the company logs of phosphine monitor readings. Because real-time monitors may cross react with other chemicals such as hydrogen sulfide and acetylene, the real-time monitors may have reflected non-phosphine exposures. Confirmatory Draeger tube sampling only sometimes confirmed

elevated phosphine concentrations. Whether this absence of confirmation reflected triggering of the real-time alarm secondary to other chemicals, or whether it was due to dissipation of phosphine gas is unknown and cannot be determined. OSHA air sampling measurements on one day did not find phosphine exposures over a 6-hour period. Sampling performed by the company's consultant on two occasions did not detect phosphine exposures. We could not ascertain evidence to confirm or refute phosphine exposure over the PEL for an entire shift. There is some evidence that exposures over short-term exposure limits may have occurred, but their frequency cannot be determined.

The company reported that employees may have violated standard operating procedures by opening railcars that were not cleared. The company had contracted out the responsibility for clearing fumigated rail cars. The contractor replaced their employee who may not have followed proper clearing procedures for fumigated railcars. Some employees at the pet food company had 1) mistakenly interpreted residue from fumigation tablets on grain as evidence of harmful exposure; 2) were anxious because of phosphine monitor alarms and phosphine odor that often accompanied symptoms; 3) complained that confirmatory Draeger sampling was often not performed in a timely manner by supervisors; 4) distrusted the contractor, who was later replaced; 5) were not reassured by pre-scheduled OSHA sampling since not all fumigated rail cars posed an exposure to phosphine in their view; and 6) were upset that respiratory protection appropriate for phosphine exposure was not provided after the plant physician consultant suggested it. Phosphine respiratory protection is expensive, as it requires a special cartridge [NIOSH 2010]. In the absence of phosphine measurements indicating overexposures over the course of an entire workday or 15-minute intervals, it is perhaps understandable that the company had not provided phosphine respiratory protection.

The question remains whether the symptoms allegedly related to phosphine exposure by the employees may have been work-related. The evidence for possible work-related health effects came from requesters, review of medical records, review of literature, and interviews with employees who worked in different areas of the plant. Additionally, a physician has attributed two workers' respiratory disease to exposures at the plant. It is important to note that the number of workers interviewed was small and non-random. Thus, our interviews were neither systematic nor representative of the plant population. Analysis of the information from such interviews was undertaken to inform a decision about returning for a full medical survey and was not intended to be formally released. Given the closure of the plant and our subsequent inability to conduct a medical survey, we decided to share this information so readers of this report will understand our reasons for desiring to return, and can use this for guidance if they would like to conduct their own medical surveillance. Yet though these interviews were not definitive, neither were they reassuring that work-related disease did not exist. They showed that some symptoms such as respiratory problems, gastrointestinal symptoms, and allergies were common in those who reported ever working in the pet food mill room.

The short-term absenteeism did not differ significantly by subgroups of employees. Yet, this may not have detected problems that exist. Short-term absenteeism might be a poor measure of health outcome with respect to possible work-related disease. Many of those we interviewed had short-term symptoms within a shift that did not result in taking time off

work. Because only total hours and not instances of leave were recorded, multiple occurrences of partial-shift absences were not able to be identified.

In the face of these limitations of the walk-through and investigations to date, we felt that we needed to further evaluate this question of possible work-related disease by conducting population-based symptom questionnaire interviews and medical testing of the plant population to see if clustering existed by exposure categories. This effort would have collected reports of potential exposures of interest and job title history with which to minimize misclassification of exposures. Medical testing would have established objective measures of health outcomes to supplement symptom reporting. Although the analyses of such data do not establish diagnoses in individuals, population-based data is useful to a company in managing occupational risks by prioritizing interventions, if necessary, to lower exposures or safeguard the health of susceptible workers. Unfortunately, we were not able to schedule this evaluation in the face of plant closure. Although headache and gastrointestinal symptoms are recognized effects of phosphine exposure, chronic effects (for example, on the respiratory system) from intermittent sub-lethal exposures have not been well studied, though case reports indicate that there may be some cause for concern [Brautbar and Howard 2002; CDC 2012; Burgess 2001; Preisser et al. 2011]. Our proposed medical investigation might have addressed the gaps in knowledge about occupational health consequences of intermittent sub-lethal phosphine exposure.

In addition to phosphine exposures, NIOSH investigators had concerns about other potential causes of occupational disease in the plant, including volatile flavoring chemicals, grain dust, endotoxin, molds, and mycotoxins including aflatoxins. A case report of bronchiolitis obliterans exists in an animal feed manufacturing setting [Spain et al. 1995]. For most of these potential exposures in the manufacture of pet food and biscuits, no measurement data were available with which to assess risk. Indeed, there are no permissible exposure limits for most of these potential exposures. However, several are known to cause occupational disease and should be handled with care, as indicated on MSDSs and our findings from bulk headspace sampling (e.g., diacetyl and 2,3-pentanedione). Even when regulations for permissible concentrations are not violated or do not exist, we support efforts to educate associates through hazard communication training about potential hazards and ways of protecting themselves.

Volatile Organic Compounds

The hickory flavoring headspace results showed that it is a potential source of two toxic chemicals that can result in irreversible respiratory damage if associates inhale them at sufficient concentrations. Though they are not listed on MSDSs, this does not preclude their presence, as ingredients less than 1% by volume do not need to be reported. The lung disease associated with these chemicals is constrictive bronchiolitis (bronchiolitis obliterans), which manifests as shortness of breath with exertion. This is a rare lung disease for which physicians have poor tools for diagnosis. It can manifest with normal chest x-rays, normal high-resolution computed tomography scans, and normal lung function tests. Classical advanced cases have abnormal spirometry in either an obstructive or restrictive pattern,

and high-resolution computed tomography scans can show air trapping on expiratory films. Diacetyl and 2,3-pentanedione do not have enforceable permissible exposure limits, but the draft NIOSH recommended exposure limits are 5 ppb and 9.3 ppb (eight-hour time-weighted averages) for diacetyl and 2,3-pentanedione, respectively. The corresponding proposed 15-minute STELs are 25 ppb for diacetyl and 31 ppb for 2,3-pentanedione [NIOSH 2011]. The NIOSH draft recommended exposure limits are higher for 2,3-pentanedione than for diacetyl largely because analytic measures are not available in a validated OSHA method to detect 2,3-pentanedione at lower levels. The presence of these chemicals, even at a low concentration, is potentially hazardous.

The hickory flavoring was not being used when we were in the plant, and we do not know whether a hazard exists to the workers during its use. The headspace analysis of the hickory flavor revealed the emission potential of the liquid. However, headspace values cannot be directly compared to air concentrations in worker breathing zones. The NIOSH proposed recommended exposure limits are based on concentrations of diacetyl and 2,3-pentanedione in workplace air, regardless of their concentration in the ingredients or products used or processed at a facility. Certainly, we support efforts to assess associate exposure to these chemicals when hickory flavoring is used so that the company knows whether precautionary measures are needed to protect associates from potential chemical exposure to flavorings.

It is important to note that though flavoring manufacturers may not include diacetyl on their MSDSs, these chemicals can still be present. The implication that diacetyl and 2,3-pentanedione are naturally occurring as a result of the roasting or smoking process and are therefore safe, is misleading. These diketones have respiratory toxicity, whether naturally derived, or added as synthetic chemicals. We found unsuspected diketones in health hazard evaluations at a coffee roasting facility and in a smoke flavoring at a cream cheese manufacturing facility [CDC 2013; NIOSH 2013].

Phosphine

Phosphine has been reported in the literature as a potent inhalation hazard, which in certain circumstances can lead to cardiovascular collapse. Additionally, some case reports suggest that single, high-level exposures can lead to persistent respiratory effects [Brautbar and Howard 2002; CDC 2012; Burgess 2001]. Others have questioned whether repeated exposures below the OSHA PEL can also lead to long-term symptoms, but this has not been addressed as clearly in the literature [Preisser et al. 2011; Misra et al. 1988].

The fact that some instantaneous phosphine measurements were greater than the OSHA STEL raises some concern due to the nature of possible severe health effects resulting from phosphine exposures. We understand from the instrument manual that the personal monitor may respond to other chemicals such as hydrogen sulfide and acetylene [Draeger 2012]. This chemical interference may contribute to false-positive or erroneously elevated phosphine concentrations displayed by the real-time monitors. The time between monitor alerts and confirmatory measurements by Draeger tubes may also have contributed to the discrepancies between measurements from different sampling techniques due to phosphine degradation

or dilution. We support the company's use of phosphine detectors, as smell is not a reliable indicator of exposure. We also encouraged the company to resolve this issue by training others to perform the Draeger confirmatory testing, and by storing the test equipment closer to point-of-use for easy access.

We intended to measure phosphine using real-time meters during the walk-through site visit, but they were damaged in shipment. It may not have mattered due to the seasonal nature of fumigation. We relied on the company-provided data to evaluate the potential for phosphine exposure. While the records on the phosphine log are instantaneous readings, we believe that short-term exposures above the STEL may be possible. We encourage the company to work with their contractor who oversees clearing phosphine cars to make sure that this is done in a safe manner, which decreases risks to associates. Ideally, cars should be cleared and off-gassed away from the primary work building, so that any phosphine emitted during the opening of the car or during the off-gassing process does not affect employees. Monitoring of adjacent enclosed areas, where aeration may occur, is required by the U.S. Environmental Protection Agency (EPA) to ensure no one is exposed above the OSHA PEL of 0.3 ppm as an 8-hour time weighted average [EPA 2005]. The EPA has additional information on this topic, which should be considered, if it has not already been included, in the company's standard operating procedures for handling fumigated/aerated railcars [EPA 1998].

Particles/Organic Dust/Mold

Repeated exposures to both organic and inorganic dust can lead to respiratory problems, either through acute events, or through the cumulative effect of many exposures. These lung diseases can be quite severe. Though company associates noted that dust levels had improved compared with conditions under prior management, we noted several activities that could lead to exposure to grain dust and other dusts in the plant. Employee reports of blowing powdered dye from their noses (or coughing it up) days later indicated that dusts had been inhaled.

The MSDSs for Dog Trace, Cat Trace, Milled Wheat Products, and several dyes suggest the use of respiratory protection during activities that generate dust. The MSDS for Gold Fat states that inhalation may cause an allergic respiratory response, which may include coughing, wheezing, shortness of breath, or chest tightness. Some types of grain processing may generate dusts potentially containing aflatoxins. For example, studies have found that substantial amounts of dust are generated during the processing and handling of corn, and a number have evaluated aflatoxin in dust from grain elevators, terminals, and corn dumping stations [Burg et al. 1981; Sorenson et al. 1981]. Studies have shown that the amount of aflatoxin in grain does not correlate with the amount in air [Selim et al. 1998]. Serious attention should be given to environments that have the potential for mycotoxin-containing airborne particles. Although many reports of aflatoxin exposure have been associated with ingestion of food, evidence exists that airborne mycotoxins can also produce disease [Saad-Hussein et al. 2013; Autrup et al. 1993; Dvorackova and Pichova 1986]. Epidemiology studies also strongly suggest that aflatoxin may act as a human carcinogen in the liver [Hendry and Cole 1993]. However, during the preliminary survey, NIOSH did not test for mycotoxins in airborne dust.

Organic agents can cause disease by immune and nonimmune mechanisms. Grain dust can be a mixture of grain, soil, plant material, fungi, bacteria, agricultural chemical residues, and excreta of insects, birds, and rodents. As noted in the literature, whole kernel corn can be infected by fungal species [Bothast et al. 1974; Greene et al. 1992]. During our visit, we noted opportunities for exposure to organic materials, which can pose a risk of allergic rhinitis, asthma, inhalation fevers, or hypersensitivity pneumonitis. Inhalation fever (also known as grain fever [doPico et al. 1982] and silo unloader fever [Pratt and May 1984]) are flu-like illnesses with symptoms such as fever, chills, malaise, and muscle aches; symptoms usually occur within a few hours after exposure to organic dusts and subside within 24 to 48 hours. Inhalation fever occurs when individuals breathe in organic dust contaminated with microorganisms such as fungi or bacteria. “Bag house flu,” which was described during our site visit, may be a form of inhalation fever. It is also consistent with hypersensitivity pneumonitis due to repeated insults to the lung.

Two workers with respiratory symptoms had lung biopsies consistent with hypersensitivity pneumonitis. Hypersensitivity pneumonitis is a lung disease that can have an insidious onset, or can be associated with scarring after multiple acute illnesses. Symptoms include cough, exercise intolerance, and fatigue. Granulomas may be seen on lung biopsy. A case report from Spain documented hypersensitivity pneumonitis in a worker occupationally exposed to dust from stored corn; evidence was found that linked the lung disease to mold (*Aspergillus* spp.) exposure from contaminated corn dust [Moreno-Ancillo et al. 2004].

A possible mechanism for mold exposure could be the presence of mold in the grain dust. We obtained sampling results from weekly air sampling for mold conducted by the plant. These results showed higher than measurable airborne concentrations in some locations on some days. The company sampling results did not have reference samples (i.e., outside or designated clean area samples) for comparison. Respiratory diseases and symptoms which may result from exposure to indoor fungi include asthma, asthma exacerbation, hypersensitivity pneumonitis, cough, wheeze, shortness of breath, and respiratory infections [WHO 2009; Park and Cox-Ganser 2011].

Musty odors, visible mold growth, or water damage are indicators of potential mold contamination. Several employees reported water damage and surface mold in the plant and stated that this was painted over periodically but never removed. We did not observe or smell mold during our visit nor did we see any evidence of water intrusion or damage. We did not identify mold spores or mycelia on three tape-lift samples we collected.

Conclusions

We have reviewed multiple documents provided by the company, interviewed workers, and researched potential exposures. We planned to do a comprehensive medical survey at the facility to better characterize the health of the associates at the facility but were unable to do so secondary to closure of the plant. From what we have been able to observe, we

cannot determine whether an increased risk of health-related problems among employees existed due to working at the facility. We did find many areas of concern that warrant further investigation, including organic dust exposure, the use of flavorings, and phosphine exposure. Medical records which document shortness of breath with abnormal spirometry or lung radiographs in several employees, as well as two cases of biopsy-confirmed lung disease also support the need for further evaluation. Given the closure of the plant, such an investigation cannot be undertaken at this location, but similar pet food manufacturers may want to consider an evaluation at other facilities.

Recommendations

We make the following recommendations with the understanding that this pet food manufacturing facility has closed so that this guidance will be available to other pet food manufacturing facilities, and this facility, should it be reopened.

Elimination and Substitution

Elimination and substitution of a toxic/hazardous process material have traditionally been highly effective means for reducing hazards. However, these may not be feasible approaches in this facility, because the potential hazards are inherent to the production of pet food. If sampling confirms elevated diacetyl and 2,3-pentanedione when certain flavors are being used (such as hickory), and these chemicals are “naturally” produced, elimination of the flavoring may be considered.

Administrative Controls

Administrative controls are management-dictated work practices and policies to reduce or prevent exposures to workplace hazards. The effectiveness of administrative changes in work practices for controlling workplace hazards is dependent on management commitment and employee acceptance. Regular monitoring and reinforcement is necessary to ensure that control policies and procedures are not circumvented in the name of convenience or production.

1. Avoid the use of compressed air as much as possible during cleaning. Instead, use the central vacuum system and wet methods whenever possible.
2. Aerate and clear fumigated railcars away from building intakes and enclosed or semi-enclosed spaces.
3. Based on the bulk headspace results, we recommend full-shift and short-term personal air sampling for alpha-diketones (e.g., diacetyl and 2,3-pentanedione) of workers who use hickory flavor or any other alpha-diketone containing ingredient, whether added or derived from roasting or sweating food ingredients.
4. We understand that fumigation practices by raw material suppliers are seasonal in nature with more frequent application during the summer months. We recommend convening a health and safety committee to incorporate employee input into ways

of safely assessing the potential for airborne phosphine concentrations that may be more prevalent in the summer months. Some employees have been concerned about delays in confirmatory sampling by supervisory personnel after a real-time monitor alarm. Procedures can be developed to guide employees about appropriate responses to measurements that are confirmatory of those suggested by real-time monitors. A few suggestions for consideration of the committee are:

- a) training of additional supervisory personnel such as line managers to collect phosphine air samples using colorimetric tubes (Draeger tubes) with hand pumps when real-time phosphine monitors alarm;
 - b) storing the colorimetric tubes in or near the dry product mill control room and keeping the log in the same area where employees can view it;
 - c) considering whether personal protective equipment is prudent for confirmatory testing in response to phosphine monitor alarms since potentially hazardous concentrations may exist;
 - d) including full-shift and short-term sampling during peak fumigation season in the phosphine monitoring program; and
 - e) developing a mechanism for reporting and documenting suspected acute health symptoms from suspected phosphine exposure.
5. Ensure workers understand the potential hazards in the pet food manufacturing industry (such as phosphine, flavorings, and organic dust) and how to protect themselves. OSHA's Hazard Communication Standard, also known as the "Right to Know Law" [29 CFR 1910.1200] requires that employees are informed and trained of potential work hazards and associated safe practices, procedures, and protective measures.
 6. Workers should report new, persistent, or worsening symptoms to their personal healthcare provider and, as instructed by their employer, to a designated individual at their workplace. An individualized management plan (such as assigning an affected employee to a different work location) is sometimes required, depending upon medical findings and recommendations of the physician. Workers with symptoms should provide their personal physician or other healthcare provider with a copy of this report.

Personal Protective Equipment (PPE)

PPE is the least effective means for controlling employee exposures. Proper use of PPE requires a comprehensive program, and calls for a high level of employee involvement and commitment to be effective. The use of PPE requires the choice of appropriate equipment to reduce the hazard and the development of supporting programs such as training, change-out schedules, and medical assessment if needed. PPE should not be relied upon as the sole method for limiting employee exposures. Rather, PPE should be used until engineering and administrative controls can be demonstrated to be effective in limiting exposures to acceptable levels.

1. Continue voluntary use of N95 respirators.

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- a) Ensure N95 respirators in various sizes are readily available in each mill room and at the coating station (mezzanine level of the extruder room) for dusty tasks including but not limited to: hand-adds of ingredients into mixers in the mill rooms, which also includes the weighing step; emptying bags of ingredients into bins on the micro-ingredient deck in the pet food mill room as well as adding dry ingredients at the coating station; and cleaning (i.e., use of compressed air, sweeping powdered ingredients) and maintenance of the C&T mill room, pet food mill room, and bag house.
 - b) Ensure that each potential N95 user receives a copy of Appendix D of the OSHA Respiratory Protection Standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=9784).

A NIOSH document showing how to put on and take off a disposable respirator correctly can be obtained at <http://www.cdc.gov/niosh/docs/2010-133/pdfs/2010-133.pdf>.

Please be aware that N95s are not protective against alpha-diketones (diacetyl, 2,3-pentanedione, and 2,3-hexanedione). In cases of dual exposure to dust and alpha-diketones, NIOSH-certified organic vapor cartridges (for the alpha-diketones) and particulate cartridges/filters (for the dust) would be warranted. Further information on respirators can be obtained at http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html.

2. Provide workers who have respiratory conditions such as asthma the option of using respiratory protection with a higher protection factor, such as a powered air-purifying respirator. Before an employee is evaluated by a physician or licensed healthcare provider (LHCP), the employer should provide the physician or LHCP with:
 - a) a copy of the company's written respiratory protection program;
 - b) a copy of CFR 1910.134 Sec.(3); and
 - c) the proposed respirator type and weight, length of time and frequency required to wear the respirator, expected physical work load (light, moderate, or heavy), potential temperature and humidity extremes, and any additional protective clothing required.

After an employee in the respirator protection program is evaluated, the physician or LHCP provides the employer and employee with a written opinion regarding the employee's ability to use a respirator. The OSHA respiratory protection standard specifies that the content of the physician or LHCP's recommendation must:

- a) identify whether or not the worker is medically able to wear a respirator;
- b) list any limitations on respirator use;
- c) identify the need, if any, for follow-up medical evaluation; and
- d) make a statement acknowledging the worker's receipt of a copy of the recommendation form.

Fit testing for respirators is done after the employee is medically cleared and prior to first use and annually thereafter as well as with changes in model, size, make, or style of facepiece, or with any change in physical condition of the worker that might affect fit.

An OSHA respiratory protection program includes the following elements:

- a) written policy;
- b) change-out schedule for cartridges/filters;
- c) medical evaluation prior to use to determine fitness;
- d) fit testing and training prior to use and annually; and
- e) establishment and implementation of procedures for proper respirator use, such as prohibiting use with facial hair when this would impair the seal; ensuring user seal-check and inspection of respirators prior to each use; ensuring proper cleaning, disinfection, and maintenance of respirators; and ensuring proper storage of respirators to protect respirators from damage, contamination, dust, sunlight, and extreme temperatures.

Medical Surveillance

Given the decreased lung function seen in the medical records of several workers, and the potential for lung injury from repeated phosphine, diacetyl, grain dust, and microbial aerosol exposure as reported in the literature, medical surveillance would be appropriate, until such time as population analyses of workers demonstrate that work-related hazards are unlikely to have resulted in illness. We recommend that workers potentially exposed to grain dust, mold, and potentially toxic lung chemicals (such as phosphine and diacetyl) undergo regular lung function testing to identify disease at an early stage (excessive decline in forced expiratory volume in one second within the normal range of spirometry) and prioritize areas or tasks of concern in the facility for preventative intervention.

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Table

Table 1. Quantitative volatile organic compound results (in ppb*) from canister whole-air samples, NIOSH site visit, December 2012

Work Area/Process	Field Blank		Field Blank	Dry Product	Dry Product	Dry Product	Care & Treats	Care & Treats	Care & Treats	Undiluted LOD/LOQ† (ppb)
	Field Blank	Field Blank	Field Blank	Coating	Ingredients Warehouse	Drying	Hand add in sausage flavor bin	Hand add in chicken meal bin	Lay down tanks in packaging area	
Sample ID	897	873	887	545	875	903	536	911		
ethanol	—	—	280	66	260	170	160	2000		1.5 / 5.0
acetone	—	—	210	170	250	66	130	350		0.9 / 2.9
isopropyl alcohol	(1.1)	(1.5)	110	5.6	130	53	41	300		1.0 / 3.2
methylene chloride	—	—	—	(0.92)	—	—	—	—		0.4 / 1.5
2,3-butanedione (diacetyl)	—	—	(1.8)	—	(1.5)	—	(3.1)	—		0.9 / 3.0
hexane	—	—	67	6.1	110	5.5	6.9	3.6		0.5 / 1.6
chloroform	—	—	—	—	—	—	—	—		0.6 / 1.9
benzene	—	—	3.0	—	(1.7)	—	—	—		0.5 / 1.8
2,3-pentanedione	—	—	—	—	—	—	6.2	—		1.1 / 3.5
methyl methacrylate	—	—	—	—	—	—	—	—		2.7 / 9.0
toluene	—	—	(1.0)	14	(1.0)	(2.3)	—	—		0.6 / 2.0
2,3-hexanedione	—	—	—	—	—	—	—	—		1.0 / 3.3
ethylbenzene	—	—	—	—	—	—	—	—		0.6 / 1.9
m,p-xylene	—	—	—	(1.4)	—	(1.4)	(1.6)	—		0.6 / 1.9
o-xylene	—	—	—	—	—	—	—	—		0.6 / 2.0
alpha-pinene	—	—	(1.2)	—	(1.4)	—	—	(1.8)		0.7 / 2.3
limonene	—	—	—	—	—	—	—	—		1.3 / 4.4
Dilution factor	1	1	1.60	1.50	1.50	1.50	1.50	1.50	1.50	

*ppb = parts per billion. †LOD/LOQ = Limit of Detection/Limit of Quantification. () = value is between LOD and LOQ. Dash = not detected at the LOD. NA = not applicable.
 Notes: No recovery correction was performed. All samples collected instantaneously. Multiply undiluted LOD/LOQ for each compound by dilution factor to obtain actual limit for each sample.

Keywords: NAICS 311111 (Dog and Cat Food Manufacturing), SIC 2047 (Dog and Cat Food), respiratory, hypersensitivity pneumonitis, phosphine, flavorings, diacetyl, 2,3-pentanedione, organic dust, mold, engineering controls

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NIOSH Health Hazard Program Description

The Health Hazard Evaluation Program investigates possible health hazards in the workplace under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. § 669(a) (6)). The Health Hazard Evaluation Program also provides, upon request, technical assistance to federal, state, and local agencies to investigate occupational health hazards and to prevent occupational disease or injury. Regulations guiding the Program can be found in Title 42, Code of Federal Regulations, Part 85; Requests for Health Hazard Evaluations (42 CFR Part 85).

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Availability of Report

Copies of this report have been sent to the employer and requesters. The Missouri Department of Health & Senior Services and the Occupational Safety and Health Administration Regional Office have also received a copy. This report is not copyrighted and may be freely reproduced.

This report is available at <http://www.cdc.gov/niosh/hhe/reports/pdfs/2012-0260-3202.pdf>.

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