NIOSH HEALTH HAZARD EVALUATION REPORT

HETA #2001-0474-2943
American Pop Corn Company
Sioux City, Iowa

July 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 (OSHA) 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 Dr. Richard Kanwal, Randy Boylstein, and Chris Piacitelli of the Field Studies Branch (FSB), Division of Respiratory Disease Studies (DRDS). Field assistance was provided by Daniel Yereb, Stephen Martin, and Thomas Jefferson. In addition, the following DRDS staff assisted in the medical Survey: Diana Freeland, Terry Rooney, Christie Kerrigan, Jennifer Keller, Susan Englehart, Jim Taylor, and David Spainhour. Analytical support was provided by DataChem Laboratories. Desktop publishing was performed by Terry Rooney. Review and preparation for printing were performed by Penny Arthur.

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For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

Highlights of the NIOSH Health Hazard Evaluation At American Pop Corn Company, Sioux City, Iowa

After NIOSH identified a risk for lung disease in workers exposed to airborne butter flavoring chemicals at a microwave popcorn plant in Missouri, the Iowa Department of Public Health asked NIOSH to see if workers at American Pop Corn Company were also at similar risk.

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 mixing room (other areas in the plant had very low levels).
- Diacetyl air concentrations in the mixing room were highest when liquid and paste-type flavorings were used.
- Mixers' exposure to diacetyl increased greatly when pouring flavorings into tanks.
- Some of the dust in the air from powdered flavorings was small enough that it could be inhaled into the lung.
- Six of 13 workers with experience as mixers had abnormal lung function.
- Aside from mixers, workers in other areas of the plant did not appear to be at risk.

What Managers Can Do

- Identify engineering solutions to decrease the potential for exposures to flavoring chemicals in the mixing room.
- Train workers on the potential health risks from exposures to flavorings and on the best ways to minimize exposures.
- Assure that all workers who enter the mixing room wear NIOSH-approved respirators that protect against dust and organic vapors (Provide respirators as part of a formal respiratory protection program that adheres to the requirements of the OSHA Respiratory Protection Standard.)
- Perform regularly scheduled spirometry tests for all workers that enter the mixing room or work in the QC lab.
- Periodically measure the amount of flavoring chemicals in the air, especially when processes or flavorings are changed.

What Employees Can Do

For all workers that enter the mixing room:

- Know how to properly wear and maintain your respirator.
- Wear your respirator 100 percent of the time when in the mixing 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 QC lab workers and all workers that enter the mixing 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.

CDC Workplace Safety and Health

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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 #2001-0474-2943

NIOSH

Health Hazard Evaluation Report 2001-0474-2943
American Pop Corn Company
Sioux City, Iowa
July 2004

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SUMMARY

In July 2001, NIOSH received a request for technical assistance from the Iowa Department of Public Health to evaluate the risk for lung disease in American Pop Corn Company workers exposed to butter flavorings. This request was made after NIOSH investigated severe fixed obstructive lung disease consistent with bronchiolitis obliterans in former workers of a microwave popcorn plant in Missouri and identified an association between occupational lung disease and exposure to butter flavoring vapors.

NIOSH conducted a walk-through survey at the American Pop Corn Company plant in Sioux City, Iowa on September 26, 2001. Limited industrial hygiene air sampling on that day showed that air concentrations of diacetyl, a predominant butter flavoring chemical measured as a marker of butter flavoring exposure, were very low compared to levels that were associated with abnormal lung function at the Missouri (index) plant. The company reported that workers who handled flavorings had used full-facepiece respirators with particulate filters and organic vapor cartridges since shortly after the microwave popcorn plant began operating in December 1988. In June 2002, the company informed NIOSH that one of its mixing room workers had been diagnosed with fixed obstructive lung disease consistent with bronchiolitis obliterans. NIOSH conducted a medical survey from July 22 through July 26, 2002, and an industrial hygiene survey from July 29 through August 1, 2002. The main findings from these surveys included:

- The mixing room was isolated and ventilated separately from the packaging area;
- All tanks of heated soybean oil and flavorings were located in the mixing room and had local exhaust ventilation;
- Workers (mixers) measured flavorings in open containers in a separate area in the warehouse and then carried the flavorings into the mixing room and poured the flavorings into open tanks of heated soybean oil;
- Area diacetyl air concentrations in the mixing room were 0.57 parts per million (ppm) parts air by volume when liquid and paste flavorings were in use on July 29 and were below the limit of detection of the sampling method when powder flavorings were in use on July 31 and August 1;
- Personal diacetyl exposures for the mixers for the three days of sampling were 0.04, 0.004, and 0.005 ppm respectively;
- Mixers' exposure to diacetyl increased to 80 to 120 ppm for several minutes while pouring liquid butter flavoring into a tank;

- Six of 13 workers with experience as mixers had abnormal lung function (three with fixed obstruction and three with restriction);
- The average percentage of time that workers reported using respirators when in the mixing room prior to June 2002 was 20 percent (workers usually did not wear respirators when handling flavorings in the warehouse);
- The highest measured diacetyl air concentration in the packaging area was 0.03 ppm;
- Apart from workers with mixing experience, the prevalence of abnormal lung function in microwave popcorn plant workers did not differ significantly from the prevalence in non-microwave popcorn plant workers, and was similar to the expected prevalence based on national general population surveys;
- Unlike the index plant, risk for lung disease in workers who popped many dozens of bags of product in microwave ovens per shift was not identified in this plant (these workers popped fewer bags per shift than at the index plant).

NIOSH conducted an industrial hygiene survey on September 17 and 18, 2003 to measure air concentrations of respirable and total dust during the handling of powdered flavorings. This survey showed that:

- Air concentrations varied depending on the particular powdered flavoring being handled and the manner in which it was handled
- Some of the airborne dust was of respirable size

The findings from the NIOSH medical and industrial hygiene surveys at this plant show an apparent risk for lung disease in mixing room workers at much lower air concentrations of butter flavoring chemicals than those initially measured at the Missouri index plant. Lung disease risk was not identified in other areas of the plant apart from mixing. 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

In July 2001, NIOSH received a request for technical assistance from the Iowa Department of Public Health to evaluate the risk for lung disease in American Pop Corn Company workers exposed to butter flavorings. This request was made after NIOSH investigated a cluster of severe fixed obstructive lung disease consistent with bronchiolitis obliterans in former workers of a microwave popcorn plant in Missouri and identified an association between occupational lung disease and exposure to butter flavoring vapors.

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]

NIOSH's first visit to American Pop Corn occurred on September 26, 2001, during which a walkthrough of the plant and limited industrial hygiene air sampling was performed. The air concentrations of diacetyl were very low compared to levels that were associated with abnormal lung function at the Missouri (index) plant (See Appendix A). Company management reported that general dilution ventilation and local exhaust ventilation of tanks in the mixing room, and mandatory use of full facepiece respirators with organic vapor cartridges and particulate filters by mixing room workers, had been implemented soon after the start of microwave popcorn production in December 1988.

In June 2002, the company informed NIOSH that a 37 year-old mixer (for six years) of soybean oil and butter flavorings for microwave popcorn production had just been diagnosed by a pulmonologist as having medical findings consistent with bronchiolitis obliterans. A NIOSH physician interviewed this worker and reviewed his medical records. His medical history and test results, including moderate to severe fixed obstruction on spirometry and a chest computerized tomography (CT) scan showing a mosaic pattern of lung attenuation bilaterally, were consistent with this diagnosis. The company also reported that a former mixer now working in another job at the plant had experienced declines in lung function over the past several years. NIOSH performed a detailed medical and environmental survey to further characterize the risk for lung disease in mixers and other microwave popcorn production workers.

METHODS

Medical Evaluation

NIOSH performed a medical survey from July 22 through July 26, 2002. All current employees in all areas of the plant (microwave popcorn plant workers, other production workers, and office workers), and former employees who had worked as oil and flavoring mixers or in the quality control lab in microwave popcorn production, were invited to participate. After obtaining signed informed consent from participants, NIOSH interviewers administered a standardized questionnaire (see Appendix B) to collect information on symptoms, medical diagnoses, smoking history, work history, and work-related exposures. NIOSH technicians performed spirometry tests using a dry rolling seal spirometer interfaced to a personal computer and following American Thoracic Society guidelines,[5] with results compared to spirometry reference values generated from the Third National Health and Nutrition Examination Survey (NHANES III).[6] 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. Borderline obstruction was defined as an FEV1/FVC ratio below the lower limit of normal with a normal FEV1. 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. Reversible obstruction was defined as an improvement in the FEV1 of at least 12% and at least 200 milliliters after administration of albuterol. The prevalences of respiratory and other symptoms, self-reported medical diagnoses, and spirometry abnormalities among microwave popcorn production workers were compared to those of other workers in the plant. These prevalences were also compared to national data derived from NHANES III.[7]

SAS software[8] was used to perform Chi-square, Fisher's exact test, and logistic regression analyses. A probability (p) value of 0.05 or less was used as the criterion for statistical significance (i.e., a 5 percent or less probability that the difference observed was due to chance). Unless specifically noted, the results and analyses presented below are based on current worker questionnaire responses and spirometry test results.

Survey participants' test results were mailed to their home addresses on August 27, 2002. A letter from NIOSH to company management on November 18, 2002 summarized analyses of the data from the medical survey and provided relevant recommendations.

Industrial Hygiene Evaluation

From July 29 through August 1, 2002, NIOSH performed an industrial hygiene survey that consisted of an inspection of the entire microwave popcorn production process, air sampling for butter flavoring chemicals as well as total and respirable dust, and collection of bulk flavoring samples. A letter from NIOSH to company management on February 28, 2003 provided air sampling results and relevant recommendations.

Quantitative area air sampling was performed for diacetyl, acetoin, 2-nonanone, total hydrocarbons, butyric acid, acetic acid, acetaldehyde, and total and respirable dust. In addition, diacetyl, acetoin, and 2-nonanone were collected on personal samplers. Diacetyl, acetoin, and 2-nonanone were collected on carbon molecular sieve (CMS) tubes at a flow rate of 50 cubic centimeters per minute (cc/min) and were analyzed quantitatively by gas chromatography (GC) according to NIOSH Method 2557.[9] Total hydrocarbons were collected on coconut shell charcoal (CSC) tubes at a flow rate of 100 cc/min and analyzed by GC according to NIOSH Method 1550.[9] Butyric and acetic acid were collected on silica gel sorbent tubes at a flow rate of 500 cc/min and analyzed by high pressure liquid chromatography (HPLC) according to NIOSH Method 7903.[9] Acetaldehyde was collected on solid sorbent tubes (XAD-2) at a flow rate of 50 cc/min and analyzed by GC according to NIOSH Method 2538.[9] Total dust samples were collected at a flowrate of 2.0 liters per minute (lpm) and respirable dust samples at 4.2 lpm on polyvinyl chloride (PVC) filters behind BGI Respirable/Thoracic Cyclones™ and analyzed gravimetrically according to NIOSH Methods 0500 and 0600, respectively.[9]

Area air samples were collected using semi-quantitative sampling methods to assess the types of volatile organic compounds (VOCs) present in air during the production of microwave popcorn. The samples were collected on thermal desorption tubes at a flow rate of 20 cc/min and were analyzed by gas chromatography with a mass selective detector according to NIOSH Method 2549.[9]

A Gasmet DX-4010™ Fourier Transform Infrared (FTIR) Gas Analyzer (Temet Instruments Oy, Helsinki, Finland) was used to detect peak levels of selected volatile organic chemicals (VOCs) present in the breathing zones of workers during normal activities. The sampling was simultaneously videotaped in order to determine the process or task associated with a particular peak air concentration. During personal sampling the FTIR detection tube was attached to the worker in the breathing zone.

One pair of North 7581™ organic vapor/P100 respirator cartridges, previously worn by a mixer under normal working conditions for approximately 33 hours during mixing tasks, was collected to determine the remaining capacity of the carbon media in the cartridges under laboratory conditions. Carbon tetrachloride (CCl_4) was used to determine the remaining capacity of the carbon media in the cartridges. This test is similar to that described in 42 CFR 84, Subpart L, *Chemical Cartridge Respirators* (Section 84.204). Each respirator cartridge was enclosed inside an exposure chamber having a constant concentration of 1000 ppm CCl_4. A vacuum pump was used to pull air from the exposure chamber through the respirator cartridge at 32 lpm. The temperature and relative humidity were maintained throughout the test at 25 °C and 50%, respectively. A Foxboro MIRAN 1A Infrared Analyzer was used to monitor the concentration of CCl_4 downstream of the respirator cartridge. Breakthrough was considered to have occurred when the downstream CCl_4 vapor concentration reached 5 ppm. The percentage of carbon capacity remaining in the used respirator cartridges was determined by the equation:

$$\text{remaining carbon capacity (\%)} = (t_{used} / t_c) \times 100$$

where t_{used} is the time it took for breakthrough to occur with the used cartridges, and t_c is the time it took for breakthrough to occur through new control cartridges of the same model and lot.

On September 17 and 18, 2003, NIOSH returned to the American Pop Corn Company plant and used Grimm™ real-time optical particle counters (OPC) (Grimm Technologies, Inc., Douglasville, GA), with simultaneous videotaping, to determine airborne particulate levels and particle sizes of dust generated during the handling of four different powdered butter flavors. These measurements were obtained while a NIOSH investigator scooped the powders from their containers into a weighing tub in 3 different handling manners: *easy* – simulating an operator gently scooping powder; *hurried* – mimicking a worker who might be rushed while performing the task; and *dropped* – where the powder was dropped from a height of 1 foot into the tub to simulate an extremely hastened transfer of powder.

RESULTS

Industrial Hygiene Results

Microwave Popcorn Production Process

The American Pop Corn Company plant consists of several buildings. One of these is used solely for activities related to the production of microwave popcorn. Other activities, such as cleaning and storing of kernel popcorn, packaging of popcorn for non-microwave use, and office work, occur in other buildings on the plant property.

In microwave popcorn production, kernel popcorn is combined with a mixture of soybean oil, salt, flavorings, and colorings in microwave bags. The oil and flavorings mixture is produced in a mixing room (approximately 20 by 25 feet) which opens to a common hallway through a double door. In this room, one or two workers (i.e., mixers) per shift fill 400-gallon and 500-gallon mixing tanks with heated soybean oil and add salt to the oil through a high shear mixer. (During the survey, tank temperatures ranged from 131º to 134º Fahrenheit.) Coloring and flavorings are measured by hand in a storage area (located in the warehouse) and manually added to the mixing tanks in the mixing room. The mixture is piped to other tanks in the mixing room and then to the packaging lines. The tanks have loose-fitting lids and local exhaust ventilation. The local exhaust air moves through a scrubber before being vented outdoors. The mixing room is on a general dilution ventilation system that is separate from other plant areas; this system is designed to move air into the mixing room from the plant's ventilation system and then out of the building through an exhaust vent. NIOSH testing with smoke indicator tubes showed the mixing room to be under negative pressure with respect to the hallway. During the NIOSH survey, mixing room workers wore full-facepiece, air-purifying respirators with organic vapor cartridges and particulate filters while they were in the mixing room.

The flavoring storage area in the warehouse (approximately 10 by 20 feet) has solid walls on three sides and thick plastic sheeting on its fourth side separating it from the rest of the warehouse. A refrigeration unit cools and recirculates air in this room. There was no additional ventilation in this area at the time of the survey. During the NIOSH survey, mixing room workers wore full-facepiece respirators while handling open containers of flavorings. Some flavorings are stored in a refrigerator located adjacent to this storage area in the warehouse. Containers of flavorings were kept sealed when not being used. Some empty, open flavoring containers (five-gallon buckets) containing residual flavorings were located outside the storage area on a nearby pallet in the warehouse. Company management informed NIOSH that this practice was discontinued within one week of the survey.

Packaging of microwave popcorn occurs in a large room across the hallway from the mixing room. The hallway entrance to this room was kept closed and this room had a general dilution ventilation system separate from the mixing room and flavoring storage areas. Some of the entrances to this room from the warehouses were kept open. This room had eight packaging lines where packaging machines combine kernel popcorn (from holding bins located in a room above the machines) with the oil and flavorings mixture (piped from the mixing room) in microwave bags that are then sealed. Additional machines are used to place the bags into cartons and boxes. There were approximately 15-30 workers in this room per shift.

In the quality control (QC) lab (approximately 10 by 15 feet in size) one worker per shift uses several commercial microwave ovens to test recently produced microwave popcorn products. This worker microwaves approximately 75 bags of microwave popcorn per nine-hour work shift. The room had a strong odor of butter flavor. Testing with smoke indicator tubes showed the lab to be under negative pressure with respect to the hallway. The lab had only general dilution ventilation in July 2002. During the survey in September 2003, NIOSH observed that a local exhaust hood system had been installed to exhaust air from the microwave ovens and the weigh station area in the lab. QC workers reported that the air quality had improved in the lab due to these changes. (The butter odor was much less intense than in July 2002.) Visual testing with smoke indicator tubes showed that the hood appeared to be able to exhaust the intended work zone adequately.

Environmental Measurements

Table 1 lists the means and ranges for diacetyl, total dust, and respirable dust time-weighted average (TWA) air concentrations for twelve different job categories. Diacetyl concentrations (area and personal combined) are reported in parts per million parts air by volume (ppm).

Total and respirable dust concentrations are reported in milligrams per cubic meter of air (mg/m^3). The mean diacetyl air concentration in the mixing room was 0.08 ppm and the highest measured concentration was 0.57 ppm. The highest measured diacetyl air concentration in the packaging area (bartelt operator) was 0.03 ppm. Total dust concentrations in the mixing room ranged from 1.4 mg/m^3 to 3.8 mg/m^3. Respirable dust in the mixing room ranged from 0.09 to 0.31 mg/m^3. Ambient total dust levels ranged from 0.02 mg/m^3 to 0.40 mg/m^3 and all other total dust levels in the plant were below 0.40 mg/m^3. 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).

Table 2 shows the mixing room air concentrations of diacetyl on three different days for both area and personal samples. When only powdered flavorings were used, area air concentrations were below the limit of detection of 0.001 ppm diacetyl compared to 0.57 ppm when a liquid and a paste flavoring were used. The highest concentration measured in the mixers' breathing zones (0.05 ppm) when a liquid and a paste flavoring were in use was 10 times higher than the highest concentration measured on the other days when only powder flavorings were used.

Other analytes sampled throughout the plant were generally below the limit of detection of the sampling method used (or were present at low levels) and are not presented in tabular format. Acetoin levels ranged from less than the minimum detectable concentration of 0.002 ppm to a maximum of 0.03 ppm (personal sample from a mixer). Levels of 2-nonanone ranged from less than the minimum detectable concentration of 0.001 ppm to a maximum of 0.02 ppm (area sample at a packaging machine operators station). Acetic acid was detected in only three out of thirty samples at just above the minimum detectable concentration of 0.02 ppm. Butyric acid was not detected in any of the thirty samples collected above the minimum detectable concentration of 0.03 ppm. Acetaldehyde was detected in sixteen out of twenty-nine samples but all measured concentrations were between the minimum detectable concentration of 0.007 ppm and the minimum quantifiable concentration of 0.024 ppm.

Figures 1A-C show results of the semi-quantitative area air samples collected to assess the types of volatile organic compounds (VOCs) present in the air of the mixing room during the production of microwave popcorn. Figure 1A is the chromatogram from a day when the company used only paste and liquid flavorings and Figures 1B and 1C are from two days when only powdered flavorings were used. The diacetyl peak (peak #20) goes off scale on the day that pastes and liquids were used and is almost non-detectable on the two consecutive days when only powder flavors were used. (See Figure 1D for identification of the chemicals represented by the various peaks in Figures 1A-C.)

Table 3 shows the levels of total hydrocarbons found at various locations throughout the plant during three days of sampling. The analysis excluded the contribution of both diacetyl and acetoin but represents all other hydrocarbons present in the air, which could include cleaners and solvents used in the plant.

Figure 2 shows an example of the results of FTIR real-time monitoring for diacetyl and simultaneous videotaping in the mixing room while liquid and paste flavors were being used on July 30, 2002. Diacetyl levels peaked at 83 ppm near the breathing zone of a mixer for approximately five minutes during mixing activities, which included pouring several five-gallon containers of liquid butter flavoring into mixing tanks.

The respirator cartridge capacity evaluation of a pair of North 7581™ OV/P100 cartridges used by mixers at American Pop Corn Company revealed that an average of 97.8% of the carbon media's capacity to filter out organic vapors within the cartridges remained after 33 reported hours of normal use by a mixer.

During the September 2003 survey, three different techniques for hand-scooping four different powder flavorings were used to simulate possible worker situations. Figure 3 shows the dust air concentrations generated during these simulations. The handling of all four powders generated airborne dust that contained particles of respirable size. The highest levels of dust occurred when the powders were dropped into a weighing tub. One of the flavors, Powder 2 (oiled), had been misted with soybean oil by the flavoring manufacturer at the request of American Pop Corn due to the original product's dustiness. The oil-misted powder generated much less dust, even when the product was dropped from a height of one foot.

Medical Results

Participation

One hundred fifty-seven of 193 (81%) current plant employees participated in the survey. This included 87 of 103 (84%) from microwave popcorn production and 70 of 90 (78%) from all other areas of the plant. An additional 8 former workers also participated.

Symptoms

Table 4 contains questionnaire data on the prevalences of several symptoms including reported trouble breathing in the last 12 months, shortness of breath on exertion, cough, wheezing, fever and chills, and unusual fatigue, according to work area and smoking status for current workers. Fourteen percent of microwave popcorn production workers and nineteen percent of other plant workers reported having had any trouble breathing during the last 12 months. Current and former smokers in both groups of workers reported this finding more often than nonsmokers. Shortness of breath when "hurrying on level ground or walking up a slight hill" was more common among current and former smokers in microwave popcorn production (44%) than it was among current and former smokers in other areas of the plant (25%). Shortness of breath when "walking with people your own age on level ground" was reported by eight percent of microwave popcorn production workers and by three percent of workers in other areas of the plant. A large proportion of workers reporting shortness of breath on exertion said that it started after they began working at the plant. Usual cough was reported by similar percentages of workers from microwave popcorn production (19%) and other areas of the plant (20%). Chronic cough (cough on most days for three consecutive months or more during the year) with onset after hire was more common among current and former smokers in microwave popcorn production (12%) than among current and former smokers in other areas of the plant (5%), but the numbers in these categories were small. Similar percentages of workers in both microwave popcorn production (7%) and other areas of the plant (9%) reported wheezing apart from colds with onset after hire. Frequent fever, chills, and night sweats were also reported by six percent of workers in microwave popcorn production and ten percent of workers in other areas of the plant. Unusual fatigue lasting more than a few days or occurring frequently was reported by seventeen percent of workers in microwave production and by eleven percent of workers in other areas of the plant. Overall, none of the observed differences regarding any symptoms between ever-smokers in microwave production and ever-smokers in other areas of the plant were statistically significant. The same was true for never-smokers. When compared to national data from NHANES III after adjusting for age, sex, race, and smoking history, the prevalences among microwave popcorn production workers of shortness of breath when "hurrying on level ground or walking up a slight hill", chronic cough, and wheezing apart from colds were similar to expected prevalences (Tables 5 and 6).

Spirometry Abnormalities and Worker Reports of Respiratory Illnesses

Table 7 contains the prevalences of abnormalities on NIOSH spirometry testing and self-reported history of bronchitis, chronic bronchitis, pneumonia, and asthma in current workers. Bronchitis was reported by ten percent of workers in microwave popcorn production and by thirteen percent of workers in other areas of the plant. Chronic bronchitis with onset after hire was reported infrequently in microwave popcorn production and other areas of the plant. Pneumonia was reported by five percent of workers in microwave popcorn production and by nine percent of workers in other areas of the plant. Asthma was reported most frequently among current and former smokers in other areas of the plant (18%). Few microwave popcorn production workers reported asthma and none reported onset after hire. The difference in onset of asthma after hire in microwave popcorn production workers (0%) compared to workers in other areas (9%) was statistically significant. Otherwise, there were no statistically significant differences between ever-smokers in microwave popcorn production and ever-smokers in other areas of the plant with regard to reported respiratory illnesses. The same was true for never-smokers.

The prevalences of obstruction (including borderline obstruction and mixed pattern), restriction without obstruction, and any abnormality on spirometry tests in current workers are presented in Table 7. The percentage of workers with any abnormality on spirometry was somewhat higher among microwave popcorn production workers (17%) than among workers in other areas of the plant (13%) and both current/former smokers and never-smokers in microwave popcorn production had somewhat higher percentages of abnormalities than the corresponding groups in other areas of the plant. The percentage of workers with obstruction or a mixed pattern was similar in microwave popcorn production (9%) and in other areas of the plant (11%). Restriction was more common in microwave popcorn production (8%) than in other areas of the plant (1%). None of the differences were statistically significant.

When compared to national general population data from NHANES III after adjusting for age, sex, race, and smoking history, the prevalences among microwave popcorn production workers of self-report of physician diagnosed chronic bronchitis and asthma, and of spirometry abnormalities on NIOSH tests, were similar to expected prevalences (Tables 5 and 6). The prevalence ratios for obstruction and restriction in Tables 5 and 6 are slightly different than first reported by NIOSH to the company in the November 2002 letter (see Appendix C) because the earlier ratios were only adjusted for age and smoking history. Also, the number of workers reported earlier to have restriction was higher because workers with a mixed pattern were included in both the “obstruction and mixed pattern” *and* “restriction” categories. In Tables 5 and 6, workers with a mixed pattern are only included in the “obstruction and mixed pattern” category.

Spirometry Abnormalities in Workers Who Reported Working in Quality Control

Ten current workers reported performing repeated popping of microwave popcorn in microwave ovens for quality control, presently or at some time in the past. Of the five who reported also having worked as mixers, three had abnormal spirometry results. The other five had normal results.

Spirometry Abnormalities in Workers Who Reported Working in the Mixing Room

Thirteen current workers reported ever having worked as a mixer, for at least one day. Six of these workers (including the two workers discussed in the Background section) had abnormal spirometry results (one had borderline obstruction, two had a mixed pattern, and three had restriction). Four of five who had worked eight months or more as mixers had abnormal spirometry compared to two of eight who had worked less than eight months (six of these eight reported ten days or less of work as a mixer). Among current workers, there was a statistically significant association between ever having worked as a mixer and having an abnormal spirometry test compared to never having worked as a mixer, after adjusting for the effects of smoking (odds ratio 6.5, 95% confidence interval 1.9 – 22.4).

Among former workers, two of five that reported having worked as a mixer had abnormal spirometry results (one with obstruction, and one with a mixed pattern).

Respirator Use among Ever-Mixers

The 13 current workers who reported ever having worked as a mixer were asked what percentage of the time they used a respirator prior to June 2002 (a) for weighing or handling open containers of flavorings, (b) while pouring flavorings into tanks in the mixing room, (c) while pouring other ingredients into tanks in the mixing room, (d) while checking the levels in the tanks, and (e) for other duties in the mixing room. The reported percentages of time respirators were used during these activities ranged from 0 to 100%. The median reported percentage was 20% for all activities, except for (c) where the median was 50%. The reported percentages of time respirators were used were similar among workers with spirometry abnormalities and workers with normal spirometry.

Workers Entering the Mixing Room for Reasons Other Than Mixing

Forty-five current workers reported having spent time in the mixing room while doing other jobs at the plant (e.g., supervisor, maintenance, electrician, quality control, machine operator, etc.). Only eight of them reported using a respirator when they entered the mixing room. Nine of the 45 had abnormal spirometry tests. Six of these nine had also worked as mixers.

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.[14] 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,[10,11] 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 heterogeneous aeration 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 necessary.

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.[12] 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.[13] 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.[12] Also not known 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 airborne powder when handling these flavorings may increase worker risk for lung problems.

Exposures and Worker Health at American Pop Corn Company

At 0.08 ppm (area and personal measurements combined), the average diacetyl air concentration measured in the mixing room at American Pop Corn was among the lowest that NIOSH has measured in the mixing areas of several microwave popcorn plants.[1,15,16,17,18] Average diacetyl air concentrations in the packaging area were even lower. (Many were below the limit of detection of the sampling method.) While the NIOSH medical survey did not identify significant evidence that packaging workers were at increased risk for lung problems related to work exposures, NIOSH tests did find that six of 13 workers with past mixing experience had abnormal spirometry tests. Three of these six workers had obstruction or a mixed pattern, and three had restriction. Although fixed obstruction on spirometry is the most common finding in workers with flavoring-related lung disease, it is possible that restriction may also occur with this type of exposure. One of the eight index cases from the plant where the association of bronchiolitis obliterans with microwave popcorn production was first observed has restriction on spirometry, but has chest CT scan findings that are similar to those of the other seven cases.[4] Some workers with mixing experience at the American Pop Corn Company plant may have developed abnormal lung function due to brief, intense exposures during mixing activities, such as those that occur when workers weigh and measure flavorings, pour them manually into open tanks of heated soybean oil, and look into tanks, especially if respiratory protection is not consistently and appropriately utilized. This risk can be present even when ventilation maintains low average air concentrations of flavoring chemicals.

Air concentrations of total and respirable dust in the mixing room were below the OSHA PEL for particulates not otherwise regulated (PNOR) and the ACGIH TLV for particulates not otherwise specified (PNOS). However, the PNOR PEL and PNOS TLV may not be fully protective with regard to levels of dust in the mixing room, as some of the dust is due to flavoring powders, the inhalation of which may pose a risk for lung disease.

Average diacetyl air concentrations in the quality control (QC) lab were below the sampling method's limit of detection, and work in quality control was not identified as an independent risk factor for lung disease. However, the microwave popping of many dozens of bags of product per shift was associated with abnormal lung function in quality control workers in another plant.[1] It is possible that QC workers at American Pop Corn have lower risk due to lower exposures because fewer bags are popped, or because there is greater ventilation of the quality control room compared to the other plant. NIOSH surveys at other microwave popcorn plants have found that average air concentrations of diacetyl in QC labs are generally lower than in the mixing rooms and packaging areas. QC workers may be at risk from brief, intense exposures during microwave popping and opening bags of product even when general dilution ventilation maintains low average exposures. Also, QC workers' exposures may be substantially different from those of mixers because of the much higher temperatures that occur in microwave popping of product compared to the temperatures of oil and flavorings in heated tanks. Shortly after the NIOSH surveys, American Pop Corn Company management installed a local exhaust ventilation system for the microwave ovens in the QC lab in an attempt to reduce any potential risk to quality control workers from QC-related exposures.

Diacetyl air concentrations in the mixing room were substantially higher on the day when liquid and paste flavorings were used in production compared to the days when only powdered flavorings were used (Table 2). When NIOSH heated samples of these butter flavorings to approximately 120 degrees Fahrenheit in the laboratory and measured the relative amounts of volatile organic compounds (VOCs) emitted, the liquid and paste butter flavorings emitted amounts of diacetyl that were approximately ten (or more) times higher than the amounts emitted by the powdered butter flavorings. Many of the other compounds emitted also followed this pattern. In general, the powders emitted substantially lower amounts of VOCs than did liquids or pastes. Lower emission from the powders could be due to lower amounts of the specific chemical ingredients in the powders compared to the liquids and pastes (NIOSH does not know the percent by weight compositions of these flavorings). However, some powdered flavorings are encapsulated in such a way that there is much less release of these chemicals during microwave popcorn production, which may explain the lower VOC emissions from the powders used at American Pop Corn.

The survey results of respirator use by mixers and others with access to the mixing room indicated that past respirator use was sporadic or non-existent by many of these workers prior to June 2002. American Pop Corn Company management indicated that it had placed greater emphasis on compliance with respirator use by workers entering the mixing room after the diagnosis of work-related lung disease in a mixer in June 2002.

The results of the respirator cartridge capacity evaluation indicate that, at the levels of organic vapors present during the 33 hours of use, these cartridges were adequately working to remove contaminants from the breathing air of the mixer wearing them and had not reached their maximum life span. Given similar conditions in the mixing room, the same model of cartridge could be safely used for a period of one week (40 hours) before needing to be changed. Other brands of cartridges or changes in the conditions of the mixing room would require independent evaluation.

CONCLUSIONS

Despite good ventilation and low average air concentrations of diacetyl in the mixing room at American Pop Corn Company, some workers with a history of mixing experience probably were affected by brief, intense exposures during processes that involve the open handling of flavorings. Evidence of significant risk for lung disease in packaging workers and QC lab workers was not identified. There was less exposure to flavoring-related chemicals when powdered flavorings were in use, but some of the airborne dust generated when these powdered flavorings were handled was respirable, suggesting potential risk to workers if inhaled.

RECOMMENDATIONS

The following recommendations were provided by NIOSH to American Pop Corn Company from November 2002 through July 2003:

1. Engineering Controls

- Implement general dilution ventilation for the pre-mixing area in the warehouse where flavorings are stored and weighed. Maintain negative pressure in this area relative to the warehouse. Provide local exhaust ventilation to the part of this area where open measuring and weighing of flavorings occurs.

- Regularly check and maintain all ventilation systems to minimize the possibility of a malfunction.

- Perform periodic air sampling for diacetyl to verify that the ventilation systems in use are functioning optimally.

- Obtain engineering consultation to identify process changes that would allow the handling of flavorings in closed or sealed systems for addition to heated soybean oil.

2. Flavoring Substitution

Although much remains to be learned regarding the compounds in butter flavorings that may have toxicity and what are safe levels of exposure, the possibility of replacing liquid or paste flavorings formulations with low emissions powders should be explored. A powdered flavoring that generates little dust when handled, and has low emissions of VOCs before and after it is added to heated soybean oil, may be safer than a dustier powder that can be inhaled by workers.

3. Work Practices

- Always keep containers of flavorings tightly sealed when not in use. Empty flavoring containers that still have residual flavorings in them also need to be tightly sealed. If they are to be washed, the worker doing this should wear a respirator.
- Limit access to the mixing room and to areas where flavorings are handled to only those workers whose job duties require them to be in those areas.

4. Respiratory Protection Program

- Maintain a written respiratory protection program that meets the requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134).
- Require mandatory respirator use for mixers, and any other workers that enter the mixing room and flavoring pre-mixing area in the warehouse.
- Assure that workers understand how and when to wear a respirator, the nature of the respiratory hazard, and that a respirator must be used 100% of the time when handling open containers of flavorings and for any duties in the mixing room.
- Continue to use NIOSH-certified full-facepiece respirators with organic vapor cartridges and particulate filters, or use more protective respirators.

5. Medical surveillance with spirometry

- Perform spirometry tests
    - Every three to four months for all mixers of oil and flavorings and all microwave QC lab workers.
    - Every six months for all non-mixers who enter the mixing room frequently.
    - Obtain baseline spirometry on workers before they are assigned to these areas.
    - Assure that the technician performing spirometry follows the guidelines of the American Thoracic Society[5] (ATS) to ensure high quality tests.
    - Assure that the physician reviewing the spirometry tests is familiar with this report.
- Compare spirometry results over time to identify any declines in lung function. (See Appendix D, July 2003 NIOSH letter to American Pop Corn Company containing recommendations for a spirometry testing program.)
- Encourage mixing room and QC lab workers to report any persistent shortness of breath or cough to their supervisor (or the company health and safety department) and to their physician.

- Refer any symptomatic workers and those with abnormal or declining spirometry results for further medical evaluation to establish a diagnosis.
- Prevent further flavoring exposure for any worker with lung disease or impairment that is considered to be either likely due to, or worsened by, flavorings exposure. (Obtain physician guidance on the affected worker's work restrictions in this circumstance.)

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Table 1. Time-weighted average diacetyl (area and personal) and total and respirable dust air concentrations by job

Job / Area	Diacetyl (ppm)				Total Dust (mg/m^3)				Respirable Dust (mg/m^3)			
	N	Mean	Min	Max	N	Mean	Min	Max	N	Mean	Min	Max
Mixing room	8	0.08	ND	0.57	3	2.40	1.40	3.80	3	0.23	0.09	0.31
Bartelt Operator*	8	0.006	ND	0.03	3	0.08	0.04	0.12	4	0.03	0.01	0.04
Langen Operator*	1	ND	ND	ND	-	-	-	-	-	-	-	-
Quality Control	6	ND	ND	ND	3	0.08	0.06	0.10	3	0.03	0.01	0.05
Production Worker*	6	0.002	ND	0.004	3	0.04	0.02	0.06	3	0.03	0.02	0.03
Stacker*	6	ND	ND	ND	3	0.17	0.05	0.30	3	0.04	0.01	0.06
Maintenance	1	ND	ND	ND	2	0.13	0.05	0.21	2	0.08	0.01	0.15
Supervisor	4	ND	ND	ND	2	0.03	0.02	0.04	2	0.01	0.01	0.01
Fork Lift Operator	1	ND	ND	ND	-	-	-	-	-	-	-	-
Sanitation	1	ND	ND	ND	-	-	-	-	-	-	-	-
Poly Packaging**	2	ND	ND	ND	1	0.30	0.30	0.30	1	0.01	0.01	0.01
Office	2	ND	ND	ND	-	-	-	-	-	-	-	-
Ambient	2	ND	ND	ND	2	0.21	0.02	0.40	2	0.03	0.01	0.05

*Microwave popcorn packaging area
N – Number of samples collected
mg/m^3 – milligrams per cubic meter of air
**Plain kernel (non-microwave) popcorn packaging
ppm – parts per million parts air
- Indicates no samples taken in this area
ND – not detectable; measurements were below the limit of detection (0.001 ppm)

Table 2. Air concentrations of diacetyl in the mixing room

Date	Shift	Type	Concentration (ppm)	Type of butter flavored popcorn being made[1]	Type of butter flavor being used
7/29/2002	1st	area	0.57	low fat butter #1 low fat butter #2	paste liquid
7/29/2002	1st	personal	0.05		
7/29/2002	1st	personal	0.03		
7/31/2002	2nd	area	ND	butter heavy butter	powder powder
7/31/2002	2nd	personal	0.004		
8/01/2002	2nd	area	ND	heavy butter	powder
8/01/2002	2nd	personal	ND		
8/01/2002	2nd	personal	0.005		

[1]Not the actual product name ppm – parts per million parts air
ND – not detectable; measurements were below the limit of detection (0.001 ppm).

Table 3. Total Hydrocarbons excluding diacetyl and acetoin

Date	Concentration (mg/m^3)	Job / Area Description
7/29/2002	0.71	Ambient
7/31/2002	0.21	Ambient
7/29/2002	0.72	Machine Operator*
7/31/2002	1.02	Machine Operator*
1/8/2002	1.44	Machine Operator*
1/8/2002	1.21	Machine Operator*
7/29/2002	0.82	Maintenance
1/8/2002	1.10	Maintenance
7/29/2002	0.43	Manager
1/8/2002	0.17	Manager
7/29/2002	0.65	Mixer
7/31/2002	0.51	Mixer
1/8/2002	0.41	Mixer
7/29/2002	0.85	MW** Quality Control
7/31/2002	0.42	MW** Quality Control
1/8/2002	0.21	MW** Quality Control
7/29/2002	1.00	Production worker
7/31/2002	0.93	Production
1/8/2002	1.31	Production
7/29/2002	0.58	Stacker
7/31/2002	0.85	Stacker
1/8/2002	0.78	Stacker
7/31/2002	0.73	Poly packaging***
1/8/2002	0.49	Poly Quality Control
7/31/2002	0.19	Office
7/29/2002	0.56	Other
7/29/2002	0.93	Other
7/31/2002	0.45	Other
7/31/2002	1.16	Other
1/8/2002	1.51	Other

*Bartelt or Langen operator (microwave popcorn packaging)
**Microwave production ***Plain kernel (non-microwave) popcorn packaging

Table 4. Worker symptoms by current work area and smoking status

	Microwave popcorn plant workers			Workers in other plant areas (including office)			Total participants (N=157)
	Current/former smoker (N=41)	Never smoker (N=46)	Total (N=87)	Current/former smoker (N=44)	Never smoker (N=26)	Total (N=70)	
Any trouble breathing in last 12 months	7 (17%)	5 (11%)	12 (14%)	11 (25%)	2 (8%)	13 (19%)	25 (16%)
Shortness of breath on exertion:							
– Hurrying on level ground or walking up slight hill	18 (44%)	10 (22%)	28 (32%)	11 (25%)	5 (19%)	16 (23%)	44 (28%)
- Onset after hire	12 (29%)	8 (17%)	20 (23%)	8 (18%)	5 (19%)	13 (19%)	33 (21%)
– Walking with people your own age on level ground	4 (10%)	3 (7%)	7 (8%)	1 (2%)	1 (4%)	2 (3%)	9 (6%)
- Onset after hire	4 (10%)	3 (7%)	7 (8%)	1 (2%)	1 (4%)	2 (3%)	9 (6%)
Usually cough	11 (27%)	5(11%)**	16 (19%)	10 (23%)	4 (15%)	14 (20%)	30 (19%)
Chronic cough*	6 (15%)	4 (9%)**	10 (11%)	5 (11%)	3 (12%)	8 (11%)	18 (11%)
– Onset after hire	5 (12%)	4 (9%)	9 (10%)	2 (5%)	3 (12%)	5 (7%)	14 (9%)
Wheezing	11 (27%)	8 (17%)	19 (22%)	14 (32%)	8 (31%)	22 (31%)	41 (26%)
– Aside from cold	9 (22%)	4 (9%)	13 (15%)	7 (16%)	4 (15%)	11 (16%)	24 (15%)
– Onset after hire	3 (7%)	3 (7%)	6 (7%)	4 (9%)	2 (8%)	6 (9%)	12 (8%)
Fever/chills/sweats	1 (2%)	4 (9%)	5 (6%)	4 (9%)	3 (12%)	7 (10%)	12 (8%)
Unusual fatigue	5 (12%)	10 (22%)	15 (17%)	4 (9%)	4 (15%)	8 (11%)	23 (15%)

N= total individuals in category
*Usually cough on most days for 3 consecutive months or more during the year.
**One individual did not answer cough questions.

Table 5. Prevalence ratios for respiratory symptoms, self-report of physician diagnosed respiratory disease, and spirometry abnormalities in microwave popcorn plant workers, with expected numbers from NHANES III

Condition	No.[b]	# Obs[c]	# Exp[d]	O/E (95% CI)
Shortness of breath when hurrying on the level or walking up a slight hill				
< 40 years	36	8	5.4	1.5 (0.8-2.9)
≥ 40 years	47	18	12.5	1.4 (0.9-2.3)
Total	83	26	17.9	1.5 (1.0-2.1)
Chronic cough[a]				
< 40 years	35	2	2.3	0.9 (0.2-3.2)
≥ 40 years	47	8	4.5	1.8 (0.9-3.5)
Total	82	10	6.8	1.5 (0.8-2.7)
Wheezing aside from a cold				
< 40 years	36	4	3.4	1.2 (0.4-3.0)
≥ 40 years	47	8	5.4	1.5 (0.8-2.9)
Total	83	12	8.9	1.4 (0.8-2.4)
Asthma confirmed by MD				
< 40 years	36	2	2.4	0.8 (0.2-3.0)
≥ 40 years	47	3	3.7	0.8 (0.3-2.4)
Total	83	5	6.1	0.8 (0.4-1.9)
Chronic bronchitis confirmed by MD				
< 40 years	36	0	1.0	0.0 (0.0-3.9)
≥ 40 years	47	4	3.3	1.2 (0.5-3.1)
Total	83	4	4.3	0.9 (0.4-2.4)
Obstruction or Mixed Pattern				
< 40 years	36	2	1.0	1.9 (0.5-7.0)
≥ 40 years	45	4	3.4	1.2 (0.5-3.1)
Total	81	6	4.4	1.4 (0.6-3.0)
Obstruction (including borderline) or Mixed Pattern				
< 40 years	36	2	2.5	0.8 (0.2-2.9)
≥ 40 years	45	6	6.0	1.0 (0.5-2.2)
Total	81	8	8.5	0.9 (0.5-1.8)
Restriction (without obstruction)				
< 40 years	36	0	1.8	0.0 (0.0-2.1)
≥ 40 years	45	6	3.8	1.6 (0.7-3.5)
Total	81	6	5.6	1.1 (0.5-2.3)

[a]Usually cough on most days for 3 consecutive months or more during the year
[b]6 participants (including one with restriction) excluded from analysis due to missing information on age, race, or spirometry result
[c]Number observed
[d]Number expected

Table 6. Prevalence ratios for respiratory symptoms, self-report of physician diagnosed respiratory disease, and spirometry abnormalities in microwave popcorn plant workers (*excluding ever-mixers)*, with expected numbers from NHANES III

Condition	No.[b]	# Obs[c]	# Exp[d]	O/E (95% CI)
Shortness of breath when hurrying on the level or walking up a slight hill				
< 40 years	32	5	4.7	1.1 (0.4-2.5)
≥ 40 years	40	16	11.3	1.4 (0.9-2.3)
Total	72	21	16.0	1.3 (0.9-2.0)
Chronic cough[a]				
< 40 years	31	1	1.9	0.5 (0.1-3.0)
≥ 40 years	40	7	4.0	1.7 (0.8-3.6)
Total	71	8	5.9	1.4 (0.7-2.7)
Wheezing aside from a cold				
< 40 years	32	3	2.9	1.0 (0.4-3.1)
≥ 40 years	40	6	4.8	1.3 (0.6-2.7)
Total	72	9	7.6	1.2 (0.6-2.2)
Asthma confirmed by MD				
< 40 years	32	2	2.1	1.0 (0.3-3.5)
≥ 40 years	40	3	3.2	0.9 (0.3-2.8)
Total	72	5	5.2	1.0 (0.4-2.2)
Chronic bronchitis confirmed by MD				
< 40 years	32	0	0.9	0.0 (0.0-4.4)
≥ 40 years	40	4	3.0	1.3 (0.5-3.4)
Total	72	4	3.9	1.0 (0.4-2.6)
Obstruction or Mixed Pattern				
< 40 years	32	1	0.9	1.1 (0.2-6.4)
≥ 40 years	38	3	3.0	1.0 (0.3-3.0)
Total	70	4	3.9	1.0 (0.4-2.7)
Obstruction (including borderline) or Mixed Pattern				
< 40 years	32	1	2.2	0.5 (0.1-2.6)
≥ 40 years	38	4	5.2	0.8 (0.3-2.0)
Total	70	5	7.4	0.7 (0.3-1.6)
Restriction (without obstruction)				
< 40 years	32	0	1.6	0.0 (0.0-2.5)
≥ 40 years	38	4	3.2	1.2 (0.5-3.2)
Total	70	4	4.8	0.8 (0.3-2.2)

[a]Usually cough on most days for 3 consecutive months or more during the year
[b]6 participants (including one with restriction) excluded from analysis due to missing information on age, race, or spirometry result
[c]Number observed
[d]Number expected

Table 7. Self-reported diagnoses and spirometry abnormalities by current work area and smoking status

	Microwave popcorn plant workers			Workers in other plant areas (including office)			Total participants (N=157)
	Current/former smoker (N=41)	Never smoker (N=46)	Total (N=87)	Current/former smoker (N=44)	Never smoker (N=26)	Total (N=70)	
Bronchitis confirmed by MD while working in plant	4 (10%)	5 (11%)	9 (10%)	8 (18%)	1 (4%)	9 (13%)	18 (11%)
Chronic bronchitis confirmed by MD – Onset after hire	2 (5%) 1 (2 %)	2 (4%) 1 (2 %)	4 (5%) 2 (2%)	4 (9%) 2 (5%)	0 0	4 (6%) 2 (3%)	8 (5%) 4 (3%)
Pneumonia while working in plant	2 (5%)	2 (4%)	4 (5%)	4 (9%)	2 (8%)	6 (9%)	10 (6%)
Asthma confirmed by MD – Onset after hire	4 (10%) 0	1 (2%) 0	5 (6%) 0	8 (18%) 5 (11%)	2 (8%) 1 (4%)	10 (14%) 6 (9%)	15 (10%) 6 (4%)
Abnormal Spirometry – obstruction (incl. Borderline) + mixed – restriction (without obstruction)	9 (22%) 5 (12%) 4 (10%)	6 (14%) * 3 (7%) 3 (7%)	15 (17%) 8 (9%) 7 (8%)	7 (16%) ** 7 (16%) 0	2 (8%) 1 (4%) 1 (4%)	9 (13%) 8 (11%) 1 (1%)	24 (15%) 16 (10%) 8 (5%)

N= Total individuals in category.
* There were 2 individuals that were not included in the percent calculation. One did not undergo spirometry testing and the other had a test result that could not be interpreted.
** There was 1 individual that did not undergo spirometry testing.

Figure 1A. GC-MS chromatogram of mixing room air sample, July 29, 2002. Only paste and liquid butter flavorings were in use. Peak number 20 represents diacetyl.

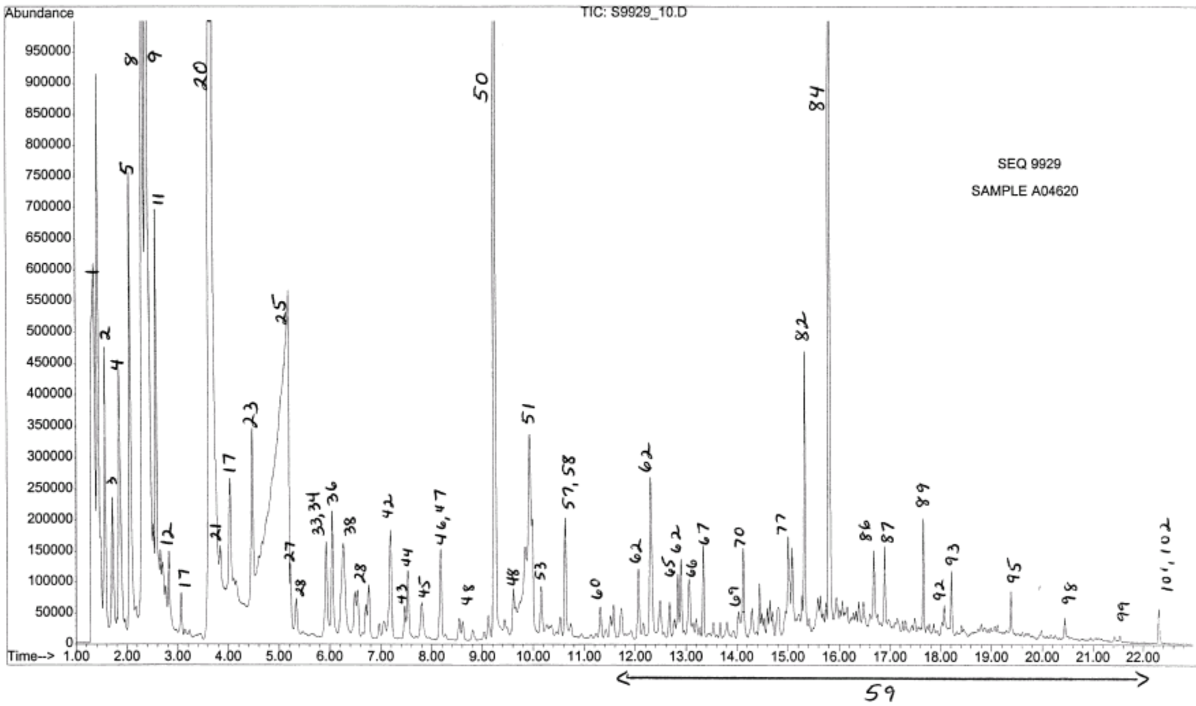


Figure 1B. GC-MS chromatogram of mixing room air sample, July 31, 2002. Only powdered butter flavorings were in use. Peak number 20 represents diacetyl.

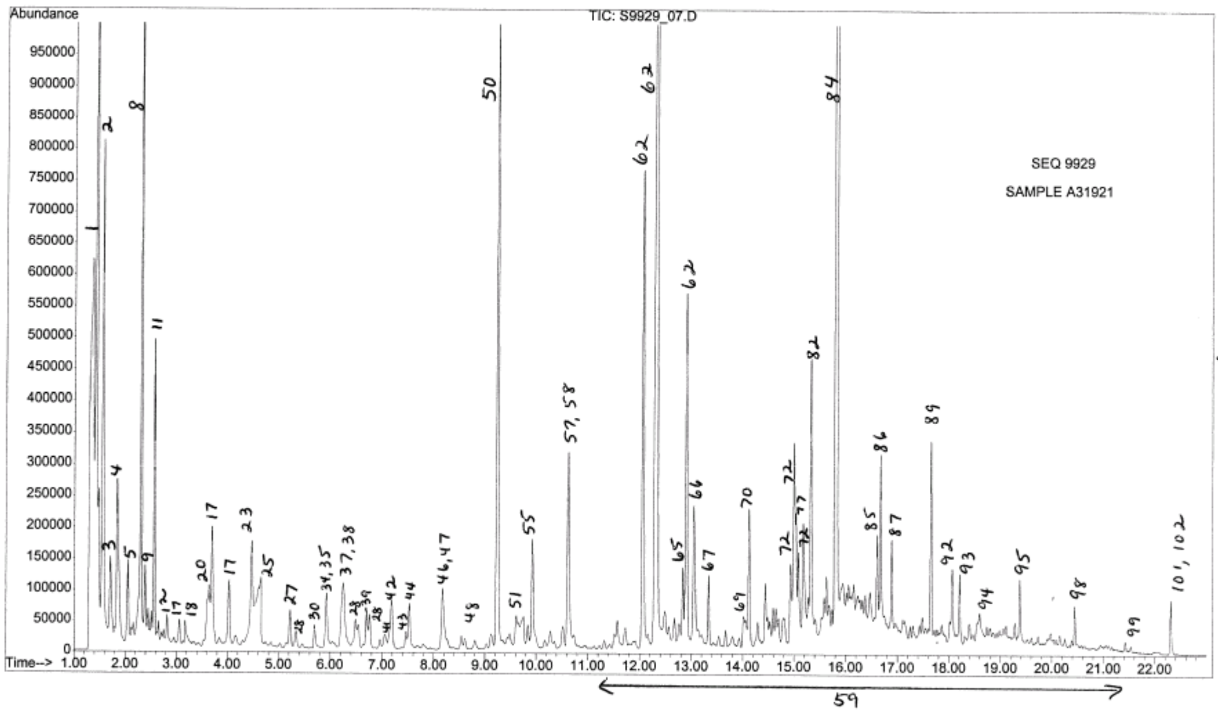


Figure 1C. GC-MS chromatogram of mixing room air sample, August 1, 2002. Only powdered butter flavorings were in use. Peak number 20 represents diacetyl.

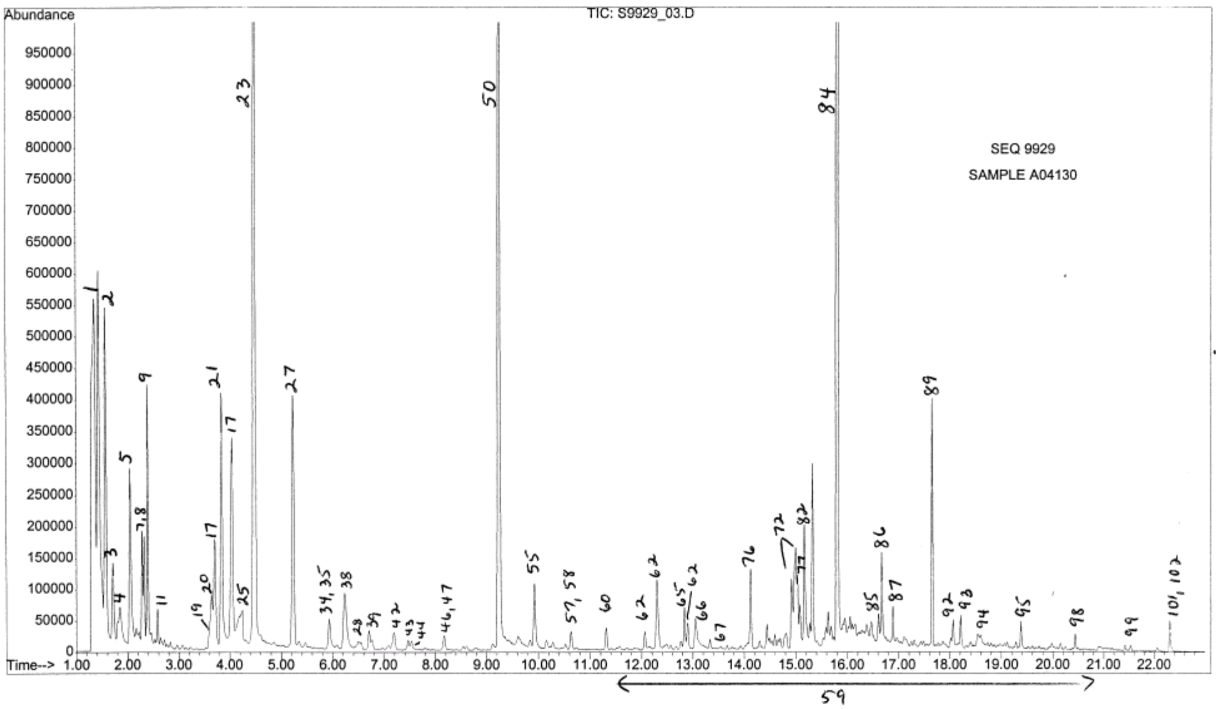


Figure 1D. Key of peaks for Figures 1A-C

SEQ 9929-AA
THERMAL DESORPTION TUBES
PEAK IDENTIFICATION
Page 1 of 2

1) Air*/CO_2*
2) Propane*
3) Isobutane*/methanol*/ acetaldehyde**
4) Butane
5) Ethanol
6) Acetonitrile
7) Acetone
8) Isopentane*
9) Isopropanol
10) Trichlorofluoromethane
11) Pentane*
12) C_5H_{10} isomers
13) t-Butanol
14) Methyl acetate
15) Methylene chloride
16) 1-Propanol
17) C_6 aliphatic hydrocarbons
18) Formic acid
19) 3-Buten-2-one
20) Diacetyl (2,3-butanedione)
21) Methyl ethyl ketone (MEK)
22) 2-Methylfuran
23) Hexane
24) Ethyl acetate
25) Acetic acid
26) Tetrahydrofuran (THF)
27) Methylcyclopentane
28) C_7 aliphatic hydrocarbons
29) 1,1,1-Trichloroethane
30) Acetol
31) Methyl propyl ketone
32) Butyronitrile
33) Isopropyl acetate
34) Benzene*
35) Butanol
36) 3-Methyl-3-buten-2-one
37) Cyclohexane
38) 1-Methoxy-2-propanol
39) Pentanal*
40) Propanoic acid
41) Trichloroethylene
42) Isooctane
43) Propyl acetate
44) Heptane
45) 3-Hydroxy-3-methyl-2-butanone
46) Methylcyclohexane
47) Methyl isobutyl ketone (MIBK)
48) C_8 aliphatic hydrocarbons
49) Pentanenitrile
50) Toluene
51) Butyric acid
52) Methyl butyl ketone (MBK)
53) Ethyl butyrate
54) Ethyl lactate
55) Hexanal*
56) 2-Propoxyethanol
57) Furfural
58) Perchloroethylene/octane
59) C_9-C_{16} aliphatic hydrocarbons, mostly branched alkanes, plus some C_9-C_{10} alkyl benzenes
60) Hexamethylcyclotrisiloxane*
61) Propylene glycol methyl ether acetate
62) Ethyl benzene/xylene isomers
63) Styrene
64) Butyl acrylate
65) Heptanal*
66) Butyl cellosolve
67) Nonane
68) 1-Butoxy-2-propanol
69) Benzaldehyde
70) α-Pinene
71) C_9H_{12} alkyl benzenes
72) Dipropylene glycol methyl ether/ $C_7H_{16}O_3$ isomers
73) Tribromoethylene
74) Octanone
75) α-Methylstyrene
76) β-Pinene
77) Octanal*
78) $C_{10}H_{16}$ terpene
79) Octamethylcyclotetresiloxane*
80) p-Dichlorobenzene
81) Decane

CEMB Analytical Laboratory Report: Sequence 9929-AA   Page 3 of 4

SEQ 9929-AA
THERMAL DESORPTION TUBES
PEAK IDENTIFICATION
Page 2 of 2

82) Branched hydrocarbon (pentamethylheptane?)
83) p-Cymene
84) Limonene
85) Dimethyl styrene
86) Nonanal*
87) Undecane
88) Isopropyl-2-ethylhexanoate
89) Decamethylcyclopentasiloxane*
90) 2-(2-Butoxyethoxy)ethanol
91) Naphthalene
92) Decanal*
93) Dodecane
94) 1-Phenoxy-2-propanol
95) Tridecane
96) Piperonal
97) $C_{12}H_{24}O_3$, methyl propanoic acid esters such as:
    a) 2,2-dimethyl-1-(2-hydroxy-1-methylethyl) propyl ester
    b) 3-hydroxy-2,4,4-trimethyl pentyl ester
98) Tetradecane
99) Pentadecane
100) Diethyl phthalate*
101) Methyl propanoic acid ester*
102) Hexadecane

*Also present on some media and/or field blanks.
**May be present as a thermal decomposition product and/or impurity in ethanol.

Figure 2. Results of FTIR real-time diacetyl air concentrations in the mixing room on July 30, 2003. The diacetyl peak occurred immediately after the mixer poured several five-gallon containers of liquid butter flavoring into a mixing tank (over two minutes) and then closed the lid to the tank.

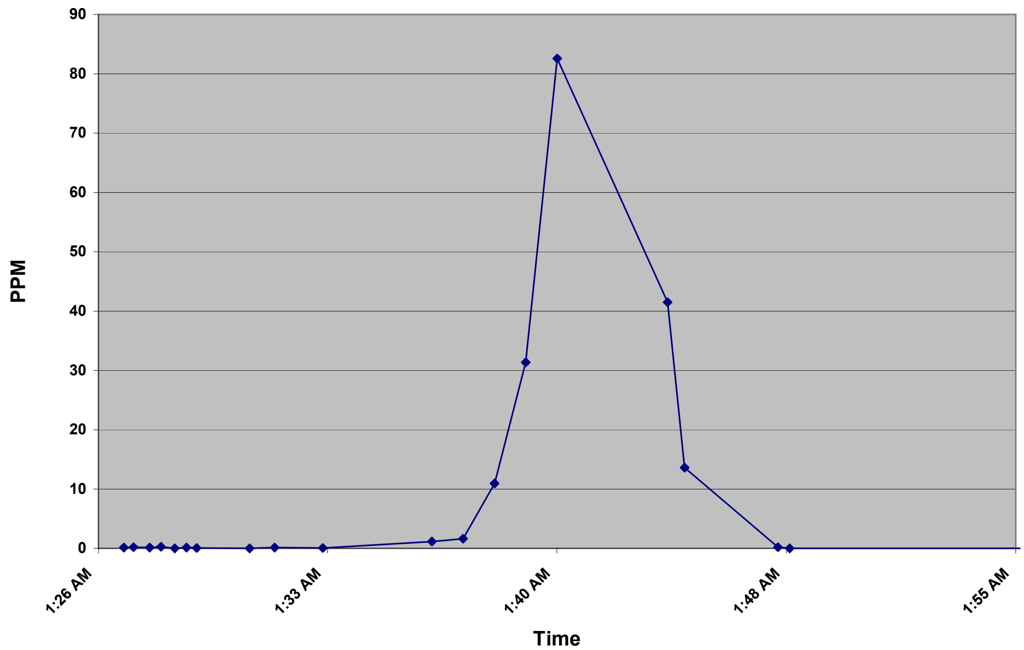
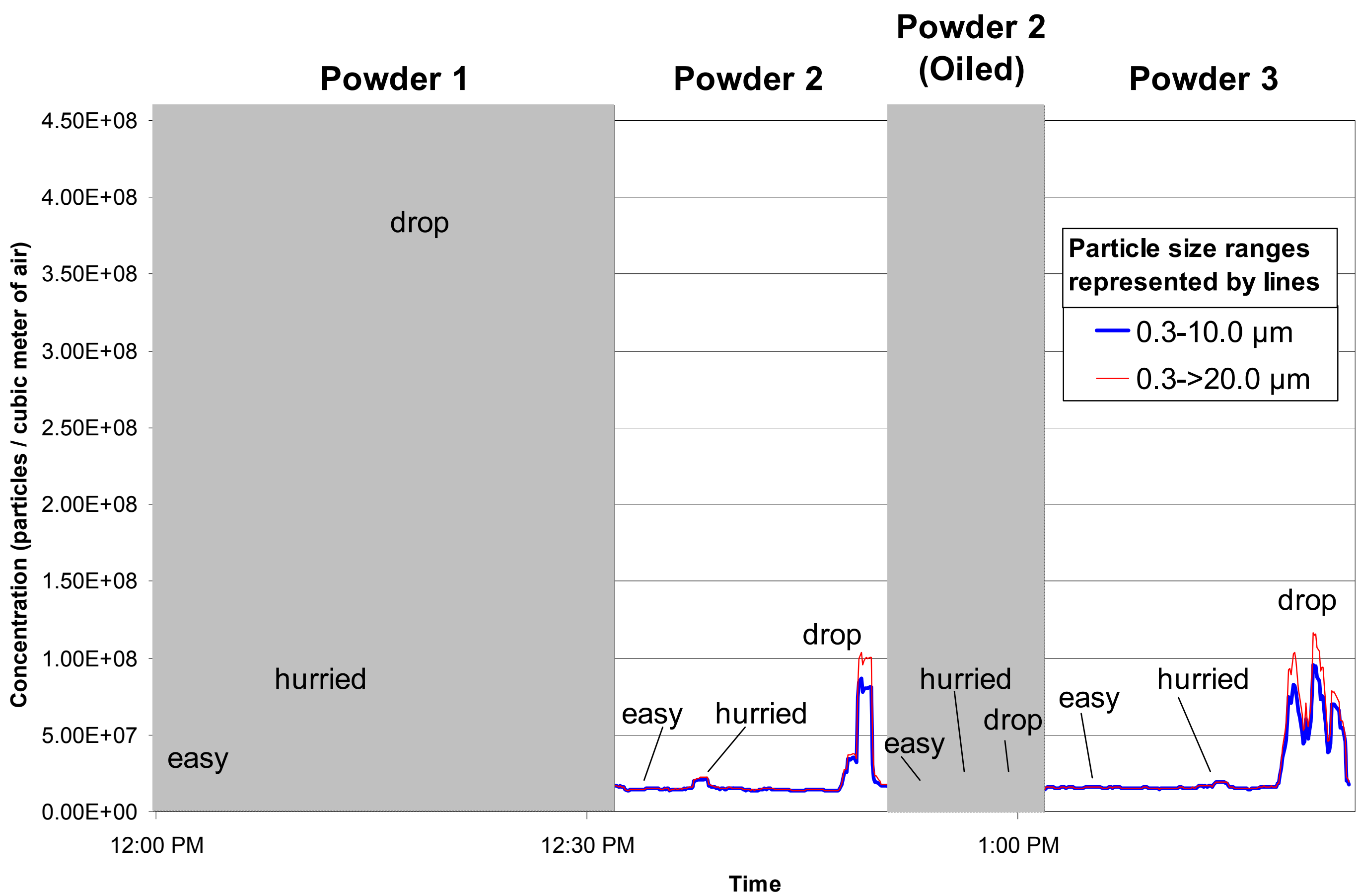


Figure 3. Real-time air sampling data during simulated hand scooping of four different powder butter flavorings.



APPENDIX A

May 30, 2002
HETA 2001-0474

Mr. Greg Hoffman
American Popcorn Company
4332 Grant Street
Sioux City, Iowa 51108

Dear Mr. Hoffman:

This letter is in followup to a site visit conducted on September 26, 2001, by the National Institute for Occupational Safety and Health (NIOSH) at your American Popcorn Company microwave popcorn plant in Sioux City, Iowa. NIOSH conducted this visit in response to a request for technical assistance made by the Iowa Department of Health (DOH). The Iowa DOH requested that NIOSH evaluate adverse health effects associated with employment in the microwave popcorn industry. Results from this site visit were communicated to you previously by telephone.

NIOSH collected area air samples using semi-quantitative sampling methods to assess the types of volatile organic compounds present in air during the production of microwave popcorn. The samples were collected from three locations: the mixing room, the machine operators area, and the stacking area. The samples were collected on thermal desorption tubes and were analyzed by gas chromatography with a mass selective detector according to NIOSH Method 2549.

The major organic compounds identified in plant air included propane, butanes, ethanol isopropanol, fluorodichloroethane, toluene, limonene, a-pipene, 1-phenoxy-2-propanol, and methyl ethyl ketone. Other compounds detected included diacetyl, diacetone alcohol, various C6 - C14 aliphatic hydrocarbons, dipropylene glycol methyl ether, di-tert-butylbenzene, and trichloroethylene. These results provide a perspective on the types of compounds present in air during the production of microwave popcorn.

NIOSH also obtained quantitative sampling results for diacetyl and acetoin at the three sampling locations. These ketones are major constituents of the butter flavorings used in the production process. The diacetyl and acetoin samples were collected on charcoal sorbent tubes at a flow rate of 50 cubic centimeters per minute (cc/min). The samples were analyzed quantitatively by gas chromatography according to NIOSH Method 2557. Two of the diacetyl samples had concentrations below the minimum detectable concentration of 0.008 parts per million air by volume (ppm). Only one of the three diacetyl samples had a detectable concentration, and that concentration was equal to the minimum detectable concentration of 0.008 ppm. That sample was collected in the mixing room. All three acetoin samples were below the minimum detectable concentration for that compound in air (approximately 0.008 ppm).

At present, the specific chemical component(s) and concentration(s) in the flavorings that cause obstructive respiratory problems in the microwave popcorn industry are unknown. Additionally,

there are no applicable exposure standards or guidelines for diacetyl or acetoin. However, the diacetyl and acetoin concentrations measured at American Popcorn Company are hundreds of times lower than those measured at another microwave popcorn plant where obstructive respiratory health problems have been found among workers. These sampling results indicate that the engineering controls in place at American Popcorn Company are effective in maintaining ketone concentrations below or at the detectable limit. When combined with the use of respiratory protection in the mixing room, worker exposures to volatile organic compounds from microwave popcorn production should be minimal to non-detectable.

If you have any questions about these sampling results, please contact me by phone (304-285-5959) or E-mail (gkullman@cdc.gov). My colleagues and I thank you and your staff at American Popcorn for your cooperation and commitment to occupational safety and health.

Sincerely,

Greg J. Kullman, Ph.D., CIH
Hazard Evaluations and Technical
Assistance Team
Field Studies Branch
Division of Respiratory Disease Studies

cc:
John Johnson, Iowa Department of Health

APPENDIX B

Medical Questionnaire

RDHETA 2001 - 0474
(Current Worker)

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)

Telephone Number: ( ) _______ - __________

~~~~~~

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

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

3. Race:
   1. ___ White
   2. ___ African-American or Black
   3. ___ Asian
   4. ___ American Indian or Alaska Native
   5. ___ Native Hawaiian or Other Pacific Islander
   6. ___ Other (*specify below*)
   ____

1
~~~~~~

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."

4. During the last 12 months, have you had any trouble with your breathing? 1.____Yes 2. ____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

5. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? 1. ___ Yes 2. ___ No

IF YES:

a) Do you get short of breath walking with people of your own age on level ground? 1. ___ Yes 2. ___ No

b) Do you ever have to stop for breath when walking at your own pace on level ground? 1. ___ Yes 2. ___ 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 2. ___ No

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

2

6. Do you usually have a cough? 1. ___ Yes 2. ___ 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 2. ___ No
b)	In what month and year did this cough begin?	__ __ / __ __ __ __ (Month) (Year)

7. Have you ever had wheezing or whistling in your chest? 1. ___ Yes 2. ___ No

IF YES:

a)	Have you had this wheezing or whistling when you did *not* have a cold?	1. ___ Yes 2. ___ 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 2. ___ No

8. Have you ever had to change your job, job duties, or work area at this plant because of breathing difficulties? 1. ___ Yes 2. ___ 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

9. While working at this plant, have you had fever, chills, or night-sweats once a month or more often? 1. ___ Yes 2. ___ No

10. While working at this plant, have you had unusual tiredness or fatigue that lasted more than a few days or occurred frequently? 1. ___ Yes 2. ___ No

11. Since you began working at this plant, have you ever had attacks of bronchitis? 1. ___ Yes 2. ___ No

IF YES:

a) Was it confirmed by a doctor? 1. ___ Yes 2. ___ No

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

4

12. Have you ever had chronic bronchitis? 1. ___ Yes 2. ___ No

IF YES:

a)	Was it confirmed by a doctor?	1. ___ Yes 2. ___ No
b)	How old were you when it began?	______ Years old

13. Since you began working at this plant have you ever had pneumonia? (*Include bronchopneumonia*) 1. ___ Yes 2. ___ No

14. Have you ever had asthma? 1. ___ Yes 2. ___ No

IF YES:

a)	How old were you when it began?	______ Years old
b)	Was it confirmed by a doctor?	1. ___ Yes 2. ___ No
c)	Do you still have it?	1. ___ Yes 2. ___ No

15. Have you ever had a pneumothorax (collapsed lung)? 1. ___ Yes 2. ___ No

16. 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 2. ___ No

IF YES:

a) Is there an exposure at work that causes or aggravates these nose symptoms? 1. ___ Yes 2. ___ No

IF Yes:
b) Describe exposure(s):
____
____

5

17. 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 2. ___ No

IF YES:

a) Is there an exposure at work that causes or aggravates these eye symptoms? 1. ___ Yes 2. ___ No

IF Yes:

b) Describe exposure(s):

____

____

18. Since working at this plant, have you developed any new skin rash or skin problems? 1. ___ Yes 2. ___ No

6

Section III. Work Information

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

19.

a)	Have you ever worked as a mixer, even for as little as one day?	1. ___Yes	2.___No
b)	Have you ever spent time in the mixing room while doing any other job at this plant? (e.g. supervisor, maintenance, electrician, QC, machine operator, etc.)	1.___Yes	2.___No
c)	Have you ever work in quality control? (popping bags in microwave ovens to check the product.)	1.___Yes	2.___No

20. What is your usual work shift? ____

21. During an average work week, how many hours do you work? ______ Hours per week

7

IF EVER a Mixer:

22. Before June 2002 what percentage of time did you wear a respirator:

a)	for weighing or handling open containers of flavorings?	___________%
b)	while pouring flavorings into tanks in the mixing room?	___________%
c)	while pouring other ingredients into tanks in the mixing room?	___________%
d)	while checking the levels in the tanks?	___________%
e)	for other duties in the mixing room?	___________%
f)	How long have you worked (or did you) worked as a mixer?	_______ years _______ months _______ days
g)	When mixing, how many hours per day do you (or did you) spend in the mixing room?	_______ hours/day

IF Any Respirator Use:

h) What type of respirator did you use? (if one type mark 100, if more than one type specify the percentage of time used for each type.)

___________% Non-Powered full face mask with cartridge
___________ % Powered full face mask with cartridges
___________ % Half-face mask with cartridges
___________ % Dust mask
___________ % Other
___________ IF Other Specify

8

IF Ever spent time in Mixing Room for any other reason:

23a. What percentage of time did you wear respiratory protection when you were in then mixing room? ___________%

IF Any Respirator Use?

23b. What type of respirator did you use? (if one type mark 100, if more than one type specify the percentage of time used for each type.)

___________% Non-Powered full face mask with cartridges
___________ % Powered full face mask with cartridges
___________ % Half-face mask with cartridges
___________ % Dust mask
___________ % Other
___________ IF Other Specify

24. Have you ever been exposed to a spill or unusual chemical release at work? 1. ___ Yes 2. ___ No

IF YES:

a) Did you have any symptoms from it? 1. ___ Yes 2. ___ No

IF YES:

b) What were your symptoms?

____

9

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. T

	Job Title	Start Month/Year	End Month/Year	Major Work Areas	Comments
A					
B					
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					

25. Have you ever:

a) Worked in mining? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

b) Worked in farming? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

c) Worked in chemical manufacturing like explosives, dyes, lacquers, and celluloid? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

d) Been exposed to fire smoke? *(Do not count campfires, stoves.)* 1. ___ Yes 2. ___ No *IF YES:* _____ Years

e) Been exposed to irritant gases like chlorine, sulfur dioxide, ammonia, and phosgene? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

f) Been exposed to mineral dusts including coal, silica, and talc? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

g) Been exposed to grain dusts? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

h) Been exposed to oxides of nitrogen including silo gas? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

i) Been exposed to asbestos? 1. ___ Yes 2. ___ No *IF YES:* _____ Years

j) Been exposed to any chemical or substance that affected your breathing? 1. ___ Yes 2. ___ No

IF YES TO Question j):

k) *Describe exposure:*

____

____

Section IV: Tobacco Use Information

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

26. Have you ever smoked cigarettes? 1. ___ Yes 2. ___ No
(*NO if less than 20 packs of cigarettes in a lifetime or less than 1 cigarette a day for 1 year.*)

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 2. ___ No
	IF NO: d) How old were you when you stopped smoking regularly?	______ Years old

Thank you for participating in this survey!

APPENDIX C

Table 3 and Table 4 from NIOSH letter to American Pop Corn Company, November 18, 2002

Table 3. Airway obstruction and mixed pattern on spirometry testing by current work area, comparison with expected from NHANES III

	Current and former smokers				Never smokers				All participants			
	No.	# Exp	# Obs	Ratio Obs/Exp (95% CI)	No.	# Exp	# Obs	Ratio Obs/Exp (95% CI)	No.	# Exp	# Obs	Ratio Obs/Exp (95% CI)
Microwave plant												
– < 40 yrs old	18	1.7	1	0.6 (0.1 , 3.3)	19	1.1	1	0.9 (0.2 , 5.2)	37	2.8	2	0.7 (0.2 , 2.6)
– ≥ 40 yrs old	23	4.7	4	0.9 (0.3 , 2.2)	24**	1.6	2	1.2 (0.3 , 4.6)	47	7.1	6	0.8 (0.4 , 1.8)
– Total	41	6.2	5	0.8 (0.3 , 1.9)	43**	2.7	3	1.1 (0.4 , 3.3)	84	9.2	8	0.9 (0.4 , 1.7)
Office & Other												
– < 40 yrs old	10	0.9	0	0 (0.0 , 4.3)	12	0.7	0	0 (0.0 , 5.5)	22	1.7	0	0 (0.0 , 2.3)
– ≥ 40 yrs old	33*	6.7	7	1.0 (0.5 , 2.2)	14	0.9	1	1.1 (0.2 , 6.3)	47	7.1	8	1.1 (0.6 , 2.2)
– Total	43	6.4	7	1.1 (0.5 , 2.3)	26	1.6	1	0.6 (0.1 , 3.5)	70	7.7	8	1.0 (0.5 , 2.1)

CI= confidence interval.
* 1 individual did not undergo spirometry testing.
** Age data were missing for 2 individuals, and 1 individual did not undergo spirometry testing.

Table 4. Restriction on spirometry testing by current work area, comparison with expected from NHANES III

	Current and former smokers				Never smokers				All participants			
	No.	# Exp	# Obs	Ratio Obs/Exp (95% CI)	No.	# Exp	# Obs	Ratio Obs/Exp (95% CI)	No.	# Exp	# Obs	Ratio Obs/Exp (95% CI)
Microwave plant												
– < 40 yrs old	18	1.2	1	0.8 (0.2 , 4.7)	19	0.9	0	0 (0.0 , 4.3)	37	2.1	1	0.5 (0.1 , 2.7)
– ≥ 40 yrs old	23	3.4	5	1.5 (0.6 , 3.4)	24**	2.0	4	2.0 (0.8 , 5.1)	47	5.8	9	1.6 (0.8 , 3.0)
– Total	41	4.4	6	1.4 (0.6 , 3.0)	43**	2.7	4	1.5 (0.6 , 3.8)	84	7.3	10	1.4 (0.7 , 2.5)
Office & Other												
– < 40 yrs old	10	0.7	0	0 (0.0 , 5.5)	12	0.6	0	0 (0.0 , 6.4)	22	1.3	0	0 (0.0 , 3.0)
– ≥ 40 yrs old	33*	4.9	2	0.4 (0.1 , 1.5)	14	1.2	1	0.9 (0.2 , 4.7)	47	5.8	3	0.5 (0.2 , 1.5)
– Total	43	4.6	2	0.4 (0.1 , 1.6)	26	1.6	1	0.6 (0.1 , 3.5)	70	6.1	3	0.5 (0.2 , 1.5)

CI= confidence interval.
* 1 individual did not undergo spirometry testing.
**Age data were missing for 2 individuals, and 1 individual did not undergo spirometry testing.

APPENDIX D

July 16, 2003
HETA 2001-0474

Greg Hoffman
Vice President of Production
American Pop Corn Company
One Fun Place, Box 178
Sioux City, Iowa 51102

Dear Mr. Hoffman:

This letter contains our recommendations for spirometry testing of your workers that are potentially exposed to flavoring-related chemicals in the course of their work. Please note that we are recommending more frequent testing than we did in our November 2002 letter. We are also recommending a more conservative approach to follow-up of workers with abnormalities on testing than we have in recent phone conversations (i.e., if a test is of good quality, immediately send for medical evaluation any workers with abnormalities or excessive declines as indicated below, rather than waiting and re-testing).

NIOSH Recommendations for a Spirometry Testing Program at American Pop Corn Company

Purpose: To detect obstructive lung disease 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 (see attached) 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 these recommendations, and the American Thoracic Society guidelines.

Who should be tested and how often? *

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

*These revised recommended testing intervals replace our previous recommendations for American Pop Corn Company

Criteria

- Obstruction: FEV1/FVC ratio below the lower limit of normal as indicated by the Hankinson 1999 spirometry interpretation algorithm.

- Excessive decline in FEV1: A decrease greater than 300 milliliters from the baseline value. This threshold assumes that both the baseline and current test sessions are of excellent quality.

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). Provide the physician with information on flavoring-related lung disease (e.g. August 2002 New England Journal of Medicine article, or NIOSH *Alert* when published).
  - Avoid placement of the worker in QC or mixing job, or job requiring frequent entry into mixing room.
- Obstruction, or decline in FEV1 greater than 300 milliliters, in a current worker
  - Refer the worker to an occupational medicine physician or pulmonary specialist (provide the physician with information on flavoring-related lung disease) 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
  - 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.
- 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.

We encourage you to continue to periodically send us copies of spirometry tests performed by your technician so that we can review them for quality. The quality of the tests you have sent so far has been excellent. As always, please do not hesitate to call with any questions or concerns that you have.

Sincerely,

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Enclosures

Rick Hartle (HETAB)

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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