NIOSH HEALTH HAZARD EVALUATION REPORT

HETA # 2003-0112-2949
ConAgra Snack Foods
Marion, Ohio

December 2004

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

PREFACE

The Respiratory Disease Hazard Evaluations and Technical Assistance Program (RDHETAP) of the National Institute for Occupational Safety and Health (NIOSH) conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health (OSH) Act of 1970, 29 U.S.C. 669(a)(6), or Section 501(a)(11) of the Federal Mine Safety and Health Act of 1977, 30 U.S.C. 951(a)(11), which authorize the Secretary of Health and Human Services, following a written request from any employers or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

RDHETAP also provides, upon request, technical and consultative assistance to federal, state, and local agencies; labor; industry; and other groups or individuals to control occupational health hazards and to prevent related trauma and disease. Mention of company names or products does not constitute endorsement by NIOSH.

ACKNOWLEDGMENTS AND AVAILABILITY OF REPORT

This report was prepared by Drs. Richard Kanwal and Greg Kullman of the RDHETAP, Division of Respiratory Disease Studies (DRDS). Field assistance was provided by Chris Piacitelli, Randy Boylstein, and Thomas Jefferson. In addition, the following DRDS staff assisted in the medical survey: Diana Freeland, Jim Taylor, David Spainhour, Terry Rooney, Brian Tift, and Kathleen Fedan. Desktop publishing was performed by Terry Rooney. Review and preparation for printing were performed by Penny Arthur.

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HIGHLIGHTS OF THE NIOSH HEALTH HAZARD EVALUATION AT CONAGRA SNACK FOODS, MARION, OHIO

The National Institute for Occupational Safety and Health (NIOSH) evaluated exposures and worker health related to the production of microwave popcorn. This evaluation was requested by workers after a slurry room worker was found to have the same type of lung disease that has affected workers exposed to butter flavorings in other microwave popcorn plants.

What NIOSH Did

- We measured the air concentrations of butter flavoring chemicals at several locations within the microwave popcorn plant.
- We conducted a questionnaire survey focusing on symptoms, medical history, and work history.
- We tested workers' lung function with spirometry.

What NIOSH Found

- Air concentrations of diacetyl, a butter flavoring chemical known to cause injury to airways in animal studies, were highest in the slurry room. (Other areas in the plant had very low levels).
- The air concentrations of diacetyl in the slurry room were similar to those of other plants where mixers have developed lung disease.
- Some workers in the slurry room had abnormal lung function on NIOSH tests, indicating that some of them probably have been affected by breathing the butter flavorings.
- Abnormal lung function in some packaging area workers may mean that they were affected by flavoring chemicals from the slurry room.

What Managers Can Do

- Continue to require that any worker entering the slurry room wear a respirator at all times.
- Always keep the doors to the slurry room closed.
- Maintain appropriate ventilation to all areas of the plant at all times, and make sure the air pressure of the slurry room is less than that in the packaging area.
- Identify ways to add butter flavorings to oil such that dust or vapors from the flavorings do not contaminate the air (i.e. closed systems).
- Offer lung function tests on a regular basis to all workers that enter the slurry room and to all quality assurance workers that pop many dozens of bags of product in microwave ovens.
- Regularly measure the concentrations of butter flavoring chemicals in the air to assure that exposure controls are working.
- Train workers on the potential health risks from exposures to flavorings and on the best ways to minimize exposures.

What Employees Can Do

For all workers that enter the slurry room:

- Know how to properly wear and maintain your respirator.
- Wear your respirator 100 percent of the time when in the slurry room.
- Keep all containers of flavorings tightly closed when not in use.
- Understand and use all the exposure control devices and work practices that decrease the amount of flavorings in the air.

For quality assurance lab workers and all workers that enter the slurry room:

- Participate in spirometry tests offered by your employer.
- Promptly report any persistent shortness of breath or cough, or any problems with your eyes, nose, throat, or skin to your supervisor and your doctor and show them a copy of this page.

What To Do For More Information:

We encourage you to read the full report. If you would like a copy, either ask your health and safety representative to make you a copy or call 1-513-841-4252 and ask for HETA Report # 2003-0112-2949

Health Hazard Evaluation Report 2003-0112-2949
ConAgra Snack Foods
Marion, Ohio
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SUMMARY

NIOSH has identified evidence of fixed obstructive lung disease consistent with bronchiolitis obliterans in workers exposed to airborne butter flavoring chemicals at several microwave popcorn plants. In 2002, NIOSH learned that a worker who had mixed oil and butter flavorings for microwave popcorn production at the ConAgra Snack Foods plant in Marion, Ohio, had been diagnosed with severe fixed obstructive lung disease consistent with bronchiolitis obliterans. During an initial visit to the plant in January 2003, NIOSH identified production processes and work practices similar to those of other microwave popcorn plants. Specifically, workers handled many different butter flavorings in open containers and poured the flavorings into open tanks of heated soybean oil. The tanks did not have local exhaust ventilation and the workers did not use respiratory protection. Oil and flavoring mixing activities and all heated tanks were located in one room (slurry room) adjacent to the packaging line area, and the air pressure in this room was positive relative to the packaging line area. NIOSH proceeded to conduct a detailed health and environmental survey at this plant from March 3 to March 10, 2003, in order to characterize exposures and lung function in mixers and other workers. The main findings from this survey included:

- The mean time weighted average diacetyl air concentration in the slurry room was 1.14 parts per million parts air (ppm). This air concentration is similar to those measured by NIOSH at two other microwave popcorn plants where mixers also developed fixed obstructive lung disease.
- Three of 12 current slurry room workers were found to have airways obstruction on NIOSH spirometry tests. Two did not respond to bronchodilators, while one did respond but the forced expiratory volume in the first second of exhalation (FEV1) remained below normal. All three had normal diffusing capacity. These findings are consistent with bronchiolitis obliterans.
- After adjustments to the slurry room ventilation by ConAgra, the slurry room was found to have negative air pressure relative to the packaging area.
- The mean time weighted average diacetyl air concentration in the packaging area was 0.02 ppm.
- Five workers in the packaging area had fixed obstruction on spirometry, normal diffusing capacity, and no history of work in the slurry room. All were smokers but were relatively young (average age 36), making smoking a less likely explanation for their obstruction. If packaging area air concentrations of flavoring chemicals were higher in the past when the slurry room was under positive pressure, it is possible that some packaging area workers developed airways obstruction as a result.
- Two of 11 current quality assurance (QA) lab workers were found to have abnormal spirometry. One had obstruction that was unresponsive to bronchodilator and had a normal diffusing capacity. Another had restriction. Prior to the installation of an enclosure with exhaust ventilation for the microwave ovens, the average diacetyl air concentration in the QA lab at the ConAgra plant was 0.018 ppm, compared to 0.56 ppm in the QA lab at another plant where five of six QA workers were found to have airways obstruction.

At the ConAgra plant and other microwave popcorn plants, the pattern of lung function test abnormalities in workers who regularly mix butter flavorings with heated soybean oil implies a risk for the development of fixed airways obstruction from inhalation of flavoring-related chemicals. Nearby packaging workers may also be at risk if flavoring chemicals or dust in the air of the slurry room contaminate the air in the packaging area. Recommendations for engineering controls, use of personal protective equipment, and medical surveillance for exposed workers are provided in this report.

Keywords: SIC 2099 (food preparations, not elsewhere classified); bronchiolitis obliterans, diacetyl, fixed obstructive airways disease, chronic obstructive pulmonary disease, butter flavoring, microwave popcorn, popcorn, flavorings.

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INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) has evaluated the risk for occupational lung disease from inhalation exposure to butter flavoring chemicals at several microwave popcorn plants. In December 2002, NIOSH received a request from current workers at the ConAgra Snack Foods plant in Marion, Ohio, to conduct a health hazard evaluation after a flavoring-exposed worker was diagnosed with lung disease.

BACKGROUND

In August 2000, NIOSH learned that eight former workers of a microwave popcorn production plant in Missouri had moderate to severe fixed obstructive lung disease consistent with the rare illness, bronchiolitis obliterans. A NIOSH investigation at this plant revealed an excess of current workers with obstruction on spirometry testing. Increasing cumulative exposure to diacetyl, the predominant butter flavoring chemical present in the air of the plant, was associated with an increased prevalence of abnormal lung function.[1] In animal exposure experiments conducted by NIOSH, rats exposed to vapors from a butter flavoring used at this plant developed severe injury to their airway epithelium.[2]

In bronchiolitis obliterans, inflammation and scarring occurs in the small airways of the lung and can lead to severe, permanent shortness of breath.[3] The main respiratory symptoms are cough and shortness of breath on exertion that typically do not improve much when the worker goes home at the end of the workday or on weekends or vacations. Usually symptoms are gradual in onset and progressive, but severe symptoms can occur suddenly. Most cases do not respond to medical treatment. Lung function testing with spirometry generally reveals fixed airways obstruction, and some workers develop obstruction before they become symptomatic. Because medical treatment does not reverse the condition, some workers with severe disease have been placed on lung transplant waiting lists.[4]

In addition to lung disease, workers exposed to butter flavoring vapors may develop problems with their eyes and skin. Eye irritation is common, and occasionally workers report chemical burns of the eyes requiring medical treatment. Similarly, exposed workers may report skin irritation, and one worker at another plant developed a disabling skin allergy to butter flavorings.[4]

Prior to the request for a health hazard evaluation by ConAgra workers, NIOSH had performed medical and environmental evaluations at five microwave popcorn plants. In three of these plants, workers who performed mixing of soybean oil with butter flavorings, salt, and colorings, had fixed obstruction, normal diffusing capacity for carbon monoxide (DLCO), and findings on high resolution computerized tomography (HRCT) scans of the chest that were consistent with constrictive bronchiolitis obliterans.[1,5,6] In two plants, workers on packaging lines near non-isolated tanks of heated oil and flavorings had higher than expected prevalences of obstruction on spirometry tests.[1,7] In one plant, five of six workers who performed repeated microwave popping of product for quality control had obstruction.[1] (Approximately 100 bags were popped per worker per work shift.)

In 2002, NIOSH learned that a worker who had mixed oil and butter flavorings for microwave popcorn production at the ConAgra Snack Foods plant in Marion, Ohio, had been diagnosed with severe fixed obstructive lung disease consistent with bronchiolitis obliterans. This worker was approximately 40 years of age and had not smoked for many years. The worker reported the onset of progressive shortness of breath on exertion approximately one year after beginning work at the plant. Several months later, the worker's condition worsened acutely. DLCO testing was normal and an HRCT scan of the chest revealed mosaic attenuation on the expiratory view, consistent with bronchiolitis obliterans.

After receiving the request for a health hazard evaluation, NIOSH visited the plant in January 2003 to conduct a walkthrough survey. The walkthrough revealed production processes and

work practices similar to those of other microwave popcorn plants. There were several large (e.g., 500-gallon) tanks containing heated oil, butter flavorings, salt, and colorings in the mixing (slurry) room. Mixers handled liquid, paste, and powdered butter flavorings in open containers and poured them into open tanks of heated soybean oil without using respiratory protection. The pouring of powdered butter flavorings generated significant amounts of airborne dust. The lids on many tanks did not seal tightly and no tanks had local exhaust ventilation. A large garage-type door separated the slurry room from an adjacent large area where the microwave popcorn packaging lines were located. The lower part of this door did not seal tightly with its frame, leaving an opening to the packaging area, and testing with smoke tubes showed the slurry room to be under positive air pressure relative to the packaging area (i.e., air moved out of the slurry room and into the packaging area). There were no tanks of heated oil and flavorings in the packaging area. The mixture of oil, flavorings, colorings, and salt was piped from the tanks in the slurry room to machines on the packaging lines where the mixture was combined with kernel popcorn and sealed in microwaveable bags. QA workers performed repeated microwave popping of product in a separate QA lab (up to 130 bags per worker per 12-hour work shift). Other areas of the plant included offices, a warehouse, and the press area (assembly of and printing on microwave popcorn bags). All areas of the plant were ventilated by rooftop heating, ventilation, and air conditioning (HVAC) units. Based on these observations, NIOSH provided initial recommendations to decrease potential exposures in the slurry room, packaging area, and QA lab (Appendix A – NIOSH interim report dated January 28, 2003).

NIOSH proceeded to conduct a detailed health and environmental survey at this plant from March 3 to March 10, 2003, in order to characterize exposures and lung function in mixers and other workers.

METHODS

Medical Evaluation

All current workers were invited to participate. After obtaining signed, informed consent from participants, NIOSH interviewers administered a standardized questionnaire to collect information on symptoms, medical diagnoses, smoking history, work history, and work-related exposures. This questionnaire (Appendix B) included questions from the American Thoracic Society (ATS) standardized respiratory symptom questionnaire[8] and the 3rd National Health and Nutrition Examination Survey (NHANES III),[9] supplemented with questions about respiratory, mucous-membrane, and constitutional symptoms, and work history.

NIOSH technicians performed spirometry tests using a dry rolling seal spirometer interfaced to a personal computer and following American Thoracic Society guidelines,[10] with results compared to spirometry reference values generated from the Third National Health and Nutrition Examination Survey (NHANES III).[11] The largest forced vital capacity (FVC) and forced expiratory volume in the first second of exhalation (FEV1) were selected for analysis. Obstruction was defined as an FEV1/FVC ratio and FEV1 below the lower limits of normal. Restriction was defined as an FVC below the lower limit of normal with a normal FEV1/FVC ratio. A mixed pattern (obstruction and restriction) was defined as an FEV1/FVC ratio, FEV1, and FVC below the lower limits of normal. Workers with evidence of airways obstruction or a mixed pattern were administered albuterol, a bronchodilator medication used to treat obstructive lung diseases such as asthma, and were then re-tested to see if the obstruction was reversible. Reversible obstruction was defined as an improvement in the FEV1 of at least 12% and at least 200 milliliters after administration of albuterol. Participants with abnormal spirometry results (airways obstruction, restriction, or a mixed pattern) underwent measurement of carbon monoxide diffusing capacity of the lung (DLCO) to identify evidence of lung disease apart from the airways

as might be seen in individuals with emphysema. NIOSH technicians followed ATS guidelines[12] for performing DLCO, with an abnormal DLCO defined as below the lower limit of normal compared to reference values.[13] NIOSH mailed each participant his/her test results on April 8, 2003. Participants with abnormal test results were counseled to obtain additional medical evaluation.

The observed number of workers with respiratory symptoms, self-report of physician diagnosed respiratory disease, and abnormal spirometry, were compared to the number expected based on national data from NHANES III.[9] The resulting prevalence ratios were controlled for gender, age group (17 to 39 years of age versus 40 to 69 years of age), race-ethnicity (Caucasian, African-American, or Mexican-American), and cigarette smoking status (ever versus never). Ninety-five percent confidence intervals for the prevalence ratios were calculated using the method described by Kahn and Sempos.[14]

Epi Info™ was used to calculate odds ratios and 95 percent confidence intervals for abnormal spirometry results in workers who had worked as mixers for at least 1.5 years compared to other workers.

Industrial Hygiene Evaluation

A preliminary plant site visit was made in January 2003 to review production processes and worker exposures to aid the design of an industrial hygiene sampling plan. A cross-sectional industrial hygiene survey was conducted from March 3 to 6, 2003. Four day and two night production shifts were sampled for air contaminants during the production of microwave popcorn. Full-shift, personal and area samples were taken. Personal breathing zone samples were collected for several butter-flavoring-related ketone compounds including diacetyl, acetoin, and 2-nonanone. Area samples were collected for these three ketones plus total dust, respirable dust, particle size distributions, acetic acid, butyric acid, acetaldehyde, and total volatile organic compounds. Samples were collected from various plant areas including the press area, warehouse, maintenance, office areas, slurry room, QA lab, and packaging area. Samples were also collected outside to assess surrounding ambient contributions to worker exposures. These samples were time-weighted over an 8 to 10-hour sampling period for each shift (except for the volatile organic compound which required shorter sample times - approximately 6 hours or less to prevent overloading). Sampling pumps were pre- and post-calibrated with each use, and field and media blank samples were taken for quality control purposes.

Diacetyl, acetoin, and 2-nonanone were collected on Anasorb® carbon molecular sieve tubes at a flow rate of 0.150 liters per minute (lpm). These samples were analyzed by gas chromatography (GC) according to NIOSH Manual of Analytical Methods (NMAM)[15] 2557 and 2558. Semi-quantitative air samples for **volatile organic compounds** were collected on thermal desorption tubes at a flow rate of 0.02 lpm and were analyzed by gas chromatography with a mass selective detector according to NIOSH Method 2549.[15] **Total hydrocarbons** were collected on coconut shell charcoal (CSC) tubes at a flow rate of 0.05 lpm and analyzed by GC according to NIOSH Method 1550.[15] The total hydrocarbons concentrations in this report include the sum of all gas chromatographic peaks in the spectrum minus diacetyl, acetoin, and 2-nonanone. **Butyric and acetic acid** were collected on silica gel sorbent tubes at a flow rate of 0.3 lpm and analyzed by high pressure liquid chromatography (HPLC) according to NIOSH Method 7903.[15] **Acetaldehyde** was collected on solid sorbent tubes (XAD-2) at a flow rate of 0.03 lpm and analyzed by GC according to NIOSH Method 2538.[15]

Total dust samples were collected at a flow rate of 3.0 lpm on closed-face filter cassettes using 37-mm poly vinyl chloride (PVC) filters with a pore size of 5 micrometers (µm). **Respirable dust** samples were collected at 4.2 lpm on similar filters with BGI Respirable / Thoracic Cyclones™ (BGI Inc., Waltham, MA). The cyclone has a median cut point for particles 4 micrometer (µm) in aerodynamic diameter. The filters were analyzed gravimetrically according to NIOSH Methods 0500 and 0600, respectively.[15] (NIOSH provided air sampling results for the

ketones diacetyl, acetoin, and 2-nonanone, total dust, and respirable dust in an interim report dated October 2, 2003.) **Particle size distributions** were collected using a 9 stage cascade impactor operated at a flow rate of 2.0 lpm. The PVC filter samples were analyzed gravimetrically according to NIOSH Method 0500. [15]

Grimm optical particle counters (OPC) (Grimm Technologies, Inc., Douglasville, GA) were used to measure real-time airborne particle concentrations. The Grimm OPC measurements were collected over eight to ten hour periods at selected area sampling locations.

A Gasmet DX-4010™ Fourier Transform Infrared (FTIR) Gas Analyzer (Temet Instruments Oy, Helsinki, Finland) was used to measure peak concentrations of diacetyl in the slurry room during mixing operations. The instrument was operated in the center of the room to measure general area diacetyl concentrations throughout the work shift.

RESULTS

Except where noted, the following results were provided to ConAgra Snack Foods and the HHE requestors in the October 2003 interim report.

Medical Survey

Sixty-five percent of the workforce participated in the medical survey. Participation by work area is shown in Table 1, along with the mean age, percentage of males, and percentage of current or former smokers among participants. Participation in five work areas (press, slurry room, packaging area, QA lab, and maintenance) was good, ranging from 70 to 100 percent. Participation of office and warehouse workers was low (34% and 27% respectively), limiting their use as a minimally or un-exposed group (i.e., internal control) to which the prevalences of symptoms, self-reported diagnoses, and spirometry abnormalities in microwave popcorn production workers could be compared. Potential exposures to printing-related chemicals in the press area, which could lead to symptoms and/or health effects, limited the use of press area workers as an internal control group. Twenty four of 26 participating mechanics reported spending time in the slurry room every week (mean 2 hours; range 0.5 to 10 hours), which limited their use as an internal control group.

Table 2 lists the numbers and percentages of workers with symptoms by work area. The responses of four mechanics who work mostly in the press area are included with those of the press workers. All other mechanics are included in the "other" category along with the participants from the office and warehouse. Compared to workers in other plant areas, slurry room and QA lab workers had the highest percentages of workers reporting of shortness of breath on exertion (33% of mixers and 36% of QA workers participating in the survey), wheezing or whistling in chest without a cold (50% of mixers, 36% of QA workers), unusual fatigue (33% of mixers, 36% of QA workers), and nose bleeds (25% of mixers, 18% of QA workers). Nasal irritation was reported by a high percentage of all workers, especially in production (highest in mixers at 83%). Eye irritation was reported frequently by workers in all work areas (28% to 45% of workers). Skin problems were most frequently reported by workers in the press area (34% of workers).

Table 3 lists the numbers and percentages of workers with abnormal lung function on NIOSH tests and that reported that they had a respiratory diagnosis confirmed by a physician. The responses and test results of four mechanics that work mostly in the press area are included with those of the press workers. All other mechanics are included in the "other" category along with the participants from the office and warehouse. Twenty-nine of the 205 survey participants (14%) had abnormal spirometry. Only four of 19 with obstruction or a mixed pattern had a response to bronchodilator documenting reversibility. The slurry room had the highest percentage of workers with abnormal spirometry (33% of workers tested), including the highest percentage with obstruction or a mixed pattern (25%). Bronchitis while working at the plant was reported most frequently by slurry room and QA workers (33% of mixers, 36% of QA workers). Asthma was reported most frequently

and by similar percentages of packaging, slurry room, and QA workers (16% to 18% of workers).

Tables 4, 5 and 6 show the numbers of ConAgra packaging area, slurry room and QA lab, and press area workers reporting respiratory symptoms and diagnoses and having abnormal results on NIOSH spirometry tests, compared to the numbers that would be expected based on national data from NHANES III (after adjusting for age, race, sex, and smoking history). The ratio of the observed number to the expected number (prevalence ratio) gives an indication of how similar or different the observed number is to the expected number. The closer the ratio is to "1", the less unusual is the observed number. If the 95 percent confidence interval indicated includes "1", then the difference between the observed and the expected number is not statistically significant (i.e., the probability that the difference is due to chance is greater than five percent). Slurry room and QA lab workers were combined into one group due to the small numbers of workers in each group, and because of the known occurrence of increased risk in both these groups in other microwave popcorn plants. Shortness of breath on exertion was reported 1.6 times more often than expected by slurry room/QA workers but this excess was not statistically significant. Wheezing apart from colds was reported 2.1 times more often than expected by packaging area workers (statistically significant), 3.0 times more often than expected by slurry room/QA workers (statistically significant), and 1.9 times more often than expected by press area workers (borderline statistically significant). Chronic bronchitis was reported 3.3 times more often than expected by press area workers (statistically significant). Asthma was reported approximately twice as often as expected in packaging area and slurry/QA workers (statistically significant excess for packaging area workers). Obstruction or a mixed pattern on NIOSH spirometry tests was found 1.6 times as often as expected in packaging area workers (not statistically significant), 2.5 times as often as expected in slurry/QA workers (borderline statistically significant), and 1.8 times as often as expected in press area workers (not statistically significant).

The prevalence ratios in Tables 4, 5, and 6 are slightly different from the ones listed in the interim report of October 1, 2003 (Appendix C). The earlier ratios were based on expected numbers that were only adjusted for age and smoking status, whereas the ratios in this final report are based on expected numbers that are adjusted for age, race, sex, and smoking status. The only ratio that is substantially different from the ones previously reported is the one for chronic bronchitis in press area workers.

A total of 39 participants reported current or past experience working as mixers in the slurry room. Twelve of 39 reported currently working in the slurry room (nine as mixers and three as assistant supervisors) and eight reported that they were former mixers. Nineteen reported having worked as mixers (even for as little as one day) while assigned to other jobs. Seven of 39 (19%) had an abnormal spirometry test (four with obstruction or a mixed pattern, three with restriction). (In the October 2003 interim report, nine of 39 workers with mixing experience were reported to have abnormal spirometry. This number included two workers with borderline obstruction, defined as an FEV1/FVC ratio below normal with a normal FEV1.) Nine of the 20 with a current or former job title of mixer reported working in the slurry room for 1.5 or more years. Four of these nine had an abnormal spirometry test (three with obstruction or a mixed pattern, one with restriction). (The October 2003 interim report stated "Six of these nine…" because the two borderline obstruction results were included.) Taking into account all survey participants, a worker with an abnormal spirometry test was 5.5 times more likely to have worked with a job title of mixer for 1.5 years or more as opposed to having worked less time or no time as a mixer (95% confidence limits: 1, 27). (The October 2003 interim report stated "6.7 times more likely…" because of the inclusion of the borderline obstruction results.) Workers with only obstruction or a mixed pattern were 5.6 times more likely to have worked with a job title of mixer for 1.5 years or more as opposed to having worked less time or no time as a mixer (95% confidence limits: 0.8, 29). Neither of these comparisons was statistically significant (i.e., the probability that the outcome is due to chance is at least 5 % as

the 95% confidence limits include 1). (In the October 2003 interim report, these comparisons were reported as statistically significant in error. However, the fact that the number of workers that had worked as mixers for 1.5 or more years was small decreases the likelihood of finding statistical significance.)

Industrial Hygiene Survey

The predominant **volatile organic compounds** identified in plant air are presented in Table 7 by sampling location. Diacetyl and limonene were identified as predominant compounds in the GCMS spectra from most plant areas. In addition to diacetyl and limonene, the predominant compounds in the slurry room included acetoin, propylene glycol, acetoin oligomers, ethanol, hexane, and tetrahydrofuran. The QA area had the most abundant spectra of organic compounds including both diacetyl and acetoin. The press room area and office area had the least abundant spectra of predominant organic compounds in air; diacetyl was a predominant compound in the press area but was not detected among the predominant compounds in the office area.

Diacetyl concentrations ranged from below detectable levels (approximately 0.004 parts per million parts air by volume – ppm) to a high of 2.7 ppm (Table 8). The mean diacetyl concentration from the 123 personal and area measurements was 0.15 ppm with a standard deviation (STD) of 0.41. The mean diacetyl concentration from the 48 area samples (0.17 ppm) was similar to the mean concentration from the 75 personal exposure measurements (0.14 ppm). The mean **acetoin** concentration was slightly lower than diacetyl at 0.11 ppm from the 123 personal and area samples. Acetoin concentrations ranged from below detectable limits (approximately 0.004 ppm) to a high of 2.8 ppm. Diacetyl and acetoin concentrations below detectable levels (LOD) were assigned a value of 0.002 ppm (i.e., LOD/2) and those samples below quantifiable levels (LOQ) were assigned a value of 0.005 ppm (i.e., LOQ/2) to calculate mean concentrations.

Figure 1 and Tables 9 and 10 present diacetyl and acetoin air concentrations by job location for both personal and area samples. The slurry room/mixers had the highest mean ketone concentrations, 1.14 ppm for diacetyl and 0.90 ppm for acetoin (personal and area samples combined). The mean diacetyl concentration from the 7 personal samples from the slurry room was 1.03 ppm; the mean area concentration from the slurry room (6 samples) was 1.26 ppm. Supervisors had the next highest diacetyl concentration with a mean of 0.15 ppm; this included area and personal measurements from all supervisor categories including the slurry room supervisor. The mean of the 11 personal diacetyl exposure measurements collected from the supervisor category were 0.17 ppm, which was higher that the mean of the area samples collected from the supervisor's office (0.01 ppm). The packaging area had mean diacetyl concentrations by job location ranging from 0.02 ppm (case packer) to 0.03 ppm (palletizer). This included several job categories: phaser, case packer, cartoner, and palletizer. The mean acetoin concentration in these production job categories was approximately 0.01 ppm. The QA lab had a mean diacetyl concentration of 0.03 ppm for personal samples and 0.01 ppm for area samples. The mean acetoin concentration for the QA lab was 0.03 ppm from the personal samples and 0.01 from the area samples. The mean diacetyl concentration from the warehouse area was 0.03 ppm for personal and area samples combined; the acetoin concentration was 0.004 ppm. The press area and office locations had mean diacetyl concentrations below 0.03 ppm and mean acetoin concentrations below 0.01 ppm. The ambient sample collected upwind from the plant was below detectable levels for diacetyl and acetoin (less than approximately 0.004 ppm). Currently there are no Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), and NIOSH Recommended Exposure Limits (RELs) for diacetyl, acetoin or 2-nonanone.

Figure 2 provides an assessment of real-time concentrations for diacetyl, acetoin, and nonanone in the slurry room. These sampling results were obtained using the FTIR on two separate days, March 3rd and 4th, 2004.

Additionally, these sampling results were collected from general room air and would not reflect potential peak exposures to mixers from activities such as opening tank lids or manual handling of butter flavorings. The average diacetyl and acetoin concentrations measured using the FTIR were comparable to those obtained using the NIOSH Manual of Analytical Methods (NMAM 2557 and 2558). The mean diacetyl concentration measured in the slurry room on March 3rd was 2.32 ppm (the comparable diacetyl concentration measured by NMAM was 2.68 ppm). On March 4th, the average diacetyl concentration measured using the FTIR was 1.86 compared to the NMAM diacetyl concentration measure of 1.12 ppm. The peak diacetyl concentration in the slurry room on March 3rd was 16.1 ppm, approximately 7 times the average concentration. The peak diacetyl concentration on March 4th was 5.3 ppm, approximately 3 times the average concentration on this day. Nonanone concentrations were much lower, with mean concentrations below 0.1 on both days.

Figure 3 presents area diacetyl concentrations collected in side-by-side sampling in the slurry room using two different sampling flow rates, 0.15 lpm (used by NIOSH) and 0.02 lpm (used by ConAgra consultants). This sampling was done at the request of plant management to assess the impact of sampling flow rate on diacetyl concentrations. The diacetyl concentrations collected at the higher flow rate (3 samples) had a mean concentration of 0.71 ppm and the samples collected at the lower flow rate (3 samples) had a mean diacetyl concentration of 0.43 ppm. A flow rate of 0.15 lpm (consistent with NMAM 2557 method for diacetyl), was chosen to quantify diacetyl at lower airborne concentrations.

Total hydrocarbon concentrations in air (excluding diacetyl, acetoin, and nonanone) ranged from below detectable limits to a high of 5.53 milligrams per cubic meter of air (mg/m^3) as seen in Table 11. (These data provide a perspective on the contributions of hydrocarbons other than the three ketones, diacetyl, acetoin, and 2-nonanone, since these three compounds were excluded from this analysis.) The mean concentration from the 48 area samples was 1.25 mg/m^3 with a standard deviation of 0.92. Twenty-seven of the hydrocarbon samples were below quantifiable limits (LOQ - approximately 1.60 mg/m^3) and assigned a value of 0.8 mg/m^3 to calculate mean concentrations (LOQ/2). Four of the 48 samples were below detectable limits (LOD - approximately 0.44 mg/m^3) and assigned a value of 0.22 mg/m^3 to calculate mean concentrations (LOD/2). Table 11 presents hydrocarbon concentrations by sampling location. The phaser operator area had the highest hydrocarbon concentration, 2.06 mg/m^3 (excluding diacetyl, acetoin, and 2-nonanone). The slurry room, supervisor, press operator, case packer, and QA all had a mean hydrocarbon concentrations between 1 mg/m^3 and 2 mg/m^3. Currently there are no Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) and NIOSH Recommended Exposure Limits (RELs) for total hydrocarbon concentrations.

Acetaldehyde concentrations ranged from below detectable limits to a high of 0.17 ppm (Table 12). The 48 area acetaldehyde samples had a mean of 0.05 ppm with a standard deviation of 0.05. Twenty-one of the acetaldehyde samples were below quantifiable limits (approximately 0.036 ppm) and assigned a value of 0.018 ppm (LOQ/2) to calculate mean concentrations. Six of the 48 samples were below detectable limits (approximately 0.014 ppm) and assigned a value of 0.007 ppm to calculate mean concentrations. Table 12 presents acetaldehyde concentrations by sampling location. The maintenance, press room and QA areas had the highest acetaldehyde concentrations with a means ranging from 0.12 ppm to 0.15 ppm. The highest concentration in the slurry room was 0.05 ppm. Acetaldehyde mean concentrations in the production areas were all below 0.05 ppm, and concentrations in the office areas were all below quantifiable levels. These levels are all below the OSHA PEL for acetaldehyde, 200 ppm as an eight-hour TWA. The ACGIH TLV for acetaldehyde is 25 ppm as a ceiling concentration (C) not to be exceeded. NIOSH considers acetaldehyde to be a potential occupational carcinogen and

recommends that exposures be reduced to the lowest feasible concentration.

Most of the **acetic and butyric acid** samples were below quantifiable levels. Only 12 of the acetic acid samples had quantifiable concentrations (greater than 0.004 ppm). The highest concentrations were in the mixing room where the highest acetic acid concentration was 3.31 ppm Acetic acid was also detected at quantifiable levels in other plant areas (the QA area, packaging lines, warehouse, office, maintenance area) but concentrations in these areas were below 0.15 ppm. Only 3 of the 48 butyric acid samples had detectable concentrations and these were all from the slurry room. The highest butyric acid concentration was 0.16 ppm. These levels are all below the OSHA PEL, ACGIH TLV, and NIOSH REL for acetic acid, all 10 ppm as an eight-hour TWA. ACGIH and NIOSH also provide a short term exposure limit (STEL) recommendation of 15 ppm. Currently, there is no OSHA PEL, ACGIH TLV or NIOSH REL for butyric acid.

The **total dust** concentrations ranged from below detectable levels (approximately 0.014 milligrams per cubic meter of air – mg/m^3) to a high of 1.74 mg/m^3, as presented in Table 13. The mean total dust concentration from the 49 area samples was 0.24 mg/m^3. **Respirable dust** concentrations ranged from below detectable levels (approximately 0.01 mg/m^3) to a high of 0.65 mg/m^3. The mean respirable dust concentration was 0.09 mg/m^3. Total dust samples below the limit of detection (LOD) were assigned a value of 0.007 mg/m^3 (i.e., LOD / 2) to calculate mean concentrations; respirable dust samples below the LOD were assigned a value of 0.005 mg/m^3

The slurry room had the highest mean total and respirable dust concentrations, 1.1 and 0.49 mg/m^3 respectively (Figure 4). The packaging area had mean total dust concentrations ranging from 0.11 mg/m^3 (cartoner and palletizer) to 0.16 mg/m^3 (phaser). Mean respirable dust concentrations by location in the packaging area ranged from 0.03 to 0.05 mg/m^3. The QA lab had a mean total dust concentration of 0.07 mg/m^3 and a mean respirable dust concentration of 0.03 mg/m^3. The office had the lowest total and respirable dust concentrations, 0.02 mg/m^3 and 0.009 mg/m^3 respectively. These levels are below the Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) for particulates not otherwise regulated (PNOR) of 15 mg/m^3 as an eight-hour TWA (5 mg/m^3 for respirable dust) and the American Conference of Governmental Industrial Hygienists (ACGIH®) threshold limit value (TLV®) for particulates not otherwise specified (PNOS) of 10 mg/m^3 for inhalable particulates as an eight-hour TWA (3 mg/m^3 for respirable particulate).

Particle size distribution data from the four cascade impactor samples taken in the slurry room indicated that approximately 76 percent of the airborne mass was less than 10 micrometers (µm) in aerodynamic diameter and in the respirable size fraction. (The cascade impactor samples taken from other plant areas had insufficient mass to assess particle size distributions). Approximately 39 percent of the mass from these four slurry room samples was below 3.5 µm in aerodynamic diameter. Figures 5 through 7 present particle count data obtained using the GRIMM Optical Particle Counter in the slurry room, QA lab, and in packaging. These figures show real-time particle count data in particles per cubic centimeter (Particles/cc) by five particle size categories: 0.3 to 0.5 µm, 0.5 to 1.0 µm, 1.0 to 5.0 µm, 5.0 to 10.0 µm, and greater than 10 µm. The samples collected from the slurry room had the highest particle count concentrations in all 5 size categories; these samples also had greater fluctuations in concentration throughout the workshift than the samples collected in the QA area or the production (palletizing area).

DISCUSSION

Nature of the Disease

Bronchiolitis obliterans is a rare lung disease characterized by inflammation and scarring of the small airways of the lung, which can lead to severe, permanent shortness of breath. The constrictive form of bronchiolitis obliterans can occur after inhalation of nitrogen dioxide, silo gases, ammonia, chlorine, hydrogen fluoride,

ozone, phosgene, fly ash, and sulfur dioxide.[3] In occupational settings, an incident of overexposure often results in severe initial symptoms of pulmonary edema, followed by apparent recovery. Persistent shortness of breath occurs weeks later due to bronchiolitis obliterans. Apart from work-related exposures, most bronchiolitis obliterans cases are due to bone marrow or lung transplants. When bronchiolitis obliterans develops insidiously, as in the case of post-transplant patients, there are often no respiratory symptoms during the early stages of disease, even though lung function tests may be abnormal.[16] As lung function continues to decline, respiratory symptoms eventually develop. Several workers that have developed bronchiolitis obliterans in the setting of butter flavoring exposure during microwave popcorn production,[4] and during the manufacture of flavorings,[17,18] have experienced a slow onset of symptoms similar to post-transplant patients.

In affected individuals, lung function testing with spirometry typically shows obstruction (low FEV1/FVC ratio and FEV1) that does not improve with use of an inhaled bronchodilator. In moderate to severe disease, increased residual volume may occur. The chest x-ray is usually normal, but high resolution lung computerized tomography with inspiratory and expiratory views may show mosaic attenuation on the expiratory view. The diagnosis of bronchiolitis obliterans is likely when the clinical history includes one of the known causes, the more common lung diseases are ruled out, and the above spirometry and radiology findings are present. The diagnosis can be confirmed by identifying bronchiolitis in an open (or thoracoscopic) lung biopsy specimen. However, the pathologic process in the lung is patchy in distribution, and it is only with great care, special stains, and the examination of many biopsy sections that the typical lesion can be identified. Because the process of obtaining the tissue is invasive and the yield is not certain, affected individuals and their physicians should discuss in detail whether or not a lung biopsy for a tissue diagnosis is warranted.

Exposures to Flavoring-Related Chemicals

Flavorings are often complex mixtures of ingredients, many of which can be irritating to the skin, eyes, and respiratory system.[19] The effects of these ingredients may be additive, such that exposures to concentrations of compounds that would not cause harm as a sole exposure may be harmful if combined with exposures to other compounds. NIOSH measured the air levels of diacetyl and acetoin, two common ingredients in butter flavoring, as indicators of exposure to butter flavoring vapors. Animal experiments at NIOSH indicate that diacetyl is one of the chemicals in butter flavoring that can lead to airway injury.[20] The other chemical components that may contribute to toxicity, and the levels of exposure that are considered safe, are still not known. Recommended air exposure limits have not been established for most chemicals used in flavorings.[19] Also unknown is the relative safety of powdered flavorings compared to liquids or pastes. Powders that are formulated (i.e., encapsulated) to have lower emissions of volatile flavoring chemicals may pose lower risk. However, inhalation of powder of respirable size during the handling of these flavorings may increase worker risk for lung problems (due to deposition and local release of flavoring chemicals on contact with water in the airways). The particulates measured in the slurry room had a substantial respirable dust fraction (approximately 76%); these respirable dusts would be capable of penetrating to the distal regions of the lung where bronchiolitis obliterans occurs.

Patterns of Lung Function Test Abnormalities in Different Illnesses

Evaluation of lung function with spirometry can reveal several patterns of abnormal lung function. With obstruction, the movement of air out of the lungs is slowed because airways are narrowed or blocked. Obstruction occurs with diseases such as asthma, emphysema, or bronchiolitis obliterans. Obstruction due to asthma can be reversed by the administration of a bronchodilator medication. With emphysema due to smoking, the obstruction is usually fixed (i.e., no significant response to bronchodilator

medication). A diffusing capacity test for carbon monoxide (DLCO) is usually abnormally low with emphysema because there is associated damage to the lungs apart from the airways. With bronchiolitis obliterans, the obstruction is fixed and the DLCO is usually normal because the lung tissue apart from the airways is not affected. Restriction is manifested on spirometry by a decreased FVC, meaning that a lower than normal amount of air is exhaled after a maximal inhalation. Restriction results when a disease process causes scarring of lung tissue so that it is no longer fully able to expand. The scarring of lung tissue results in a low DLCO. Table 14 summarizes the test findings in obstructive and restrictive lung diseases.

Exposures and Worker Health at ConAgra Snack Foods, Marion, Ohio

Slurry room: Three of 12 current slurry room workers (mixers and supervisors) were found to have obstruction on NIOSH spirometry. Two did not respond to bronchodilators, while one did respond but the FEV1 remained below normal. All three had normal diffusing capacity. These findings are consistent with bronchiolitis obliterans, and when considered along with similar findings in former mixers in this plant and others, strongly suggest that exposures to flavoring chemicals in the slurry room pose a risk for the development of occupational lung disease. It is likely that some slurry room workers have been affected by this exposure. In two other plants with affected mixers evaluated by NIOSH, diacetyl air concentrations in the oil and flavoring mixing room/area were similar to those in the slurry room at the ConAgra plant.[5,6] The fact that the diacetyl levels at these two other plants and the ConAgra plant were much lower than those measured in the mixing room of the index plant (38 ppm in the index plant vs. approximately 1 ppm or less in the other plants) suggests that mixers may be at risk from brief, intense exposures during open handling of flavorings and looking into tanks of heated oil and flavorings, even when ventilation maintains low average air concentrations of flavoring chemicals.

Microwave popcorn packaging-lines: During the March 2003 survey, NIOSH found that the slurry room was under negative air pressure relative to the adjacent packaging area, a likely result of modifications to the slurry room ventilation system which ConAgra performed after the January 2003 NIOSH visit. This decreased the potential for slurry room emissions to contaminate the packaging area, as evidenced by the much lower diacetyl air concentrations NIOSH found in the packaging area as compared to the slurry room in March 2003. However, the ventilation in the slurry room prior to these changes allowed flavoring chemicals in the air of the slurry room to move into the air of the packaging area. Therefore, the March 2003 diacetyl air concentrations in the packaging area may underestimate past exposures. Higher exposures in the past may explain the greater than expected numbers of packaging-line workers reporting wheezing apart from colds and being told by a physician that they have asthma, and the high percentages of packaging-line workers reporting eye and nasal irritation. Nine packaging-line workers had obstruction on NIOSH spirometry tests. Five of them had no response to bronchodilator, had normal diffusing capacity, and had no history of ever having worked as mixers. Although they were all smokers, their average age was 36 and none were over age 50, making it unlikely that all five had smoking-related disease. It is possible that some packaging-line workers may have decreased lung function due to inhalation of flavoring chemicals originating in the slurry room.

QA lab: Two of 11 current QA workers were found to have abnormal spirometry. One had obstruction that was unresponsive to bronchodilator and had a normal diffusing capacity. Another had restriction. Several current QA workers reported respiratory symptoms, as well as nasal and eye irritation. At the index plant where flavorings-related lung disease in microwave popcorn workers was first identified, five of six QA workers that popped approximately 100 bags of microwave popcorn in microwave ovens per work shift per worker were found to have fixed obstruction. The average diacetyl air concentration in the QA lab at the index plant was higher than in the QA lab at the ConAgra plant (0.56 ppm vs. 0.018 ppm). Despite this lower average exposure, ConAgra

QA lab workers may be at risk from the repeated brief, intense exposures that occur with the popping of up to 130 bags per worker per 12-hour shift.

Press area: The press area had greater than expected numbers of workers reporting wheezing apart from colds and chronic bronchitis, and with obstruction on spirometry testing. Although the number of workers with obstruction was small and the excess was not statistically significant (four workers with obstruction compared to two expected, after adjusting for age, smoking history, race, and gender), the excess obstruction in these workers is concerning given their potential for exposure to volatile chemicals used in the press area. All the workers with obstruction were smokers. However, all were less than 50 years old (average age 43), making it less likely that all had smoking-related disease.

Sixty percent of survey participants reported currently smoking cigarettes. This is higher than the average for any industry or occupation surveyed and listed in the 2002 *Work-Related Lung Disease Surveillance Report* published by NIOSH.[21] This high smoking prevalence is not likely to explain all workers with obstruction in this plant, as obstructive lung disease in smokers typically does not occur before 45 years of age. However, as they age, smokers are at risk for many different smoking-related diseases, including obstructive lung disease, lung and other cancers, heart disease, and stroke. Nearly half a million Americans die each year from smoking-related diseases. Workers who smoke should seriously consider these potential health effects and commit to stop smoking. Options for workers who would like to stop smoking include company-sponsored smoking cessation programs, programs available through the American Lung Association and other similar organizations (many of which are free), and recommendations from personal physicians.

CONCLUSIONS

Findings from a NIOSH medical and environmental evaluation at the ConAgra Snack Foods microwave popcorn plant in Marion, Ohio, and from similar evaluations at the plants of several other companies, indicate that production workers are at risk for lung disease from inhalation of butter flavoring-related chemicals. Maintaining low average exposures through the use of ventilation may not eliminate risk if brief, intense exposures are still possible. Intense exposures can occur when workers manually measure or mix quantities of flavorings, look into open tanks of heated oil and flavorings, clean up flavoring spills, or pop many dozens of bags of product in microwave ovens per work shift. Packaging-line workers may be at risk when exposed to emissions from nearby flavoring mixing activities and non-isolated tanks of oil and/or flavorings. To minimize the risk of lung disease and other health effects in workers exposed to flavoring-related chemicals, ConAgra should minimize worker exposures (including brief, intense exposures) to the greatest extent possible, and monitor potentially exposed workers with regularly scheduled spirometry to make sure that exposure control interventions are effective at preventing effects on lung function.

RECOMMENDATIONS

NIOSH provided the following recommendations to ConAgra in its October 2003 interim report. (The information presented as "**Follow-up**" refers to NIOSH observations during a walkthrough of the plant on September 2, 2004, and to information provided by ConAgra during, or shortly after, that visit.)

1. Identify and implement engineering changes that allow flavorings to be added to heated oil in a closed system (i.e., no worker exposures to open containers of flavorings) and eliminate the need for workers to look into open tanks of heated oil and flavorings. A closed system requires that all aspects of the mixing process be tightly contained (e.g., all tanks should have lids that seal tightly and prevent the escape of vapors into the air). Alternatively, some powdered flavorings (e.g., encapsulated flavorings) minimize the release of volatile flavoring chemicals into the air

and may be a safer alternative to liquid and paste flavorings when handled in open containers. However, some powdered flavorings generate significant amounts of airborne dust when handled which may be harmful if inhaled. Require the use of appropriate respirators (see below) by workers handling open containers of flavorings of any type. (**Follow-up:** ConAgra management reported that it was currently reviewing consultant recommendations for implementing a closed process for flavor handling.)

2. Until a closed system for mixing of oil and flavoring is implemented, assure that ventilation minimizes worker exposures as much as possible. All production areas should have adequate general dilution ventilation. Maintain the slurry room under negative air-pressure relative to the rest of the plant, and exhaust the air from this room out of the plant. If not already done, install a local exhaust hood over the area where mixers weigh and measure amounts of flavorings, and implement local exhaust ventilation to all tanks that contain heated oil and flavorings. Regularly check and maintain all ventilation systems to assure adequate function and prevent breakdowns. (**Follow-up:** Testing with smoke tubes showed that the slurry room was under negative air pressure relative to the packaging area. NIOSH noted that an air pressure monitor and alarm had been installed. (The same observations were made regarding the QA lab.) The table in the slurry room where workers weigh flavorings in open containers had local exhaust ventilation. Testing with smoke tubes showed this local exhaust ventilation to be effective up to several feet away from the exhaust point. ConAgra management reported that local exhaust ventilation for the heated tanks had not been installed because the tanks had tight fitting lids and because of concern that some of the liquid contents might be sucked into the ventilation duct when the tanks were full.)

3. Perform regularly-scheduled air sampling for flavoring-related ketone compounds such as diacetyl to ensure the effectiveness of control interventions. (**Follow-up:** ConAgra management reported that the results of air sampling performed for the company by a consultant were similar to the results obtained by NIOSH.)

4. Assure that the slurry room remains closed off from the packaging area at all times. This may require the installation of an enclosure / air-lock system with an additional door(s) in front of the current doors. In this way, workers can enter the enclosure and close the outer door(s) before opening any of the current slurry room doors. (**Follow-up:** The slurry room door was closed. ConAgra management reported that it was not able to install the additional door for the slurry room due to insufficient space.)

5. Continue to require mandatory respirator use by mixers and any other workers who enter the slurry room, as part of a formal respiratory protection program that adheres to the requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134). Workers require medical clearance for respirator use, fit testing of the respirator they will use before they are allowed to use it, and training on the hazards they are exposed to and on how to wear and maintain their respirator. The administrator that you select for the program must have adequate training or experience to run it and regularly evaluate its effectiveness. Details on the Respiratory Protection Standard and on how a company can set up a respiratory protection program are available on the OSHA website (www.osha.gov). The minimum protective respirator that NIOSH recommends is a NIOSH-certified half-facepiece negative-pressure respirator with organic vapor

cartridges and particulate filters. A full-facepiece respirator would provide eye protection as well. A loose-fitting powered air-purifying respirator with a particulate filter and organic vapor cartridge is an option to consider for increased worker comfort and does not require fit testing. Another option is a supplied-air respirator. Require that mixers and other workers wear their respirators whenever they are in the slurry room at any time and for any reason. (**Follow-up:** According to workers and company management, ConAgra implemented mandatory use of powered air-purifying respirators for all workers that enter the slurry room shortly after the NIOSH survey in March, 2003. ConAgra management provided a copy of their respiratory protection program. A storage area with lockers to store workers' respirators, and a battery charge station, were located near the slurry room. A worker in the slurry room was seen using a powered air-purifying respirator during the September 2004 NIOSH visit.)

6. Enclose and implement local exhaust ventilation for microwave ovens in the QA lab to prevent air inside the ovens from blowing toward the QA worker. Instruct QA workers to allow popped bags to cool before opening them and to open them inside of the enclosure. Include these workers in the respiratory protection program and require that they use a respirator (from the choices above) until the enclosures and ventilation are in place and follow-up spirometry testing shows that their lung function is remaining stable. (**Follow-up:** All microwave ovens were located in a hood-type enclosure with local exhaust ventilation. After popping microwave popcorn in the ovens, the QA lab worker opened the bags of popcorn outside of the hood after the bags had cooled somewhat. Management informed NIOSH that the worker could not open the bags in the hood because the sliding panel for the hood opening would have to be in the raised (open) position, which would allow gases to escape from the hood if additional bags of popcorn were being popped in the ovens. Waiting to start the ovens to pop additional bags might mean that the worker could not accomplish all the QA popping that is usually done during the work shift. **Follow-up recommendation:** Install local exhaust for the area where the bags are opened if the worker is not able to wait until the bags have cooled before opening them.)

7. Implement a spirometry testing program as described in Appendix D for QA workers, mixers, and any other workers that enter the slurry room. (**Follow-up:** A review of worker tests performed by ConAgra's provider showed that the quality of the tests was not good enough to allow a comparison of workers' test results over time. **Follow-up recommendation:** Discuss with the spirometry provider the importance of following the American Thoracic Society guidelines for standardization of spirometry.[10] All tests must have at least three acceptable maneuvers. Additional maneuvers may be necessary in order to obtain measurements that are reproducible. (The two largest FVC and FEV1 measurements should differ by less than 200 milliliters). The spirometry technicians should attend a NIOSH-certified spirometry course and demonstrate knowledge of proper techniques for coaching test subjects.

8. Evaluate the processes and exposures in the press area to minimize any potentially harmful exposures that press workers may experience. NIOSH can perform this as part of this HHE or a separate HHE requested by company management and/or workers. Alternatively, ConAgra can arrange to have this done by private occupational health and safety consultants. (**Follow-up:** ConAgra management reported that its evaluation of the press area did not

reveal any exposures that exceeded established standards.)

9. Establish a smoking cessation program and encourage workers to utilize it. (**Follow-up:** ConAgra management reported that it was providing interested workers with referrals to a smoking cessation program.)

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Table 1. Survey participation and characteristics of participants by current work area

Work Area	Total Workers*	Survey Participants (N)	% Participation	Mean Age (Years)	Males n (%)	Current or Former Smokers n (%)
Press	40	28	70	37.3	26 (93)	22 (79)
Slurry Room	12	12	100	31.6	12 (100)	8 (67)
Packaging	155	110	71	34.1	69 (63)	82 (75)
QA	13	11	85	40.5	2 (18)	10 (91)
Warehouse	30	8	27	37.1	6 (75)	7 (88)
Office	29	10	34	39.1	3 (30)	5 (50)
Maintenance	34	26	76	42.1	25 (96)	14 (54)
Totals	313	205	65	36.1	143 (70)	148 (72)

*Totals as reported by Tony Jones, plant manager, at January 8, 2003 meeting

Table 2. Symptoms by current work area

Symptoms*	Packaging N=110 n (%)	Slurry N=12 n (%)	QA N=11 n (%)	Press N=32 n (%)	All Others N=40 n (%)
Trouble breathing during last 12 months	27 (25)	4 (33)	3 (27)	8 (25)	10 (25)
SOB** hurrying or slight hill	24 (22)	4 (33)	4 (36)	6 (19)	10 (25)
SOB** walking with people same age on level ground	6 (6)	0	3 (27)	4 (13)	3 (8)
Usual cough	35 (32)	3 (25)	4 (36)	9 (28)	7 (18)
Chronic cough (on most days for 3 consecutive months)	14 (13)	1 (8)	2 (18)	5 (16)	3 (8)
Wheezing apart from cold	30 (27)	6 (50)	4 (36)	8 (25)	8 (20)
Fever/chills/sweats	16 (15)	1 (8)	3 (27)	4 (13)	1 (3)
Unusual fatigue	25 (23)	4 (33)	4 (36)	4 (13)	5 (13)
Nasal irritation	69 (63)	10 (83)	6 (55)	13 (41)	17 (43)
Nose bleeds	9 (8)	3 (25)	2 (18)	2 (6)	1 (3)
Coughed up blood	9 (8)	1 (8)	1 (9)	1 (3)	1 (3)
Eye irritation	44 (40)	4 (33)	5 (45)	13 (41)	11 (28)
Skin problems	25 (23)	2 (17)	1 (9)	11 (34)	4 (10)

*See Appendix A for text of questions on questionnaire
**SOB=Shortness of breath
N= number of participants from work area
n= number of participants that reported symptom

Table 3. Abnormalities on NIOSH tests and worker-reported respiratory diagnoses by current work area

Lung Function Test Results	Packaging N=110 n (%)	Slurry Room N=12 n (%)	QA N=11 n (%)	Press N=32 n (%)	All others N=40 n (%)
Abnormal Spirometry	14 (13)	4 (33)	2 (18)	6 (19)	3 (8)
--obstruction or mixed pattern	9 (8)	3 (25)	1 (9)	4 (13)	2 (5)
--restriction	5 (5)	1 (8)	1 (9)	2 (6)	1 (3)
+ Bronchodilator Response	1 of 9	1 of 3	0 of 1	1 of 4	1 of 2
Abnormal Diffusing Capacity	6 of 14	1 of 4	0 of 2	2 of 6	1 of 3
Respiratory Diagnoses					
Bronchitis while working in plant*	13 (12)	4 (33)	4 (36)	5 (16)	0
Chronic Bronchitis*	8 (7)	0	1 (9)	5 (16)	3 (8)
Pneumonia while in plant*	7 (6)	0	0	1 (3)	0
Asthma*	18 (16)	2 (17)	2 (18)	3 (9)	5 (13)
Pneumothorax (Collapsed lung)*	2 (2)	0	0	3 (9)	0

*See appendix A for text of questions on questionnaire
N= number of participants from work area
n= number of participants with abnormality or reporting diagnosis

Table 4. Numbers of packaging area workers reporting respiratory symptoms and physician-diagnosed respiratory disease, and with abnormal spirometry test results, compared to the numbers expected from NHANES III (adjusted for age, sex, race, and smoking status)

Condition	Participants	# Obs [a]	# Exp [b]	O/E (95% CI) [c]
Shortness of breath when hurrying on the level or walking up a slight hill				
< 40 years	80	15	15.2	1.0 (0.6-1.6)
= 40 years	30	9	7.6	1.2 (0.6-2.2)
Total	110	24	22.8	1.1 (0.7-1.6)
Wheezing aside from a cold				
< 40 years	80	28	11.8	2.4 (1.6-3.4)†
= 40 years	30	6	4.0	1.5 (0.7-3.2)
Total	110	34	15.9	2.1 (1.5-3.0)†
Chronic cough [d]				
< 40 years	80	10	9.0	1.1 (0.6-2.0)
= 40 years	30	4	3.5	1.2 (0.4-3.0)
Total	110	14	12.5	1.1 (0.7-1.9)
Chronic bronchitis confirmed by MD				
< 40 years	80	7	4.6	1.5 (0.7-3.2)
= 40 years	30	1	2.0	0.5 (0.1-2.8)
Total	110	8	6.6	1.2 (0.6-2.4)
Asthma confirmed by MD				
< 40 years	80	16	6.9	2.3 (1.4-3.8)†
= 40 years	30	2	2.4	0.8 (0.2-3.1)
Total	110	18	9.3	1.9 (1.2-3.1)†
Obstruction or mixed pattern				
< 40 years	80	5	2.9	1.7 (0.7-4.0)
= 40 years	30	4	2.8	1.4 (0.6-3.6)
Total	110	9	5.8	1.6 (0.8-3.0)
Restriction				
< 40 years	80	3	4.6	0.6 (0.2-1.9)
= 40 years	30	2	2.7	0.7 (0.2-2.7)
Total	110	5	7.4	0.7 (0.3-1.6)

[a]number observed [b]number expected [c]observed/expected (95% confidence interval)
[d]Usually cough on most days for 3 consecutive months or more during the year
† Statistically significant (confidence interval (CI) does not include 1)

Table 5. Numbers of slurry room and QA workers reporting respiratory symptoms and physician-diagnosed respiratory disease, and with abnormal spirometry test results, compared to the numbers expected from NHANES III (adjusted for age, sex, race, and smoking status)

Condition	Participants	# Obs [a]	# Exp [b]	O/E (95% CI) [c]
Shortness of breath when hurrying on the level or walking up a slight hill				
< 40 years	14	5	2.4	2.1 (0.9-4.9)
= 40 years	9	3	2.8	1.1 (0.4-3.2)
Total	23	8	5.1	1.6 (0.8-3.1)
Wheezing aside from a cold				
< 40 years	14	7	1.9	3.7 (1.8-7.7)†
= 40 years	9	3	1.5	2.0 (0.7-6.0)
Total	23	10	3.3	3.0 (1.6-5.5)†
Chronic cough [d]				
< 40 years	14	0	1.5	0.0 (0.0-2.6)
= 40 years	9	3	1.3	2.3 (0.8-6.9)
Total	23	3	2.7	1.1 (0.4-3.2)
Chronic bronchitis confirmed by MD				
< 40 years	14	0	0.7	0.0 (0.0-5.2)
= 40 years	9	1	0.8	1.2 (0.2-6.7)
Total	23	1	1.6	0.6 (0.1-3.6)
Asthma confirmed by MD				
< 40 years	14	2	1.2	1.7 (0.5-6.3)
= 40 years	9	2	0.8	2.5 (0.7-9.1)
Total	23	4	2.0	2.1 (0.8-5.3)
Obstruction or mixed pattern				
< 40 years	14	1	0.5	2.2 (0.4-12.3)
= 40 years	9	3	1.1	2.7 (0.9-7.8)
Total	23	4	1.6	2.5 (1.0-6.5)
Restriction				
< 40 years	14	1	0.8	1.3 (0.2-7.3)
= 40 years	9	1	0.9	1.1 (0.2-6.4)
Total	23	2	1.7	1.2 (0.3-4.4)

[a]number observed [b]number expected [c]observed/expected (95% confidence interval)
[d]Usually cough on most days for 3 consecutive months or more during the year
† Statistically significant (confidence interval (CI) does not include 1)

Table 6. Numbers of press area workers reporting respiratory symptoms and physician-diagnosed respiratory disease, and with abnormal spirometry test results, compared to the numbers expected from NHANES III (adjusted for age, sex, race, and smoking status)

Condition	Participants	# Obs [a]	# Exp [b]	O/E (95% CI) [c]
Shortness of breath when hurrying on the level or walking up a slight hill				
< 40 years	18	2	3.1	0.7 (0.2-2.4)
= 40 years	14	4	3.6	1.1 (0.4-2.8)
Total	32	6	6.7	0.9 (0.4-2.0)
Wheezing aside from a cold				
< 40 years	18	4	2.7	1.5 (0.6-3.8)
= 40 years	14	5	2.1	2.3 (1.0-5.5)†
Total	32	9	4.8	1.9 (1.0-3.6)
Chronic cough [d]				
< 40 years	18	1	2.0	0.5 (0.1-2.9)
= 40 years	14	4	1.9	2.1 (0.8-5.4)
Total	32	5	3.9	1.3 (0.6-3.0)
Chronic bronchitis confirmed by MD				
< 40 years	18	2	0.6	3.5 (1.0-12.8)
= 40 years	14	3	0.9	3.2 (1.1-9.4)†
Total	32	5	1.5	3.3 (1.4-7.7)†
Asthma confirmed by MD				
< 40 years	18	0	1.5	0.0 (0.0-2.5)
= 40 years	14	3	1.1	2.8 (1.0-8.2)
Total	32	3	2.6	1.2 (0.4-3.4)
Obstruction or mixed pattern				
< 40 years	18	0	0.8	0.0 (0.0-5.0)
= 40 years	14	4	1.5	2.7 (1.1-7.0)†
Total	32	4	2.2	1.8 (0.7-4.6)
Restriction				
< 40 years	18	1	1.2	0.9 (0.2-4.9)
= 40 years	14	1	1.3	0.7 (0.1-4.2)
Total	32	2	2.5	0.8 (0.2-2.9)

[a]number observed [b]number expected [c]observed/expected (95% confidence interval)
[d]Usually cough on most days for 3 consecutive months or more during the year
†Statistically significant (confidence interval (CI) does not include 1)

Table 7. Summary of predominant volatile organic compounds identified in different plant areas

	Slurry Room	Phaser Operator	Palletizer Operator	Fork Lift Operator	QA	Warehouse	Press Room	Office Worker
Diacetyl (2,3-butanedione)	v	v	v	v	v	v	v	
Acetoin (3-hydroxy-2-butanone)	v				v			
Propylene glycol	v				v			
Acetoin oligimers	v							
Ethanol	v				v			
Hexane	v	v			v			
Tetrahydrofuran (THF)	v							
Limonene	v	v	v	v	v	v		v
Methanol/acetaldehyde		v	v		v			
Ethyl acetate		v			v			
Toluene		v			v	v		v
Dipropylene glycol methyl ether isomers		v			v			
1-(2-methoxypropoxy)-2-propanol		v			v			
Perchloroethylene		v			v			
a-Pinene			v	v		v		
ß-Pinene				v				
Butanol/trace benzene					v			
Acetone		v			v		v	
Methyl acetate					v			
Methylene chloride					v			
Trichloroethylene						v		
Decamethylcyclopentasiloxane								v

Table 8. Plant-wide mean, minimum, and maximum air concentrations for diacetyl, acetoin, total hydrocarbons, and acetaldehyde

Analyte	Samples	Mean	STD	Min	Max
Diacetyl - All Samples, ppm	123	0.15	0.41	ND	2.7
- Personal Samples, ppm	75	0.14	0.36	ND	2.0
- Area Samples, ppm	48	0.17	0.49	LOQ	2.7
Acetoin – All Samples, ppm	123	0.11	0.38	ND	2.8
Total Hydrocarbons*, Mg/m^3	48	1.25	0.92	ND	5.53
Acetaldehyde, ppm	48	0.05	0.05	ND	0.17

ppm- parts per million parts air by volume; Mg/m^3 *- milligrams per cubic meter of air; STD - standard deviation; ND - below the minimum detectable concentration in air, approximately 0.004 ppm for diacetyl and acetoin. LOQ – below minimum quantifiable concentrations, approximately 0.01ppm.*

Table 9. Personal ketone exposures in parts per million parts of air by volume (ppm).

Job Titles	Number of Samples	Diacetyl		Acetoin	
		Average	Range	Average	Range
Mixer	7	1.03	0.16-1.97	0.755	0.094-1.82
Supervisor	11	0.17	LOQ -1.03	0.14	ND-1.04
Press Room Operator	7	0.01	ND-0.03	0.01	ND-0.03
Phaser Operator	5	0.02	0.01-0.03	0.01	LOQ-0.02
Warehouse Worker	3	0.02	LOQ-0.03	LOQ	All LOQ
Case Packer	7	0.02	LOQ -0.03	0.01	LOQ -0.02
Cartoner	7	0.02	LOQ -0.04	0.01	LOQ -0.02
Palletizer	5	0.02	LOQ -0.04	0.01	LOQ -0.01
Janitor	1	0.02	0.02	0.01	0.01
Line Sanitation	3	0.02	0.01-0.03	0.02	LOQ -0.02
QA Worker	5	0.03	LOQ -0.04	0.02	LOQ -0.03
Office Worker	3	0.02	0.02-0.03	0.01	LOQ -0.01
Fork Lift Operator	6	0.03	0.01-0.04	0.01	ND-0.01
Worked In Many Areas of Plant	2	0.004	ND- LOQ	LOQ	LOQ
NIOSH Industrial Hygienist	1	0.10	0.10	0.09	0.09
Other	3	0.02	0.01-0.02	0.01	LOQ -0.01

ppm- parts per million parts air by volume; ND - below the minimum detectable concentration in air, approximately 0.004 ppm for both diacetyl and acetoin. LOQ – below minimum quantifiable concentrations in air, approximately 0.01ppm for both diacetyl and acetoin.

Table 10. Area ketone air concentrations in parts per million parts of air by volume (ppm).

Location	Number of Samples	Diacetyl		Acetoin	
		Average	Range	Average	Range
Slurry Room	6	1.26	0.53-2.68	1.07	0.29-2.80
Supervisor Office	2	0.01	LOQ -0.02	0.01	LOQ-0.02
Press Area	4	LOQ	All LOQ	LOQ	All LOQ
Phaser Area	5	0.02	LOQ -0.03	0.01	LOQ -0.02
Warehouse	4	0.03	0.02-0.04	LOQ	ND-LOQ
Case Packing Area	3	0.02	LOQ -0.03	0.01	LOQ -0.02
Cartoner Area	6	0.02	LOQ -0.03	0.02	LOQ -0.02
Palletizer Area	4	0.03	LOQ -0.03	0.01	ND-0.01
QA Lab	6	0.01	LOQ -0.02	0.01	LOQ -0.02
Office	3	0.01	LOQ -0.02	LOQ	ND- LOQ
Fork Lift	3	0.02	0.01-0.03	LOQ	All LOQ
Outside	1	ND	ND	ND	ND
Other	2	0.01	LOQ -0.02	0.01	LOQ -0.02

ppm- parts per million parts air by volume; ND - below the minimum detectable concentration in air, approximately 0.004 ppm for both diacetyl and acetoin. LOQ – below minimum quantifiable concentrations in air, approximately 0.01ppm for both diacetyl and acetoin.

Table 11. Total hydrocarbon area air concentrations in milligram per cubic meter (mg/m3).

Location	Number of Samples	Total Hydrocarbons*	
		Average	Range
Slurry Room	6	1.03	LOQ - 2.19
Supervisor Office	2	1.78	1.52-2.05
Press Room	4	1.90	LOQ - 2.60
Phaser Area	5	2.07	LOQ - 5.53
Warehouse	4	0.66	ND - 0.8
Case Packing Area	4	1.02	LOQ - 1.66
Cartoner Area	5	0.80 (LOQ)	All LOQ
Palletizer Area	4	0.66	ND - 0.8
QA Lab	6	1.62	LOQ - 3.29
Office	3	0.90	ND - 1.68
Fork Lift	3	0.80 (LOQ)	All LOQ
Maintenance	2	2.06	1.77 - 2.35
Outside	1	ND	ND

** Total hydrocarbon concentrations excluding the ketones diacetyl, acetoin, and nonanone.*
mg/m^3 *- milligrams per cubic meter of air; ND - below the minimum detectable concentration in air, approximately 0.44* mg/m^3. *LOQ – below minimum quantifiable concentrations in air approximately 1.6* mg/m^3.

Table 12. Acetaldehyde area air concentrations in parts per million parts of air by volume (ppm).

Location	Number of Samples	Acetaldehyde	
		Average	Range
Slurry Room	6	0.02	ND - 0.05
Supervisor Office	2	0.08	0.05 - 0.11
Press Room	4	0.13	0.07 - 0.17
Phaser Area	5	0.04	LOQ - 0.06
Warehouse	4	0.03	LOQ - 0.04
Case Packing Area	4	0.02	ND - 0.04
Cartoner Area	6	LOQ	ND - LOQ
Palletizer Area	4	0.03	LOQ - 0.04
QA Lab	5	0.12	0.10 - 0.14
Office	3	LOQ	ND – LOQ
Fork Lift	3	LOQ	All LOQ
Other	2	0.15	0.15
Outside	1	ND	ND

ppm- parts per million parts air by volume; ND - below the minimum detectable concentration in air, approximately 0.014 ppm. LOQ – below minimum quantifiable concentrations in air, approximately 0.036 ppm.

Table 13. Area total and respirable dust concentrations (mg/m^3) in air

Analyte	Samples	Mean	STD	Min	Max
Total Dust	49	0.24	0.40	ND	1.74
Respirable Dust	49	0.09	0.15	ND	0.65

mg/m^3 - milligrams per cubic meter of air; STD - standard deviation; ND - below the minimum detectable concentration in air, approximately 0.014 mg/m^3 for total dust and 0.01 mg/m^3 for respirable dust.

Table 14. Spirometry findings, bronchodilator response, and DLCO results in selected lung diseases

Disease	Spirometry	Bronchodilator Response	DLCO
Asthma	Obstruction	Yes	Normal
Emphysema	Obstruction	No	Low
Bronchiolitis Obliterans	Obstruction	No	Normal
Silicosis	Restriction	No	Low

Figure 1. Diacetyl and acetoin concentrations by job location

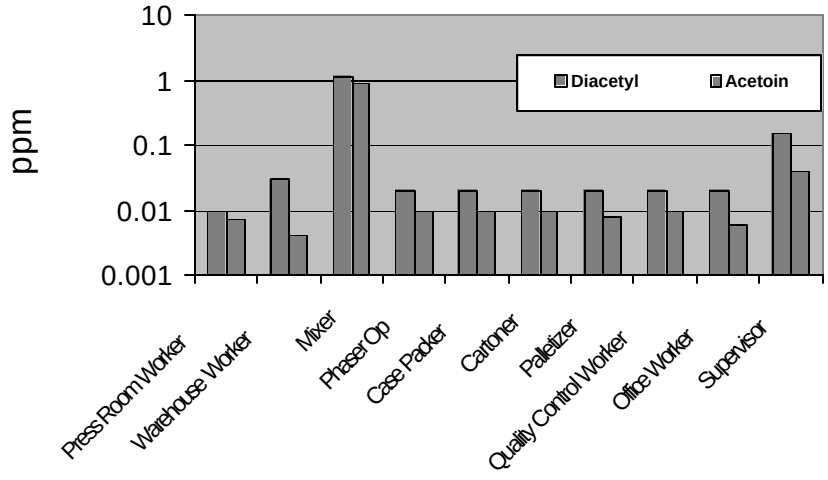


Figure 2. Real-time diacetyl, acetoin, and nonanone concentrations from the slurry room by sampling date. concentrations in ppm

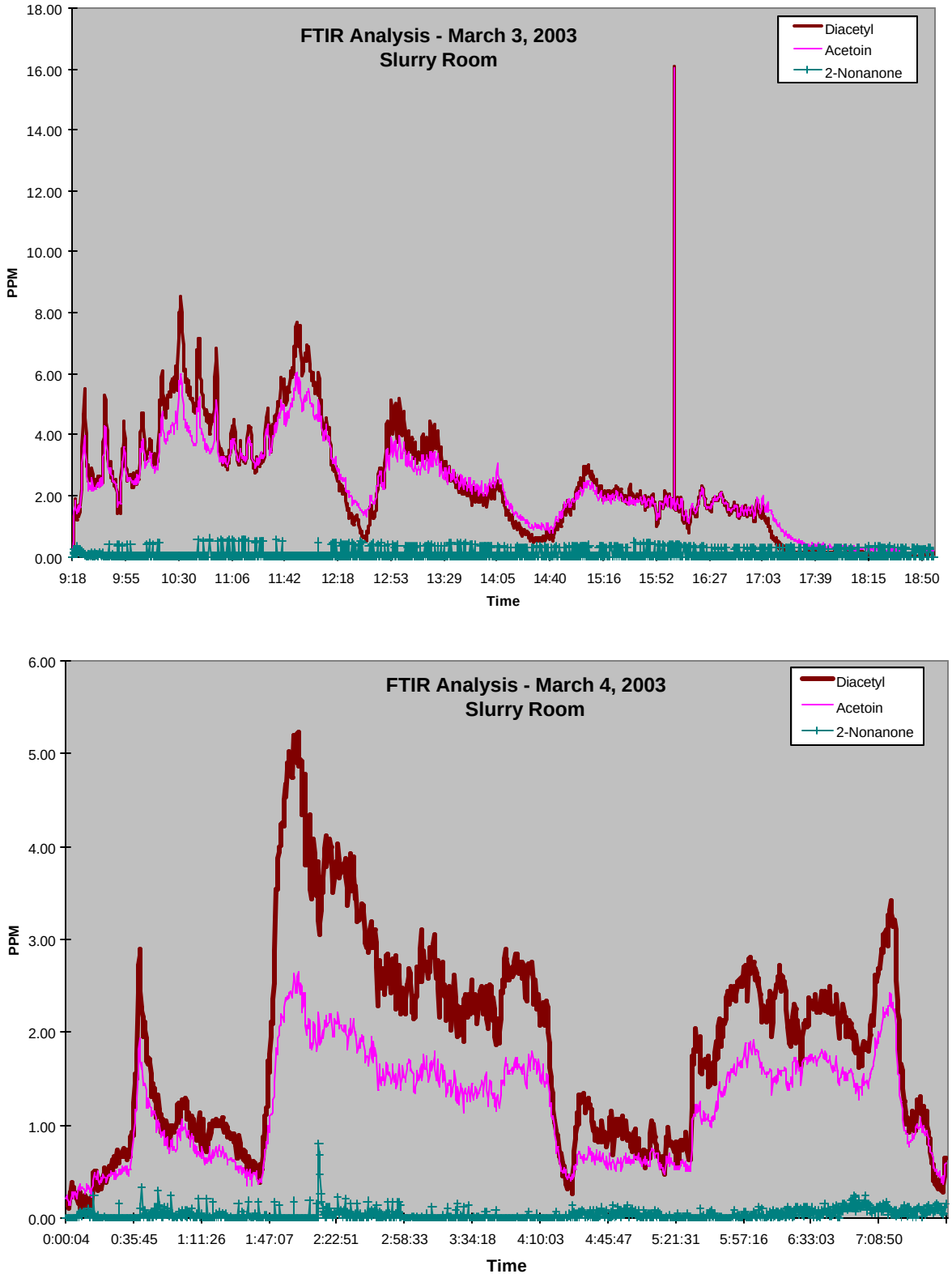


Figure 3. Diacetyl concentrations by sampling flow rate in the slurry room

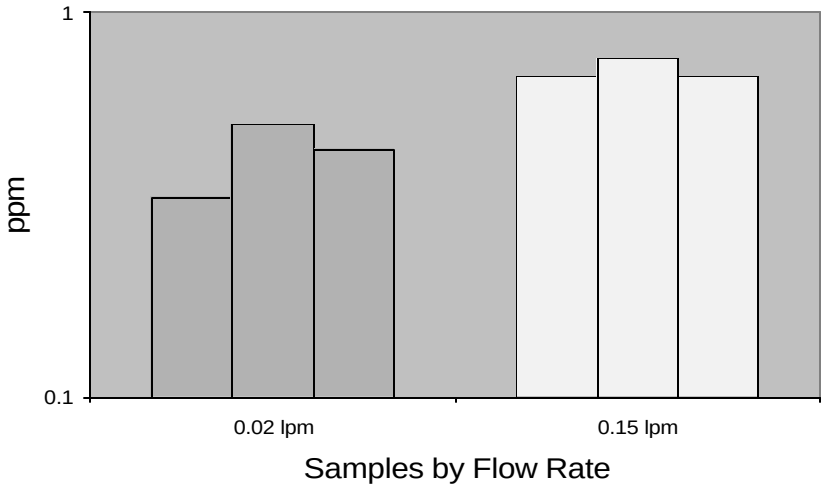


Figure 4. Total and respirable dust concentrations by job location

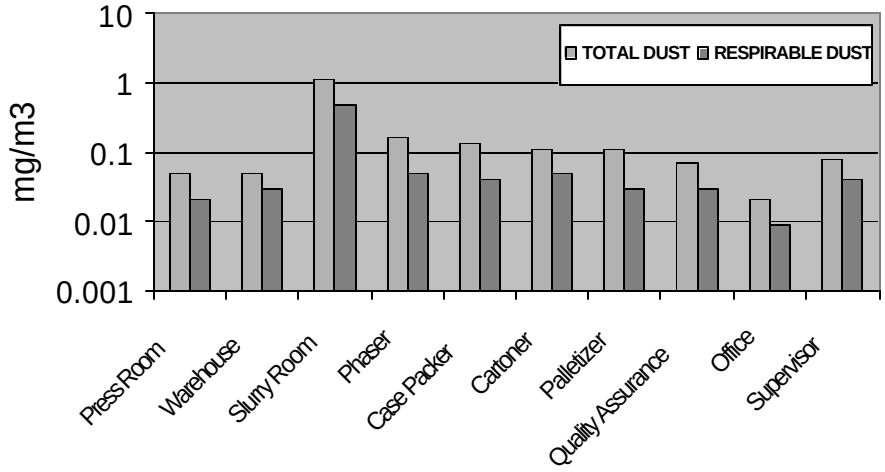


Figure 5. Real-time particle count data by size category from the slurry room on March 3, 2003. Concentrations in particles per cubic centimeter (particles / CC)

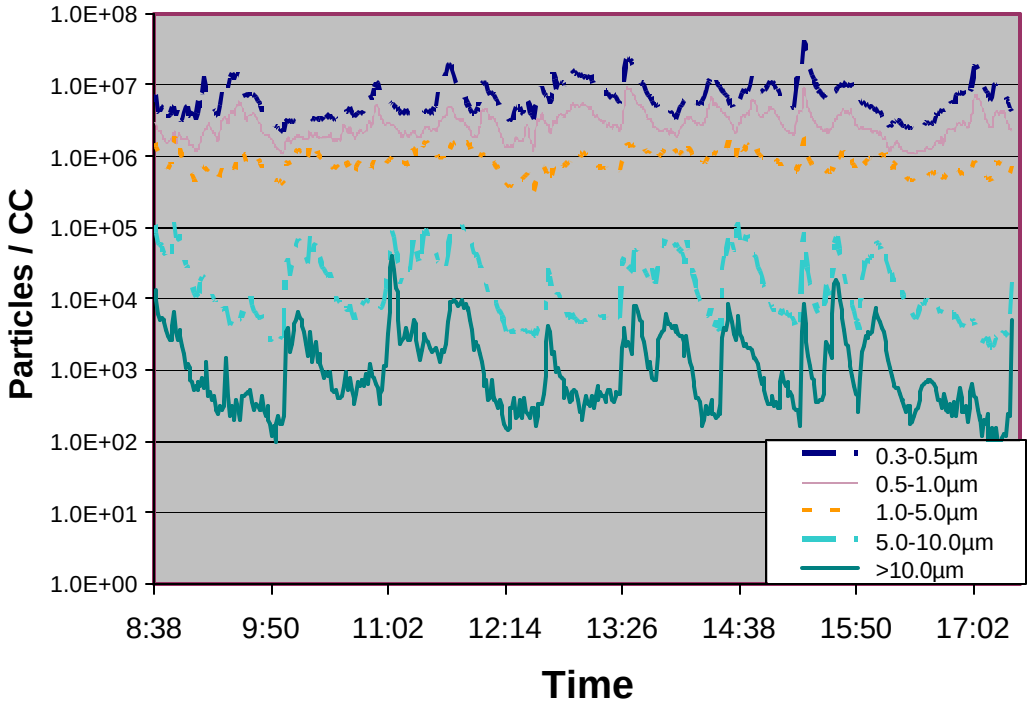


Figure 6. Real-time particle count data by size category from the QA lab on March 4, 2004. Concentrations in particles per cubic centimeter (particles / CC)

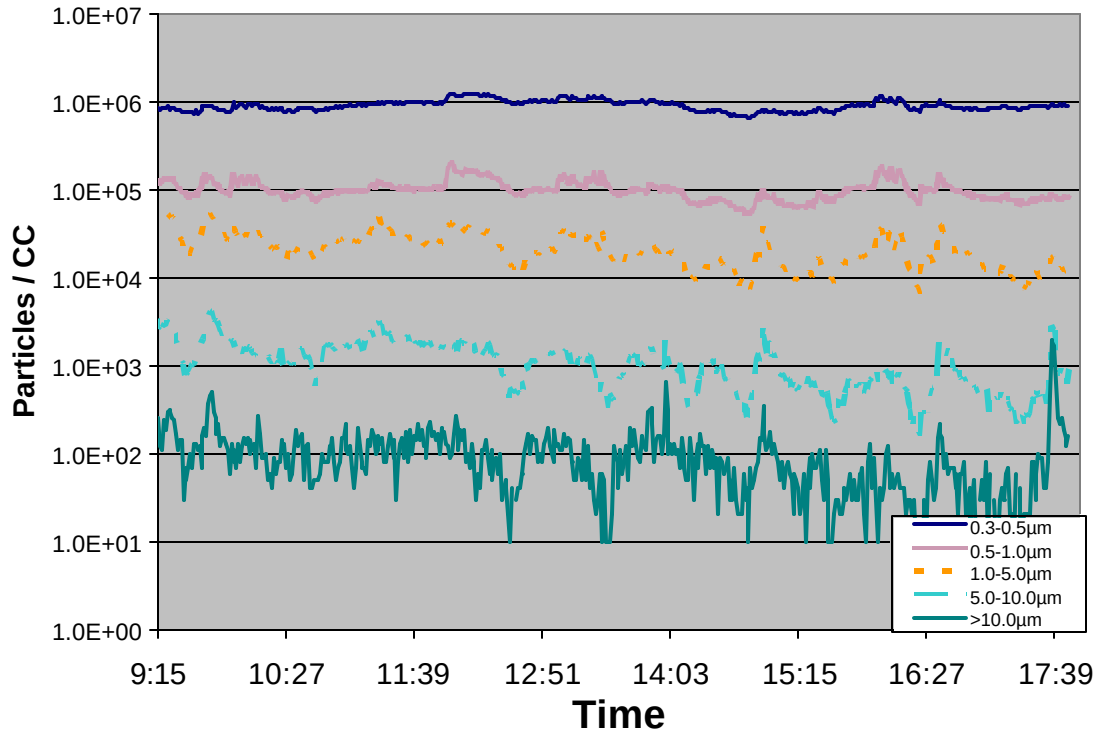
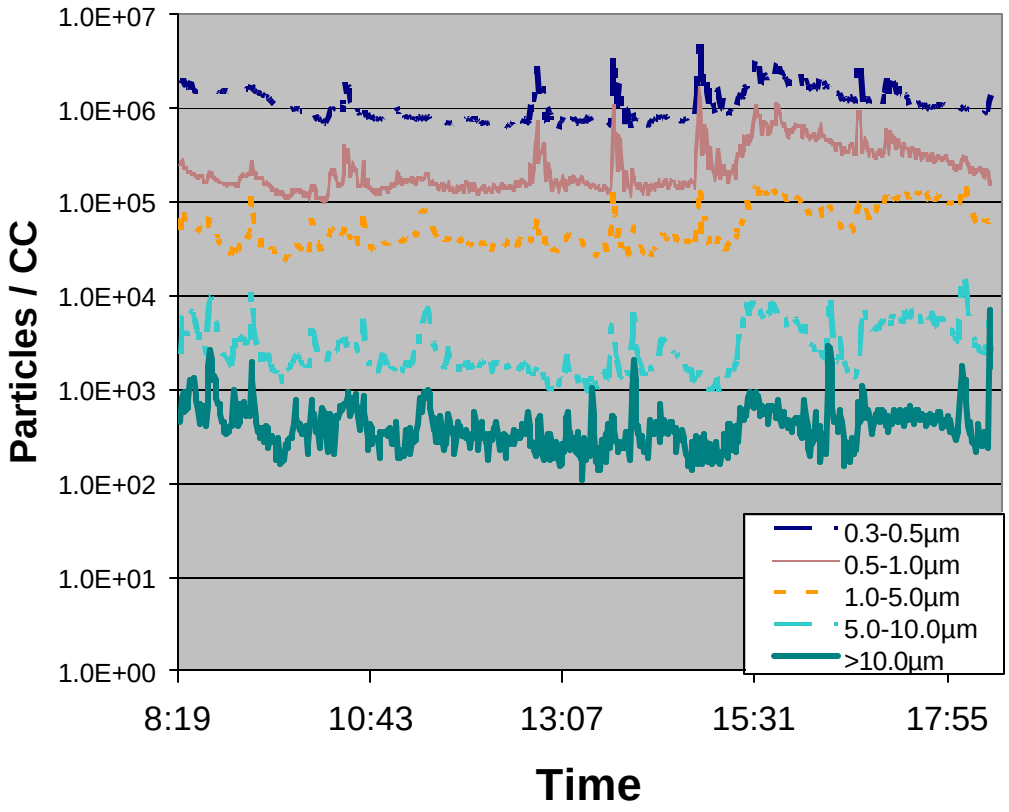


Figure 7. Real-time particle count data by size category from the packaging line area by the palletizer on March 5, 2003. Concentrations in particles per cubic centimeter (particles / CC)



APPENDIX A

January 28, 2003
HETA 2003-0112
Interim Report #1

James Montealegre
VP of Procurement, Product Development,
Graphics, and Legal Services
ConAgra Foods Retail Products Company
Snack Foods Group
7700 France Avenue South, Suite 200
Edina, Minnesota 55435

Dear Mr. Montealegre:
Thank you very much for facilitating our initial visit and walkthrough of the ConAgra Snack Foods plant in Marion, Ohio, on January 8, 2003. We initiated this visit after receiving a confidential request from current workers for a health hazard evaluation regarding respiratory problems and exposures from microwave popcorn production processes. We were able to accomplish our goals for the visit and look forward to working with you and other ConAgra staff to complete our evaluation. This letter describes our plans for a detailed medical and environmental survey to evaluate the risk for lung disease in plant workers and contains initial recommendations for actions that ConAgra should take to minimize the risks to workers from exposures to concentrated flavorings. These recommendations are based on what we have learned regarding the risks for lung disease in other microwave popcorn plants and our observations of work processes during the walkthrough at your plant.

NIOSH Evaluation of Lung Disease Risk in Microwave Popcorn Plants

As we discussed with you during our visit, the National Institute for Occupational Safety and Health's (NIOSH) investigation of lung disease in microwave popcorn plant workers has revealed that inhalation exposure to concentrated butter flavoring chemicals can lead to lung disease under certain working conditions. At the plant in Missouri where this problem was first recognized, eight former workers (four mixers and four workers on the packaging lines) developed fixed obstructive lung disease consistent with the rare disease, bronchiolitis obliterans. The illness in four of these workers was severe enough that they were placed on lung transplant lists by their physicians. A survey by NIOSH of current workers at the Missouri plant showed that three times as many workers as expected had fixed obstruction on lung function tests. Increasing cumulative exposure to indicators of butter flavoring exposure was associated with increasing rates of abnormal lung function in these workers. Quality control workers (those who microwave approximately 100 bags of microwave popcorn per worker per eight hour shift) were also found to be at risk. NIOSH is conducting animal experiments to learn more about which components of concentrated butter flavorings have potential to cause lung toxicity. Experiments so far have shown that diacetyl alone can lead to toxic effects. The other chemical components that may contribute to toxicity, and the levels of exposure that are considered safe, are still not known. Also not known is the relative safety of powdered flavorings compared to liquids or pastes. Powders that are formulated to have lower emissions of volatile flavoring chemicals may pose lower risk. However, inhalation of airborne dust when handling these flavorings may increase worker risk for lung problems.

In addition to the Missouri plant and ConAgra's plant in Marion, Ohio, NIOSH is evaluating the risk for lung disease in four other microwave popcorn plants. In one of these plants, tanks containing heated oil

and flavorings were located near packaging lines in a large open space. Nearly three times as many workers as expected were found to have obstruction on lung function testing. In two other plants, mixers were identified as having fixed obstructive lung disease consistent with bronchiolitis obliterans, with onset of symptoms after starting work as mixers. One of these plants had mixing room air concentrations of diacetyl and acetoin (measured by NIOSH as indicators of exposure to butter flavoring chemicals) that were much lower than the levels first measured by NIOSH in the Missouri plant. This finding emphasizes the fact that safe levels of exposure to concentrated butter flavoring chemicals are still not known. Short-term peak exposures while handling open containers of flavorings or looking into tanks containing heated oil and flavorings may pose risk for workers even when ventilation maintains low average air concentrations.

During our walkthrough at the ConAgra plant in Marion, Ohio, we noted processes and conditions that are similar to those we have seen in other plants. These include open handling of concentrated butter flavorings by workers, visible airborne dust from workers measuring and pouring powdered flavorings into tanks of heated soybean oil, tanks with loose fitting lids and no local exhaust ventilation, and lack of respirator use by mixing room workers. We noted that the mixing room was under slight positive pressure relative to the adjacent packaging area. We observed popping of many bags of product in microwave ovens that lacked controls to prevent worker exposure to vapors produced during heating. We were told that 136 bags are popped by one worker per 12 hour shift.
In order to evaluate the risk for lung disease in your workers from exposures related to microwave popcorn production, we plan to conduct medical and environmental surveys at the plant. The medical survey will consist of confidential worker interviews administered by NIOSH staff and lung function testing by NIOSH technicians. Please give all plant workers a copy of the attached letter and a copy of the attached flyer, which describes the survey and explains what their participation will entail. For most workers, the questionnaire and lung function testing can be completed in 30 to 75 minutes. Worker participation is voluntary, but we would like as many workers as possible to participate in order to have representative data for subgroups of workers in different aspects of production. Workers who may have little exposure, such as office workers, should also participate so that their findings can be compared to those with higher exposures. We will mail workers their lung function test results to their home address three to four weeks after the survey. After data analyses are complete, we will prepare a detailed report describing our findings and recommendations.

As discussed with you during our initial visit, we will utilize a trailer (approximately 14 feet wide by 60 feet long) to house our equipment and conduct testing on the plant grounds. Your maintenance manager, Mr. Emery Calloway, identified a location behind the plant building that he felt would accommodate the trailer. We would like to conduct the surveys from March 3rd through March 14th, 2003, Monday through Friday, from 3 pm to 11 pm. Normally we can test 3-6 workers at a time. We want to work with the plant supervisors to facilitate efficient testing with as little disruption of your production process as possible.

The environmental survey will include both personal and area sampling to quantify air contaminants. Personal sampling will be done for several different ketone compounds commonly associated with artificial butter flavoring including diacetyl, acetoin, and nonanone. This sampling will involve attaching a small sampling pump to the worker and operating it for most of the work shift. Area sampling will also be done to measure airborne concentrations of diacetyl, acetoin, nonanone, acetaldehyde, acetic acid, butyric acid, total volatile hydrocarbons, total dust, and respirable dust. The area samplers will be placed at set locations in the plant and operated throughout the work shift. As we discussed during the walk-through, we would like to work with you so that we can coordinate these sampling efforts and be aware of production schedules and products ahead of the actual survey dates.

Recommendations

We recommend that ConAgra take the steps below to minimize potentially harmful exposures to its workers. These recommendations are based on our having observed high risk to mixers or quality control workers in other microwave popcorn plants, and the similarity of some processes and conditions in your plant to those in the other plants we have evaluated.

1. Slurry room:
    - Install a local exhaust hood to control exposures where the mixers measure and weigh flavorings.
    - Install local exhaust ventilation on any mix, hold, or return tanks that cannot be tightly sealed.
    - Maintain the slurry room under negative pressure relative to the rest of the plant.
    - Evaluate air flow patterns in the slurry room and, as needed, install a duct to deflect air (entering the room from ducts near the ceiling) downward toward the workers' breathing zones.
    - Regularly check and maintain all ventilation systems to minimize the possibility of a malfunction. Perform periodic sampling for diacetyl to verify that the ventilation systems in use are functioning optimally.
    - Institute mandatory respirator use for mixers and for any other workers that enter the slurry room as part of a formal respiratory protection program that adheres to the requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134). Workers require medical clearance for respirator use, fit testing on the respirator they will use before they are allowed to use it, and training on the hazards they are exposed to and on how to wear and maintain their respirator. You can get details on the Respiratory Protection Standard and on how your company can set up a respiratory protection program at the OSHA website (www.osha.gov). The minimum protective respirator that we recommend is a NIOSH-certified half face mask negative pressure respirator with organic vapor cartridges and particulate filters. A full facepiece respirator would provide additional eye protection. A loose-fitting powered air-purifying respirator with a particulate filter and organic vapor cartridge is an option to consider for increased worker comfort and does not require fit testing. Another option is a supplied-air respirator. Require that mixers and other workers wear their respirators whenever they are in the slurry room for any reason.

2. Quality control:
    - Install local exhaust ventilation for the microwave ovens used by workers to pop many bags of product for quality control.
    - Include quality control workers in your respiratory protection program and advise them to use a respirator for popping product (choose a respirator from the same options as for mixers), until local exhaust for the microwave ovens is installed and our medical survey is complete. If our survey shows that these workers are at risk for lung problems, you should require that they wear respirators until follow-up lung function testing shows that the local exhaust ventilation is preventing hazardous exposures.
    - Require that quality control workers wear a respirator whenever they enter the slurry room.

ConAgra should also implement these recommendations at its other microwave popcorn plants. Thank you for your continued assistance and please feel free to call with any questions that you have.

Sincerely,

Richard Kanwal, MD, MPH
Medical Officer

Greg Kullman, PhD, CIH
Respiratory Disease Hazard Evaluation and
Technical Assistance Program
Field Studies Branch
Division of Respiratory Studies

cc: Confidential requestors
HETAB (Hartle)
OSHA, Region 5

Enclosures

APPENDIX B

Questionnaire Used by NIOSH During March 2003 Medical Survey at ConAgra Snack Foods, Marion, Ohio

Interviewer: _____ Interview Date: __ __ / __ __ / __ __ __ __
(Month) (Day) (Year)

Section I: Identification and Demographic Information

Name: _____ _____ ____
(Last name) (First name) (MI)

Address:_____
(Number, Street, and/or Rural Route)

_____ _____ _____
(City) (State) (Zip Code)

Home Telephone Number: ( ) _____ - _____

If you were to move, is there someone who would know how to contact you?

Name: _____ _____ ____
(Last name) (First name) (MI)

Relationship to you:_____

Address:_____
(Number, Street, and/or Rural Route)

_____ _____ _____
(City) (State) (Zip Code)

Home Telephone Number: ( ) _____ - _____

~~~~~~

1. Date of Birth: __ __ / __ __ / __ __ __ __
(Month) (Day) (Year)

2. Sex: 1. ____ Male 2. ____ Female

3. Are you Spanish, Hispanic, or Latino? 1.____Yes 0.____No.

4. Select <u>one or more</u> of the following categories to describe your race:
1. ___ White
2. ___ African-American or Black
3. ___ Asian
4. ___ American Indian or Alaska Native
5. ___ Native Hawaiian or Other Pacific Islander
~~~~~~

Section II: Health Information

I'm going to ask you some questions about your health. The answer to many of these questions will be "Yes" or "No." If you are in doubt about whether to answer "Yes" or "No," then please answer "No."

5. During the last 12 months, have you had any trouble with your breathing? 1.____Yes 0. ____No

IF YES:

a) Which of the following statements best describes your breathing?
   1. ___ I only rarely have trouble with my breathing
   2. ___ I have regular trouble with my breathing but it always gets completely better
   3. ___ My breathing is never quite right

6. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? 1. ___ Yes 0. ___ No

IF YES:

a) Do you get short of breath walking with people of your own age on level ground? 1. ___ Yes 0. ___ No

b) Do you ever have to stop for breath when walking at your own pace on level ground? 1. ___ Yes 0. ___ No

c) Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on level ground? 1. ___ Yes 0. ___ No

d) In what month and year did this breathlessness start? __ __ / __ __ __ __
   (Month) (Year)

7. Do you usually have a cough? 1. ___ Yes 0. ___ No
(Count cough with first smoke or on first going out-of-doors. Exclude clearing of throat.)

IF YES:

a) Do you usually cough on most days for 3 consecutive months or more during the year? 1. ___ Yes 0. ___ No

b) In what month and year did this cough begin? __ __ / __ __ __ __
(Month) (Year)

8. Have you ever had wheezing or whistling in your chest? 1. ___ Yes 0. ___ No

IF YES:

a) Have you had this wheezing or whistling when you did not have a cold? 1. ___ Yes 0. ___ No

b) In what month and year did this wheezing or whistling begin? __ __ / __ __ __ __
(Month) (Year)

c) When you are away from this plant on days off or on vacation, is this wheezing or whistling
1. ___ Better
2. ___ The same
3. ___ Worse
4. ___ N/A

d) During the last 12 months, have you had this wheezing or whistling in your chest when you did not have a cold? 1. ___ Yes 0. ___ No

9. Have you ever had to change your job, job duties, or work area at this plant because of breathing difficulties? 1. ___ Yes 0. ___ No

IF YES:

a) What month and year did you change your job, job duties, or work area? __ __ / __ __ __ __
(Month) (Year)

b) What was your job, job duties, and/or work area before the change?

Describe: _____

c) How did your job, job duties, and/or work area differ after the change?

Describe:_____

d) Were your breathing problems after the change:

1. ___ Better
2. ___ The Same
3. ___ Worse

10. While working at this plant, have you had fever, chills or night-sweats? 1. ___ Yes 0. ___ No

IF YES:

a) How often have you had the fever, chills, or night-sweats?

1. ___ Rarely
2. ___ Monthly
3. ___ Weekly
4. ___ Daily

11. While working at this plant, have you had unusual tiredness or fatigue? 1. ___ Yes 0. ___ No

IF YES:

a) How often have you had the unusual tiredness or fatigue?

1. ___ Rarely
2. ___ Monthly
3. ___ Weekly
4. ___ Daily

12. Since you began working at this plant, have you ever had attacks of bronchitis? 1. ___ Yes 0. ___ No

IF YES:

a) Was it confirmed by a doctor? 1. ___ Yes 0. ___ No

b) While working at this plant, how many times have you had bronchitis? _____ Times

13. Have you ever had chronic bronchitis? 1. ___ Yes 0. ___ No

IF YES:

a) Was it confirmed by a doctor? 1. ___ Yes 0. ___ No

b) How old were you when it began? _____ Years old

14. Since you began working at this plant have you ever had pneumonia? (Include bronchopneumonia) 1. ___ Yes 0. ___ No

15. Have you ever had asthma? 1. ___ Yes 0. ___ No

IF YES:

a) How old were you when it began? _____ Years old

b) Was it confirmed by a doctor? 1. ___ Yes 0. ___ No

c) Do you still have it? 1. ___ Yes 0. ___ No

16. Have you ever had a pneumothorax, which is a collapsed lung? 1. ___ Yes 0. ___ No

17. Since working at this plant, have you had symptoms of nasal irritation such as a stuffy or blocked nose, an itchy nose, a stinging or burning nose, or a runny nose? (*apart from a cold*) 1. ___ Yes 0. ___ No

IF YES:

a) Is there an exposure at work that aggravates these nose symptoms? 1. ___ Yes 0. ___ No

b) Describe exposure(s):

_____

_____

18. While working at this plant, have you had nose bleeds more than once a month? 1. ___ Yes 0. ___ No

19. While working at this plant, have you ever coughed up blood? 1. ___ Yes 0. ___ No

20. Since working at this plant, have you had any symptoms of eye irritation such as : watering or tearing eyes, red or burning eyes, itching eyes, dry eyes? 1. ___ Yes 0. ___ No

IF YES:

a) Is there an exposure at work that aggravates these eye symptoms? 1. ___ Yes 0. ___ No

b) Describe exposure(s):

_____

_____

21. Since working at this plant, have you developed any new skin rash or skin problems? 1. ___ Yes 0. ___ No

Section III. Work Information

I'm now going to ask you questions about your work history at this plant.

22. Have you ever worked as a mixer, even for as little as one day? 1. ___Yes 0. ___No

IF YES:

a) How long have you worked (or did you work) as a mixer? _____ Years
_____ Months
_____ Days

b) When mixing, how many hours per day do you (or did you) spend in the slurry room? _____ hours/day

c) When mixing, do you (or did you) wear a respirator / dust mask while handling powdered flavorings?
_____ Yes, all of the time
_____ Yes, some of the time
_____ No

23. Have you ever worked as a mechanic? 1. ___Yes 0. ___No

IF YES:

a) How long have you worked (or did you work) as a mechanic? _____ Years
_____ Months
_____ Days

b) As a mechanic, how many hours per week do you (or did you) spend in the slurry room? _____ hours/week

24. Have you ever spent time in the slurry room while doing any other job at this plant? (exclude work as a mixer or mechanic) 1. ___Yes 0 ___No

25. Have you ever worked in the QA lab (quality assurance) popping bags in microwave ovens to check the product? 1. ___Yes 0. ___No

IF YES:

a) How long have you worked (or did you work) in the QA lab? _____ Years
_____ Months
_____ Days

b) When working in the QA lab, how many hours per day do you (or did you) spend in the QA lab? _____ hours/day

26. What is your usual work shift? _____

27. During an average work week, how many hours do you work? _____ Hours per week

28. Have you ever been exposed to a spill or unusual chemical release at work? 1.___ Yes 0.___ No

IF YES:

a) Did you have any symptoms from it? 1.___ Yes 0.___ No

IF YES:

b) What were your symptoms?

_____

29. Have you ever:

a)	Worked in mining?	1. ___ Yes	0. ___ No	IF YES: _____ Years
b)	Worked in farming?	1. ___ Yes	0. ___ No	IF YES: _____ Years
c)	Worked in chemical manufacturing like explosives, dyes, lacquers, and celluloid?	1. ___ Yes	0. ___ No	IF YES: _____ Years
d)	Been exposed to fire smoke? (Do not count campfires, stoves.)	1. ___ Yes	0. ___ No	IF YES: _____ Years
e)	Been exposed to irritant gases like chlorine, sulfur dioxide, ammonia, and phosgene?	1. ___ Yes	0. ___ No	IF YES: _____ Years
f)	Been exposed to mineral dusts including coal, silica, and talc?	1. ___ Yes	0. ___ No	IF YES: _____ Years
g)	Been exposed to grain dusts?	1. ___ Yes	0. ___ No	IF YES: _____ Years
h)	Been exposed to oxides of nitrogen including silo gas?	1. ___ Yes	0. ___ No	IF YES: _____ Years
i)	Been exposed to asbestos?	1. ___ Yes	0. ___ No	IF YES: _____ Years

j) Been exposed to any chemical or substance that affected your breathing? 1. ___ Yes 0. ___ No

IF YES to Question j):

k) Describe the exposure:

_____

I'm now going to ask you some questions about all the jobs that you have had while at this plant. We will start with your current job and work back through time.

					If Work Area is Press Room or Warehouse or Office	If Work Area is Maintenance	
Job Number	Major Work Area	Job Title	Start Date (MM/YYYY)	End Date (MM/YYYY)	Hours/ Day Spent in Production	Hours/ week Spent in Slurry Room	Comments

Section IV: Tobacco Use Information

I'm now going to ask you a few questions about tobacco use.

30. Have you ever smoked cigarettes? (*NO if less than 20 packs of cigarettes in a lifetime or less than 1 cigarette a day for 1 year*.) 1. ___ Yes 0. ___ No

IF YES:

a) How old were you when you first started smoking regularly? _____ Years old

b) Over the entire time that you have smoked, what is the average number of cigarettes that you smoked per day? _____ Cigarettes/day

c) Do you still smoke cigarettes? 1. ___ Yes 0. ___ No

IF NO:

d) How old were you when you stopped smoking regularly? _____ Years old

Thank you for participating in this survey!

APPENDIX C

Prevalence Ratios for Respiratory Symptoms, Self-Reported Respiratory Illness, and Abnormalities on NIOSH Spirometry Tests, as Reported in the October 2003 NIOSH Interim Report

Shortness of breath on exertion (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	4	1.6	2.5 (1.0-6.4)	62	11	14.0	0.8 (0.4-1.4)	80	15	15.6	1.0 (0.6-1.6)
40-69	10	3	2.1	1.4 (0.5-4.2)	20	6	6.1	1.0 (0.5-2.2)	30	9	8.2	1.1 (0.6-2.1)
Total	28	7	3.7	1.9 (0.9-3.9)	82	17	20.1	0.8 (0.5-1.4)	110	24	23.8	1.0 (0.7-1.5)
Slurry room and QA												
17-39	X	X	X	**5.0 (1.4-18.2)**	10	3	2.3	1.3 (0.4-3.8)	14	5	2.7	1.9 (0.8-4.3)
40-69	X	X	X	0.0 (0.0-19.2)	8	3	2.4	1.3 (0.4-3.7)	9	3	2.6	1.2 (0.4-3.4)
Total	5	2	0.6	3.3 (0.9-12.2)	18	6	4.7	1.3 (0.6-2.8)	23	8	5.3	1.5 (0.8-3.0)
Press												
17-39	4	1	0.4	2.5 (0.4-14.2)	14	1	3.2	0.3 (0.1-1.8)	18	2	3.6	0.6 (0.2-2.0)
40-69	2	0	0.4	0.0 (0.0-9.6)	12	4	3.6	1.1 (0.4-2.9)	14	4	4.0	1.0 (0.4-2.6)
Total	6	1	0.8	1.3 (0.2-7.1)	26	5	6.8	0.7 (0.3-1.7)	32	6	7.6	0.8 (0.4-1.7)

Exp =expected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

Chronic cough (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	0	0.4	0.0 (0.0-9.6)	62	10	8.1	1.2 (0.7-2.3)	80	10	8.5	1.2 (0.6-2.2)
40-69	10	1	0.6	1.7 (0.3-9.4)	20	3	2.9	1.0 (0.4-3.0)	30	4	3.5	1.1 (0.4-2.9)
Total	28	1	1.0	1.0 (0.2-5.7)	82	13	11.0	1.2 (0.7-2.0)	110	14	12.0	1.2 (0.7-2.0)
Slurry room and QA												
17-39	X	X	0.1	0.0 (0.0-38.4)	10	0	1.3	0.0 (0.0-3.0)	14	0	1.4	0.0 (0.0-2.7)
40-69	X	X	0.1	0.0 (0.0-38.4)	8	3	1.1	2.7 (0.9-8.0)	9	3	1.2	2.5 (0.9-7.4)
Total	5	0	0.2	0.0 (0.0-19.2)	18	3	2.4	1.3 (0.4-3.7)	23	3	2.6	1.2 (0.4-3.4)
Press												
17-39	4	0	0.1	0.0 (0.0-38.4)	14	1	1.8	0.6 (0.1-3.2)	18	1	1.9	0.5 (0.1-3.0)
40-69	2	0	0.1	0.0 (0.0-38.4)	12	4	1.7	2.4 (0.9-6.1)	14	4	1.8	2.2 (0.9-5.7)
Total	6	0	0.2	0.0 (0.0-19.2)	26	5	3.5	1.4 (0.6-3.3)	32	5	3.7	1.4 (0.6-3.2)

Exp =expected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

Wheezing apart from colds (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	2	1.1	1.8 (0.5-6.6)	62	22	10.1	**2.2 (1.4-3.3)**	80	24	11.2	**2.1 (1.4-3.2)**
40-69	10	1	0.8	1.3 (0.2-7.1)	20	5	3.3	1.5 (0.7-3.6)	30	6	4.1	1.5 (0.7-3.2)
Total	28	3	1.9	1.6 (0.5-4.6)	82	27	13.4	**2.0 (1.4-2.9)**	110	30	15.3	**2.0 (1.4-2.8)**
Slurry room and QA												
17-39	X	X	X	**10.0 (2.7-36.5)**	10	5	1.6	**3.1 (1.3-7.3)**	14	7	1.8	**3.9 (1.9-8.0)**
40-69	X	X	X	0.0 (0.0-38.4)	8	3	1.3	2.3 (0.8-6.8)	9	3	1.4	2.1 (0.7-6.3)
Total	5	2	0.3	**6.7 (1.8-24.3)**	18	8	2.9	**2.8 (1.4-5.4)**	23	10	3.2	**3.1 (1.7-5.6)**
Press												
17-39	4	0	0.2	0.0 (0.0-19.2)	14	4	2.3	1.7 (0.7-4.5)	18	4	2.5	1.6 (0.6-4.1)
40-69	2	0	0.2	0.0 (0.0-19.2)	12	4	2.0	2.0 (0.8-5.1)	14	4	2.2	1.8 (0.7-4.7)
Total	6	0	0.4	0.0 (0.0-9.6)	26	8	4.3	1.9 (0.9-3.7)	32	8	4.7	1.7 (0.9-3.4)

Exp =expected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

Asthma (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	7	1.2	**5.8 (2.8-12.0)**	62	9	5.5	1.6 (0.9-3.1)	80	16	6.7	**2.4 (1.5-3.9)**
40-69	10	0	0.7	0.0 (0.0-5.5)	20	2	1.7	1.2 (0.3-4.3)	30	2	2.4	0.8 (0.2-3.0)
Total	28	7	1.9	**3.7 (1.8-7.6)**	82	11	7.2	1.5 (0.9-2.7)	110	18	9.1	**2.0 (1.3-3.1)**
Slurry room and QA												
17-39	X	X	X	**6.7 (1.8-24.3)**	10	0	0.9	0.0 (0.0-4.3)	14	2	1.2	1.7 (0.5-6.1)
40-69	X	X	X	0.0 (0.0-38.4)	8	2	0.7	2.9 (0.8-10.4)	9	2	0.8	2.5 (0.7-9.1)
Total	5	2	0.4	**5.0 (1.4-18.2)**	18	2	1.6	1.3 (0.3-4.6)	23	4	2.0	2.0 (0.8-5.1)
Press												
17-39	4	0	0.3	0.0 (0.0-12.2)	14	0	1.2	0.0 (0.0-3.2)	18	0	1.5	0.0 (0.0-2.6)
40-69	2	0	0.1	0.0 (0.0-38.4)	12	3	1.0	3.0 (1.0-8.8)	14	3	1.1	2.7 (0.9-8.0)
Total	6	0	0.4	0.0 (0.0-9.6)	26	3	2.2	1.4 (0.5-4.0)	32	3	2.6	1.2 (0.4-3.4)

Exp =expected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

Chronic bronchitis (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	2	0.5	**4.0 (1.1-14.6)**	62	5	7.3	0.7 (0.3-1.6)	80	7	7.8	0.9 (0.4-1.9)
40-69	10	0	0.6	0.0 (0.0-6.4)	20	1	2.1	0.5 (0.1-2.7)	30	1	2.7	0.4 (0.1-2.1)
Total	28	2	1.1	1.8 (0.5-6.6)	82	6	9.4	0.6 (0.3-1.4)	110	8	10.5	0.8 (0.4-1.5)
Slurry room and QA												
17-39	X	X	0.1	0.0 (0.0-38.4)	10	0	1.2	0.0 (0.0-3.2)	14	0	1.3	0.0 (0.0-3.0)
40-69	X	X	0.1	0.0 (0.0-38.4)	8	1	0.8	1.3 (0.2-7.1)	9	1	0.9	1.1 (0.2-6.3)
Total	5	0	0.2	0.0 (0.0-19.2)	18	1	2.0	0.5 (0.1-2.8)	23	1	2.2	0.5 (0.1-2.6)
Press												
17-39	4	0	0.1	0.0 (0.0-38.4)	14	2	1.7	1.2 (0.3-4.3)	18	2	1.8	1.1 (0.3-4.1)
40-69	2	0	0.1	0.0 (0.0-38.4)	12	3	1.3	2.3 (0.8-6.8)	14	3	1.4	2.1 (0.7-6.3)
Total	6	0	0.2	0.0 (0.0-19.2)	26	5	3.0	1.7 (0.7-3.9)	32	5	3.2	1.6 (0.7-3.7)

Exp =e xpected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

Spirometry abnormalities (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	0	1.2	0.0 (0.0-3.2)	62	8	5.9	1.4 (0.7-2.7)	80	8	7.1	1.1 (0.6-2.2)
40-69	10	2	1.0	2.0 (0.6-7.3)	20	4	4.3	0.9 (0.4-2.4)	30	6	5.3	1.1 (0.5-2.5)
Total	28	2	2.2	0.9 (0.3-3.3)	82	12	10.2	1.2 (0.7-2.1)	110	14	12.4	1.1 (0.7-1.9)
Slurry room and QA												
17-39	X	X	X	3.3 (0.6-18.9)	10	1	1.0	1.0 (0.2-5.7)	14	2	1.3	1.5 (0.4-5.6)
40-69	X	X	X	0.0 (0.0-38.4)	8	4	1.7	2.4 (0.9-6.1)	9	4	1.8	2.2 (0.9-5.7)
Total	5	1	0.4	2.5 (0.4-14.2)	18	5	2.7	1.9 (0.8-4.3)	23	6	3.1	1.9 (0.9-4.2)
Press												
17-39	4	0	0.3	0.0 (0.0-12.8)	14	1	1.3	0.8 (0.1-4.4)	18	1	1.6	0.6 (0.1-3.5)
40-69	2	0	0.2	0.0 (0.0-19.2)	12	5	2.6	1.9 (0.8-4.5)	14	5	2.8	1.8 (0.8-4.2)
Total	6	0	0.5	0.0 (0.0-7.7)	26	6	3.9	1.5 (0.7-3.4)	32	6	4.4	1.4 (0.6-3.0)

Exp =expected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

Obstruction or mixed pattern on spirometry (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	0	0.4	0.0 (0.0-9.6)	62	5	2.4	2.1 (0.9-4.9)	80	5	2.8	1.8 (0.8-4.2)
40-69	10	0	0.3	0.0 (0.0-12.8)	20	4	2.4	1.7 (0.7-4.3)	30	4	2.7	1.5 (0.6-3.8)
Total	28	0	0.7	0.0 (0.0-5.5)	82	9	4.8	1.9 (1.0-3.6)	110	9	5.5	1.6 (0.9-3.1)
Slurry room and QA												
17-39	X	X	X	**10.0 (1.8-56.7)**	10	0	0.4	0.0 (0.0-9.6)	14	1	0.5	2.0 (0.4-14.2)
40-69	X	X	X	0.0 (0.0-128.1)	8	3	1.0	3.0 (1.0-8.8)	9	3	1.0	2.9 (1.0-8.8)
Total	5	1	0.1	**10.0 (1.8-56.7)**	18	3	1.4	2.1 (0.7-6.3)	23	4	1.5	2.6 (1.0-6.9)
Press												
17-39	4	0	0.1	0.0 (0.0-38.4)	14	0	0.5	0.0 (0.0-7.7)	18	0	0.6	0.0 (0.0-6.4)
40-69	2	0	0.1	0.0 (0.0-38.4)	12	4	1.5	2.7 (1.0-6.9)	14	4	1.6	2.5 (1.0-6.4)
Total	6	0	0.2	0.0 (0.0-19.2)	26	4	2.0	2.0 (0.8-5.1)	32	4	2.2	1.8 (0.7-4.7)

Exp =expected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

Restriction on spirometry (ratios in **bold** are statistically significant)

	Never Smokers				Current and Former Smokers				All Participants			
Work area age group	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)	No.	Obs #	Exp #	Obs/Exp (CI)
Packaging												
17-39	18	0	0.8	0.0 (0.0-4.8)	62	3	3.5	0.9 (0.3-2.5)	80	3	4.3	0.7 (0.2-2.1)
40-69	10	2	0.8	2.5 (0.7-9.1)	20	0	1.9	0.0 (0.1-3.0)	30	2	2.7	0.7 (0.2-2.7)
Total	28	2	1.6	1.3 (0.3-4.6)	82	3	5.4	0.6 (0.2-1.6)	110	5	7.0	0.7 (0.3-1.7)
Slurry room and QA												
17-39	X	X	0.2	0.0 (0.0-19.2)	10	1	0.6	1.7 (0.3-9.4)	14	1	0.8	1.3 (0.2-7.1)
40-69	X	X	0.1	0.0 (0.0-38.4)	8	1	0.8	1.3 (0.2-7.1)	9	1	0.9	1.1 (0.2-6.3)
Total	5	0	0.3	0.0 (0.0-12.8)	18	2	1.4	1.4 (0.4-5.2)	23	2	1.7	1.2 (0.3-4.3)
Press												
17-39	4	0	0.2	0.0 (0.0-19.2)	14	1	0.8	1.3 (0.2-7.1)	18	1	1.0	1.0 (0.2-5.7)
40-69	2	0	0.2	0.0 (0.0-19.2)	12	1	1.2	0.8 (0.2-4.7)	14	1	1.4	0.7 (0.1-4.1)
Total	6	0	0.4	0.0 (0.0-9.6)	26	2	2.0	1.0 (0.3-3.7)	32	2	2.4	0.8 (0.2-3.0)

Exp =expected number, Obs =observed number, CI=confidence interval, X=data not shown in order to maintain confidentiality of participants

APPENDIX D

Recommendations Made by NIOSH in October 2003 for a Spirometry Testing Program at the ConAgra Snack Foods Plant in Marion, Ohio

Purpose: To detect abnormal lung function in workers that may be related to inhalation of flavoring chemicals.

General Considerations

Spirometry is the most sensitive and reliable test to detect airways obstruction. Performance of spirometry must carefully follow the guidelines of the American Thoracic Society (enclosed) to ensure high quality tests. Worker spirometry test results should be reviewed by a physician who is aware of the potential for workplace exposure to flavoring chemicals to adversely affect lung function, has reviewed this Appendix, and the American Thoracic Society guidelines.

Who should be tested and how often?

- Mixers every three to four months
- Non-mixers who enter the slurry room need testing every six months
- QA workers (i.e., those who microwave many bags of product per work shift) every three to four months
- Workers newly assigned to work in the QA lab, the slurry room, or in a job requiring entry into slurry room need a baseline test prior to starting work in these areas.

Criteria

- Airways obstruction: FEV1/FVC ratio below the lower limit of normal as indicated by the Hankinson 1999 spirometry reference values (reference enclosed).
- Excessive decline in FEV1: A decrease greater than 15 % from the baseline value.

Abnormal Spirometry or Excessive Decline in FEV1: How to Proceed?

- Abnormal spirometry in new worker:
  - Refer the worker to their personal physician for evaluation (unless he/she has already had an evaluation and/or diagnosis).
  - Avoid placement of the worker in the QA lab or a mixing job, or job requiring entry into slurry room.
- New airways obstruction, or decline in FEV1 greater than 15 % from the baseline, in a current worker
  - Refer the worker to an occupational medicine physician or pulmonary specialist for further evaluation which may include the following medical tests:
    - Full pulmonary function testing with spirometry followed by bronchodilator, diffusing capacity (DLCO), and lung volumes
    - Chest x-ray
    - High resolution chest CT scan with inspiratory and expiratory views
  - Provide the physician with information on flavoring-related lung disease (e.g., August 2002 New England Journal of Medicine article (enclosed), or NIOSH *Alert* (when published)).
  - Prevent any further exposure of the worker to flavoring chemicals if the physician diagnoses flavoring-related lung disease or other lung disease that may be exacerbated by exposure to flavoring chemicals.

Additional Considerations

- Any suspicion of flavoring-related lung disease in a current worker should prompt an evaluation of the workplace to identify any contributing factors. These may include:
  - Ventilation or other equipment malfunction
  - Lack of worker compliance with, or understanding of, company policies regarding respiratory protection or work practices to prevent exposure to flavoring-related chemicals.

    - Inadequate exposure controls
- The 15% fall in FEV1 criterion for referral of workers for additional medical evaluation should be reassessed in two years. The results of these evaluations may indicate the need for a lower threshold for referring workers.

EVALUATION CRITERIA

To assess the hazards posed by workplace exposures, NIOSH investigators use a variety of environmental evaluation criteria. These criteria suggest exposure levels to which most workers may be exposed for a working lifetime without experiencing adverse health effects. However, because of wide variation in individual susceptibility, some workers may experience occupational illness even if exposures are maintained below these limits. The evaluation criteria do not take into account individual hypersensitivity, pre-existing medical conditions, possible interactions with other work place agents, medications being taken by the worker, or environmental conditions.

The primary sources of evaluation criteria for the workplace are: NIOSH Criteria Documents and Recommended Exposure Limits (RELs)[1], the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs)[2], and the American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Values (TLVs®).[3] The objective of these criteria for chemical agents is to establish levels of inhalation exposure to which the vast majority of workers may be exposed without experiencing adverse health effects.

Occupational health criteria are established based on the available scientific information provided by industrial experience, animal or human experimental data, or epidemiologic studies. Differences between the NIOSH RELs, OSHA PELs, and ACGIH® TLVs® may exist because of different philosophies and interpretations of technical information. It should be noted that RELs and TLVs are guidelines, whereas PELs are standards which are legally enforceable. OSHA PELs are required to take into account the technical and economical feasibility of controlling exposures in various industries where the agents are present. The NIOSH RELs are primarily based upon the prevention of occupational disease without assessing the economic feasibility of the affected industries and as such tend to be conservative. A Court of Appeals decision vacated the OSHA 1989 Air Contaminants Standard in *AFL-CIO v OSHA,* 965F.2d 962 (11th cir., 1992); and OSHA is now enforcing the previous 1971 standards (listed as Transitional Limits in 29 CFR 1910.1000, Table Z-1-A). However, some states which have OSHA-approved State Plans continue to enforce the more protective 1989 limits. NIOSH encourages employers to use the 1989 limits or the RELs, whichever are lower.

Evaluation criteria for chemical substances are usually based on the average personal breathing zone exposure to the airborne substance over an entire 8- to 10-hour workday, expressed as a time-weighted average (TWA). Personal exposures are usually expressed in parts per million (ppm), milligrams per cubic meter (mg/m^3), or micrograms per cubic meter ($\mu g/m^3$). To supplement the 8-hour TWA where there are recognized adverse effects from short-term exposures, some substances have a short-term exposure limit (STEL) for 15-minute peak periods; or a ceiling limit, which is not to be exceeded at any time. Additionally, some chemicals have a "skin" notation to indicate that the substance may be absorbed through direct contact of the material with the skin and mucous membranes.

It is important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these occupational health exposure criteria. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, previous exposures, and/or hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other work place exposures, or with medications or personal habits of the worker (such as smoking, etc.) to produce health effects even if the occupational exposures are controlled to the limit set by the evaluation criterion. These combined effects are often not considered by the chemical specific evaluation criteria. Furthermore, many substances are appreciably absorbed by direct contact with the skin and thus potentially increase the overall exposure and biologic response beyond that expected from inhalation alone. Finally, evaluation criteria may change over time as new information on the toxic effects of an agent become available. Because of these reasons, it is prudent for an employer to maintain worker exposures well below established occupational health criteria.

Diacetyl, Acetoin, and 2-Nonanone

The ketones, diacetyl, acetoin, and 2-nonanone are predominant components of artificial butter flavorings and are extremely irritating to skin, eyes, mucous membranes and the respiratory tract. Currently, there are no NIOSH, OSHA, or ACGIH® occupational exposure standards or guidelines for them.

Acetaldehyde

Acetaldehyde is a colorless liquid used as a flavoring agent and adjuvant. When ingested or inhaled it can irritate the eye, nose, and throat. The Food and Drug Administration regulates it as a direct food additive and a synthetic flavoring substance. The OSHA PEL is 200 ppm (8-hour TWA). Acetaldehyde is considered a potential occupational carcinogen by the U.S. Environmental Protection Agency (EPA), the International Agency for Research on Cancer (IARC), and NIOSH. For this reason NIOSH recommends that occupational exposure levels of acetaldehyde be kept at the lowest feasible concentration (LFC). ACGIH® has a ceiling limit of 25 ppm.

Acetic acid and Butyric acid

Acetic acid is a colorless liquid with a strong vinegar-like odor. It is used in making dyes, drugs, plastics, food additives, and insecticides. The OSHA PEL is 10 ppm (8-hour TWA). NIOSH has an REL of 10 ppm (10-hour TWA) and a ceiling limit of 15 ppm. ACGIH® also has a TLV® of 10 ppm (8-hour TWA) and a ceiling limit of 15 ppm.

Butyric acid is a colorless liquid with the smell of rancid butter. It is a low molecular weight fatty acid and can be found as a fermentation product in butter and beer. It is used in the manufacture of plastics. Currently, there are no NIOSH, OSHA, or ACGIH® occupational exposure standards or guidelines.

Volatile Organic Compounds

Volatile organic compounds (VOCs) describe a large class of chemicals which are organic (i.e., containing carbon) and have a sufficiently high vapor pressure to allow some of the compound to exist in the gaseous state at room temperature. These compounds are emitted in varying concentrations from numerous indoor sources and chemicals including, but not limited to, carpeting, fabrics, adhesives, solvents, paints, cleaners, waxes, cigarettes, combustion sources, and the flavorings used in the production of microwave popcorn.

Studies have measured wide ranges of VOC concentrations in indoor air as well as differences in the mixtures of chemicals which are present. Research also suggests that the irritant potency of these VOC mixtures can vary. The use of total VOC concentration as an indicator, however, has never been standardized and neither NIOSH nor OSHA currently has specific exposure criteria for VOC mixtures.

Particulates, Not Otherwise Classified

Often the chemical composition of the airborne particulate does not have an established occupational health exposure criterion. It has been the convention to apply a generic exposure criterion in such cases. Formerly inappropriately referred to as "nuisance" dust, the preferred terminology for the non-specified particulate is now *"particulates, not otherwise classified" (PNOC)* (ACGIH® TLV®), or *"particulates, not otherwise regulated" (PNOR)* (OSHA PEL).

The OSHA PELs for PNOR are 15.0 mg/m^3 (total dust) and 5.0 mg/m^3 (respirable fraction), determined as 8-hour averages. The ACGIH® recommended TLV® for exposure to PNOC is 10.0 mg/m^3 (total dust, 8-hour TWA) and 3 mg/m^3 (respirable dust). [See page 5 of this report]. These are generic criteria for airborne dusts which do not

produce significant organic disease or toxic effect when exposures are kept under reasonable control. These criteria are not appropriate for dusts that have a biologic effect and may not be appropriate for evaluating general particulate matter in microwave popcorn packaging facilities.

References

1. NIOSH [2003]. Pocket guide to chemical hazards. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) publication No.97-140.

2. CFR [1997]. 29 CFR 1910.1000 Code of Federal Regulations. Washington, DC: U.S. Government Printing Office, Office of the Federal Register.

3. ACGIH [2003]. 2003 TLVs® and BEIs®; threshold limit values for chemical substances and physical agents. Cincinnati, OH: American Conference of Governmental Industrial Hygienists.

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