Report on Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant

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NIOSH *National Institute for Occupational Safety and Health*

The employer shall post a copy of this report for a period of 30 calendar days at or near the workplace(s) of affected employees. The employer shall take steps to insure that the posted determinations are not altered, defaced, or covered by other material during such period. [37 FR 23640, November 7, 1972, as amended at 45 FR 2653, January 14, 1980].

Contents

Report

Appendix I
NIOSH Industiral Hygiene Survey Communications

Appendix II
NIOSH Engineering Survey Communications

Appendix III
NIOSH Medical Survey Questionnaire and Interim Communications

Acknowledgments

ABBREVIATIONS

ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
ATS	American Thoracic Society
CA	California
Cal/OSHA	California Department of Industrial Relations' Division of Occupational Safety and Health
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CFR	Code of Federal Regulations
cfm	cubic feet per minute
DART	Division of Applied Research and Technology
DRDS	Division of Respiratory Disease Studies
DSHEFS	Division of Surveillance, Hazard Evaluations, and Field Studies
EPA	Environmental Protection Agency
EF	exhaust fan
°F	degrees Fahrenheit
FDA	U.S. Food and Drug Administration
FEMA	Flavor and Extract Manufacturers Association of the United States
FEV_1	forced expiratory volume in the first second of exhalation
FISHEP	Flavoring Industry Safety and Health Evaluation Program
fpm	feet per minute
FVC	forced vital capacity
GM	geometric mean
GRAS	generally recognized as safe
GSD	geometric standard deviation
HETA	Hazard Evaluation and Technical Assistance
HHE	Health Hazard Evaluation
HRCT	high-resolution computed tomography
l/min	liters per minute
mg	milligram
mg/m^3	milligrams per cubic meter of air
ml	milliliter
MSDS	material safety data sheet
NHANES III	Third National Health and Nutrition Examination Survey
NMAM	NIOSH Manual of Analytical Methods
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PAPR	powered air-purifying respirator
PEL	permissible exposure limit
PID	photoionization detector
ppm	parts per million
PTFE	polytetrafluoroethylene
QC	quality control
RDHETAP	Respiratory Disease Hazard Evaluation and Technical Assistance Program
REL	recommended exposure limit
SF	supply fan
SF_6	sulfur hexafluoride
STD	standard deviation
STEL	short-term exposure limit
TWA	time-weighted average
VOC	volatile organic compund

Highlights of the NIOSH Health Hazard Evaluation

On October 24, 2006, Gold Coast Ingredients requested a Health Hazard Evaluation for medical screening for occupational lung disease at their Commerce, California, flavoring manufacturing plant. The company was participating in a voluntary special emphasis program initiated by Cal/OSHA and CDPH for the flavoring manufacturing industry in California. On September 6, 2006, Cal/OSHA had requested NIOSH technical assistance with an industrial hygiene and engineering control assessment at the same plant.

What NIOSH Did

- Interviewed current workers and measured their lung function with spirometry.
- Measured air concentrations of chemicals in the production areas and other areas of the plant while workers made flavored liquid and powder products.
- Evaluated local exhaust ventilation systems (bench-top and booth-type hoods) in the liquid production room.

What NIOSH Found

- Many workers from all areas of the plant reported symptoms of eye and nasal irritation.
- Two workers with current or past work in flavoring production had fixed obstructive lung disease consistent with bronchiolitis obliterans.
- Average diacetyl concentrations were highest in the liquid production room, powder production room, and pre-production corridor. The highest single-area 2-hour air concentration of diacetyl was observed in the spray-drying room while a recipe with diacetyl was being encapsulated.
- Several work activities were associated with high diacetyl exposure: 1) pouring liquid diacetyl; 2) scooping and sifting flavored powder products; 3) packaging flavored powder products; and 4) adding ingredients into flavor formulations.
- Overall performance of the bench-top and booth-type hoods was good. However, diacetyl area air concentrations were measured in the liquid production room during use of the hoods, which may be due to deficiencies in the design or operation of the hoods.

What Gold Coast Ingredients, Inc. Managers Can Do

- Install ventilation and other engineering controls in the powder production room and spray-drying areas.
- Re-design the proximity switch on the bench-top and booth-type hoods in the liquid production room to ensure the hood exhaust systems are always "on" when work is done in the hoods.
- Install a pressure gauge in the hood exhaust ducts to provide a way to check performance.
- Install an on/off light for each hood to indicate when the hood exhaust fans are operational.

- Perform industrial hygiene air sampling and repeat air sampling regularly to ensure effectiveness of controls is maintained.
- Train workers on how to properly use the bench-top and booth-type exhaust hoods.
- Require workers to use exhaust hoods when performing high-exposure activities with diacetyl or other FEMA priority chemicals: 1) pouring liquid diacetyl; 2) scooping and sifting flavored powder products; 3) packaging flavored powder products; or 4) adding ingredients into flavor formulations.
- Require that workers wear NIOSH-certified full-facepiece respirators (with NIOSH-certified organic vapor and particulate cartridges) when they are in the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse.
- Perform pre-placement spirometry testing on all new workers who will enter the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse.
- Perform spirometry testing every 3 months on all workers who enter the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse.

What Gold Coast Ingredients, Inc. Workers Can Do

- Use the bench-top and booth-type hoods properly. Verify that hoods are "on" when using them.
- Perform activities associated with high exposure only in the exhaust hoods. These activities include: 1) pouring liquid diacetyl; 2) scooping and sifting flavored powder products; 3) packaging flavored powder products; or 4) adding ingredients into flavor formulations.
- Wear a NIOSH-certified full-facepiece respirator (with NIOSH-certified organic vapor and particulate cartridges) at all times when in the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse.
- Report any persistent cough, shortness of breath, or wheezing to your supervisor and your doctor. Give your doctor a copy of the NIOSH Flavoring Alert [NIOSH 2003b] and/or this report.
- Participate in the medical monitoring program at the plant.

Summary

Based on NIOSH measurements of flavoring chemicals in the air in the plant, NIOSH investigators found that the highest single area 2-hour TWA air concentration for diacetyl was observed in the spray-drying room while a recipe with diacetyl was encapsulated. In other areas, the mean diacetyl air levels were highest in the liquid production room, followed by the powder production room and pre-production corridor. Task-based air sampling demonstrated that high exposures to diacetyl occurred during the following activities: 1) pouring liquid diacetyl; 2) scooping and sifting flavored powder products; 3) packaging flavored powder products; and 4) adding ingredients into flavor formulations. An evaluation of a newly installed exhaust ventilation system, in the liquid production room, showed good performance in capturing air contaminants. However, improvements in the design and operation of these engineering controls are recommended. **(Continued on page vi)**

On October 24, 2006, Gold Coast Ingredients, Inc. requested a Health Hazard Evaluation (HHE) from the National Institute for Occupational Safety and Health (NIOSH) to medically screen workers for occupational lung disease at their Commerce, California, flavoring manufacturing plant. The company was participating in a voluntary special emphasis program for the flavor manufacturing industry, called the Flavoring Industry Safety and Health Evaluation Program (FISHEP).

On September 6, 2006, Cal/OSHA had previously requested technical assistance (HETA 2006-0361) from NIOSH for an industrial hygiene and engineering control assessment at the same Gold Coast Ingredients plant to characterize work tasks, processes and procedures, and potential occupational exposures. A secondary goal was to develop recommendations for and evaluate the effectiveness of exposure control techniques. Reports and correspondence regarding the industrial hygiene surveys and the engineering control surveys at the plant were sent to the company previously and are summarized in this HHE report. They are also available in their entirety in the appendices of this report.

Medical surveys of workers were conducted during October 30–November 1, 2006 and March 13–14, 2007; industrial hygiene surveys during November 14–16, 2006 and July 11–12, 2007; and engineering control surveys during November 14–16, 2006 and July 9–12, 2007.

During the initial medical survey among 41 participants, one of 14 (7%) ever-production workers had severe fixed airways obstruction, later confirmed as bronchiolitis obliterans. Post-hire eye irritation was significantly more prevalent in current production workers (11 of 12, 92%) compared to current nonproduction workers (16 of 29, 55%) (p-value=0.03). On repeat spirometry, 1 of 11 (9%) current production workers was found to have developed new obstruction, with a 1-liter drop in the forced expiratory volume in the first second of exhalation (FEV_1). Among 15 ever-production workers from both medical surveys, 2 (13%) had fixed airways obstruction.

During the initial industrial hygiene survey, mean full-shift TWA diacetyl air concentrations were 0.46 ppm in the liquid production room, 0.34 ppm in the powder production room, and 0.21 ppm in the pre-production corridor for both area and personal samples. The highest task-based diacetyl air concentration (11.04 ppm) was measured when a worker (in a full-facepiece respirator with

Among the small number of workers who have made flavorings at this plant, two workers were found to have fixed obstructive lung disease. NIOSH investigators recommend that workers wear NIOSH-certified full-facepiece respirators (with NIOSH-certified organic vapor and particulate cartridges) at all times when they are in the production areas, pre-production corridor, or distribution warehouse. Management should continue to install ventilation and other engineering controls to minimize worker exposure to flavoring chemicals in the air. Pre-placement and 3-month interval spirometry testing should be done on all workers who enter the production areas, pre-production corridor, or distribution warehouse. Workers who experience a substantial decline in their FEV_1 should be removed from exposure to flavoring chemicals until medically evaluated for appropriate restrictions.

organic vapor and particulate cartridges) was pouring diacetyl from a bulk container into smaller containers in the pre-production corridor over a 10-minute period. Mean, full-shift TWA acetoin air concentrations were 0.15 ppm in the liquid production room, 0.09 ppm in the powder production room, and 0.07 ppm in the pre-production corridor. The highest task-based acetoin air concentration (1.05 ppm) was measured during mixing and pouring of a butter flavor in the liquid production room by a worker wearing a full-facepiece respirator with combined organic vapor and particulate cartridges; this activity took 61 minutes. Mean, full-shift TWA acetaldehyde air concentrations were 0.14 ppm in the powder production room, 0.07 ppm in the liquid production room, and 0.07 ppm in the pre-production corridor. A task-based acetaldehyde air concentration of 0.19 ppm was measured during pouring and mixing of ingredients for a fruit flavor in the liquid production room; this activity took 53 minutes.

During the follow-up industrial hygiene survey, mean full-shift TWA area diacetyl air concentrations were 0.529 ppm in the liquid production room, 0.483 ppm in the powder production room, 0.098 ppm in the pre-production corridor, and 0.041 ppm in the distribution warehouse. The highest single-area 2-hour air concentration of diacetyl (6.33 ppm) was observed in the spray-drying room while a recipe with diacetyl was being encapsulated. Higher task-based diacetyl concentrations (ranging from 4.75 ppm to 17.38 ppm) were measured during some activities: 1) pouring liquid diacetyl; 2) scooping and sifting flavored powder products; 3) packaging flavored powder products; and 4) adding ingredients into flavor formulations. Mean full-shift TWA acetoin air concentrations were 0.20 ppm in the spray-drying room, 0.163 ppm in the powder production room, 0.077 ppm in the pre-production corridor, and 0.067 ppm in the distribution warehouse. The highest task-based acetoin air concentration (2.78 ppm) was measured during packaging of a dairy-flavored powder product in the powder production room over a 33-minute period. Mean full-shift TWA acetaldehyde air concentrations were 0.44 ppm in the spray-drying room, 0.343 ppm in the powder production room, 0.273 ppm in the liquid production room, and 0.029 ppm in the pre-production corridor. The highest task-based acetaldehyde air concentration (4.02 ppm) was measured during packaging of a powdered dairy-flavored product in the powder production room; this activity took 33 minutes.

During the initial engineering control survey, NIOSH investigators

performed a walkthrough of the plant to review production processes and provided recommendations on the design and implementation of engineering controls. During the follow-up survey, NIOSH investigators evaluated the local exhaust ventilation system (bench-top and booth-type hoods) installed in the liquid production room. When activated, the ventilated bench-top and booth-type hoods had good overall performance; however, NIOSH investigators made recommendations to further improve the performance and operability of the local exhaust ventilation.

NIOSH investigators also recommended that management continue to install ventilation and other engineering controls to minimize exposure to hazardous chemicals in the powder production processes. Additionally, we recommended that workers wear full-facepiece respirators (with NIOSH-certified organic vapor and particulate cartridges) at all times when they are in the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse. Workers who enter these areas should also undergo spirometry testing every three months. Workers with abnormal spirometry or a decline in FEV_1 greater than 10% should be removed from exposure to flavoring chemicals until medically evaluated for appropriate restrictions.

Keywords: NAICS 311930 (Flavoring Syrup and Concentration Manufacturing), bronchiolitis, respiratory, flavorings, diacetyl, airways obstruction, engineering controls.

INTRODUCTION

On October 24, 2006, Gold Coast Ingredients, Inc. requested a Health Hazard Evaluation (HHE) from the National Institute for Occupational Safety and Health (NIOSH) to medically screen workers for occupational lung disease at their Commerce, California, flavoring manufacturing plant. The company was participating in the Flavoring Industry Safety and Health Evaluation Program (FISHEP), a voluntary special emphasis program for the California flavor manufacturing industry. In 2006, the California Department of Health Services (now the California Department of Public Health (CDPH)) and the California Department of Industrial Relations' Division of Occupational Safety and Health (Cal/OSHA) initiated FISHEP to evaluate workers exposures, institute workplace preventive measures, and identify workers with flavoring-related lung disease, such as bronchiolitis obliterans. Under FISHEP, participating companies are required to implement control measures recommended by Cal/OSHA and to report to CDPH results of employee medical screening and worksite industrial hygiene assessments.

On September 6, 2006, Cal/OSHA had previously requested technical assistance (HETA 2006-0361) from NIOSH for an industrial hygiene and engineering control assessment at the Gold Coast Ingredients plant to characterize work tasks, processes and procedures, and potential occupational exposures. A secondary goal was an evaluation of the effectiveness of control techniques in reducing potential health hazards. Detailed reports regarding the industrial hygiene surveys (Appendix I) and the engineering control surveys (Appendix II) at the plant have been sent to the company and are summarized in this HHE report.

Medical surveys of workers were conducted during October 30–November 1, 2006 and March 13-14, 2007; industrial hygiene surveys during November 14–16, 2006 and July 11–12, 2007; and engineering control surveys during November 14–16, 2006 and July 9–12, 2007.

Bronchiolitis obliterans

Bronchiolitis obliterans is a rare life-threatening form of fixed obstructive lung disease that has previously been identified as an occupational hazard in microwave popcorn workers exposed to butter flavorings [CDC 2002; Kreiss et al. 2002; Akpinar-Elci et al. 2004; Kanwal et al. 2006]. Usual symptoms of bronchiolitis obliterans include cough and shortness of breath on exertion. Spirometry shows fixed airways obstruction not reversible with bronchodilators. Fixed obstruction may be the first indication of the disease. Lung damage is permanent, as the disease is not responsive to medical treatment. Bronchiolitis obliterans is commonly misdiagnosed as asthma, bronchitis, or emphysema. In August 2004, CDPH and Cal/OSHA received the state's first report of a flavoring manufacturing worker with bronchiolitis obliterans. In April 2006, another case of flavoring-related bronchiolitis obliterans was identified in a flavoring manufacturing worker at another California plant [CDC 2007]. CDPH and Cal/OSHA currently are aware of at least eight cases of bronchiolitis obliterans in California flavoring manufacturing workers; other possible cases are being evaluated [CDC 2007]. These affected workers all were exposed to diacetyl, a ketone used in artificial butter and other flavorings. Diacetyl is used as a synthetic flavoring agent and aroma carrier in foods such as butter, caramel, dairy products, and coffee [NTP 2007]. Diacetyl is also found naturally in foods (e.g., beer, wine, and butter) and in starter cultures and distillates [NTP 2007]. It is known that exposure to diacetyl, either alone or in combination with other flavoring chemicals, can cause severe respiratory epithelial injury in animals [Hubbs et al. 2002, 2004, 2008; Morgan et al. 2008].

Process description and controls

The Gold Coast Ingredients plant manufactures and distributes liquid and powdered flavors to other companies for use in the production of many different products. The plant started making flavorings in the 1990s. Over 800 different flavoring products are produced using over 1000 artificial or natural ingredients. The plant often produces multiple batches of different flavorings on a daily basis. Often flavors are manufactured on an as-ordered basis, with little advance notice.

The plant consists of a liquid production room, powder production room, color room, walk-in cooler and freezer, two spray-drying areas, distribution (raw materials) warehouse, finished products

warehouse, research and development laboratory (lab), quality control (QC) room, and offices (Figure 1). During the November medical survey in 2006, 47 employees worked at the plant, including 15 office workers, 12 production workers, 1 production manager, 11 QC and/or lab workers, 5 warehouse workers, and 3 maintenance/custodial workers. During the March 2007 medical survey, 46 employees worked at the plant. The plant operated on a daylight shift with some variation in start and stop times.

Workers in the liquid and powder production work areas used computerized batch tickets to pull flavoring ingredients, and then poured, measured, and transferred these ingredients into open tanks (liquid production) and ribbon blenders (powder production). Within the powder production room there were two large, stationary ribbon blenders and three small, mobile ribbon blenders. The stationary blenders were located on platforms with fixed ladders. The two blenders had local exhaust ventilation hoods above the platforms. There was no direct air supply to the powder production room. Airflow into the room came by infiltration from the pre-production corridor through a 10-foot by 10-foot door opening (with a plastic curtain) and an approximately 15-inch by 15-inch vent opening in the wall which was ducted to the pre-production corridor.

In the liquid production room, there were open stationary and mobile tanks which were moved throughout the production room according to batch requirements. Employees poured and mixed small quantities of flavoring ingredients on bench-tops and completed large pours directly into the mixing tanks. The room had six exhaust ventilation registers and one supply air register; however, only three of the exhaust registers were operational. During May to June 2007, the company (in conjunction with a ventilation contractor) developed and installed five bench-top (back-draft slotted) ventilation hoods (Figure 2) and three ventilated booth-type exhaust hoods (Figure 3) in the liquid production room. A third type of hood designed to control vapors from the largest mixer was partially installed but was not operational. Each bench-top and booth-type hood had a proximity switch. This switch opened and closed an electrical circuit to the exhaust fan to the particular hood when an object such as a container on the bench-top workstation or a mixing tank in the booth-type hood came within a certain distance of the proximity switch. Once the object was removed, the proximity switch turned off the exhaust.

The spray-drying operation took place in two work areas: 1) a spray-drying room that had a medium-sized stationary spray dryer; and 2) an area enclosed by a plastic curtain that had a large stationary spray dryer. In addition, there was a small mobile spray dryer that could be used in either of these work locations. Spray-drying is a process that encapsulates a flavor to protect the flavor during storage and to control the release of the flavor during processing and consumption of the food [Ubbink and Schoonman 2002]. Inside a spray dryer, a slurry compound is infused with a flavor, which is converted to encapsulated particles. Volatile compounds are often encapsulated in an amorphous carbohydrate, producing more stable and manageable products [Ubbink and Schoonman 2002].

ASSESSMENT

Medical Evaluation

From October 30, 2006–November 1, 2006, two medical officers and a spirometry technician from NIOSH conducted a medical survey consisting of an interviewer-administered, computerized questionnaire and spirometry testing. Prior to starting the medical survey, the medical officers conducted an initial walkthrough of the plant. We invited all workers to participate in the medical survey. After obtaining signed informed consent from participants, we administered a standardized questionnaire to collect information on symptoms, medical diagnoses, smoking history, work history, and work-related exposures (Appendix III-A). This questionnaire included questions from the American Thoracic Society (ATS) standardized adult respiratory symptoms questionnaire [Ferris 1978] and the Third National Health and Nutrition Examination Survey (NHANES III) [CDC 1996], with additional questions on asthma symptoms [Venables et al. 1993] and questions on skin, upper respiratory, and mucus-membrane irritation or problems. A bilingual Cal/OSHA staff member assisted with Spanish translation during the administration of the questionnaire and spirometry testing.

On November 1, 2006, the last day of the initial medical survey, we performed a second walkthrough with two industrial hygienists from Cal/OSHA and completed a closing meeting with the company president, vice president of operations, general manager, production manager, and the two Cal/OSHA industrial hygienists. During this meeting, we emphasized the need for a comprehensive respiratory protection program and the need for workers to wear

appropriate respiratory protection and be quantitatively fit-tested. We also recommended that workers be tested with spirometry every 3 months.

From March 13–14, 2007, a medical officer and spirometry technician from NIOSH returned to the plant to conduct follow-up spirometry testing. Workers also completed a self-administered paper questionnaire (in English or Spanish) for the CDPH and Cal/OSHA FISHEP program with assistance from NIOSH. These questionnaire results are not presented here. A bilingual Cal/OSHA employee assisted with Spanish translation during the completion of the questionnaire and spirometry testing. On the afternoon of March 13, we did a third walkthrough of the plant, and on March 14, we held a closing meeting with the company president and manager of operations. In response to our recommendations, the company relocated a worker that we identified with fixed airways obstruction from a production to a non-production work area. The worker had given permission for the spirometry results to be shared with management and was present during the discussion with management.

We performed spirometry following ATS guidelines [American Thoracic Society 1994]. We used a dry rolling-seal spirometer interfaced to a personal computer and compared spirometry results to reference values based on U.S. population data from NHANES III [Hankinson et al. 1999]. We selected each participating worker's largest forced vital capacity (FVC) and forced expiratory volume in the first second of exhalation (FEV_1) for analysis. We defined obstruction as an FEV_1/FVC ratio and an FEV_1 below their respective lower limits of normal. We defined borderline obstruction as a FEV_1/FVC ratio below the lower limit of normal with a normal FEV_1 and FVC. We defined restriction as an FVC below the lower limit of normal with normal FEV_1/FVC ratio. We defined a mixed pattern (obstruction and restriction) as an FEV_1/FVC ratio, FEV_1, and FVC all below their respective lower limits of normal. Workers with evidence of airways obstruction were administered albuterol, a bronchodilator medication used to treat obstructive lung diseases such as asthma, and were then re-tested after 10 minutes to see if the obstruction was reversible. (Note that this was worded incorrectly in our previous Interim Report as "re-tested within 10 minutes" (Appendix III-B).) We defined reversible obstruction as an improvement in the FEV_1 of at least 12% and at least 200 milliliters after administration of albuterol. This percent change and absolute change in FEV_1 suggests a

"significant" bronchodilation. We defined fixed obstruction as airways obstruction in which neither the FVC nor FEV_1 increased by 12% or more and at least 200 milliliters after the administration of albuterol. Within two to four weeks after the spirometry test, we mailed each participant a report which explained their individual spirometry results and provided recommendations for follow-up of abnormalities. We mailed Spanish speakers reports in both Spanish and English. Additionally, we sent two communications dated March 29, 2007 (Appendix III-B) and August 27, 2007 (Appendix III-C), respectively, to company management providing recommendations and updates on the progress of the NIOSH evaluation.

Data Analysis

We used SAS software [SAS Institute Inc. 2004] for data analysis. To evaluate job category-symptom relationships, we grouped workers into several job categories. We combined laboratory workers and quality control workers into one category and labeled them *lab/QC workers*. These workers often tended to go back and forth between the lab and QC areas while performing their job duties. We combined workers from the various office work areas and labeled them *office workers*. We combined the warehouse workers, custodians, and the production manager who moved around the plant complex throughout the work day into the *warehouse/other* category. We placed participants in the *ever-production* category if they answered "yes" to "Do you or did you ever work in the production room?" and/or provided a work history that indicated they had worked in production. We placed participants in the *ever-lab/QC* category if they answered "yes" to "Do you or did you work in the lab?" and/or provided a work history that indicated they had worked in the lab or QC area. We defined *flavoring-exposed workers* as workers who ever worked in production or who entered the production area on a daily basis as part of another job.

We calculated prevalences of symptoms and spirometry results for all workers and for workers in each of the above categories. For workers who answered "no" to a symptom question, the responses to corresponding subquestions were also considered to be "no." We compared prevalence of airways obstruction by severity level to general U.S. population prevalence from NHANES III [CDC 1996] U.S. population data, stratified by age.

In addition, we calculated prevalence ratios for symptoms for all workers, ever-production workers, and never-production workers by dividing the observed prevalences by expected prevalences based on data from NHANES III [CDC 1996], controlling for age (less than 50 years of age/equal or greater than 50 years of age), gender, smoking status (ever-smoked/never-smoked), and race. Statistically increased rates in the worker groups are indicated by prevalence ratios that exceed the value 1.0 associated with 95% confidence intervals that exclude the value 1.0.

Industrial Hygiene Evaluation

The following industrial hygiene methods are summarized from the NIOSH report, Evaluating Occupational Exposures and Work Practices at Gold Coast Ingredients, Inc., Commerce, CA (Appendix I-C).

During the initial industrial hygiene survey from November 14–16, 2006, NIOSH investigators collected samples at different locations in the plant, including the powder production room, liquid production room, pre-production corridor, quality control room, laboratory, and offices (Figure 4). The NIOSH investigators collected air samples for total and respirable dusts, volatile organic compounds (VOCs), ketones (diacetyl and acetoin), organic and inorganic acids (acetic, butyric, propionic, and phosphoric acids), and aldehyde compounds (2-furaldehyde, acetaldehyde, benzaldehyde, isovaleraldehyde, and propionaldehyde). Full-shift area samples were collected for all analytes except for VOCs, which were measured using thermal desorption tubes sampling over 2-hour periods. Personal full-shift sampling and short-duration, task-based air sampling were done for ketones, organic acids, and aldehydes. Video exposure monitoring was used for select tasks and work practices that were anticipated to produce elevated airborne concentrations. A photoionization detector (PID) was used to quantify real-time VOCs in air (Rae Systems, Inc., Sunnyvale, CA). Real-time total dust measurements were taken using a PersonalDataRam®, model pDR-1000An/1200 (Thermo Electron Corporation, Franklin, MA).

During the follow-up industrial hygiene survey from July 11–12, 2007, NIOSH investigators collected samples in the powder production room, liquid production room, spray-drying room, pre-production corridor, and distribution warehouse (Figure 4). They collected 2-hour TWA air samples for ketones (diacetyl and acetoin) and aldehyde compounds (2-furaldehyde, acetaldehyde,

benzaldehyde, isovaleraldehyde, and propionaldehyde); these included partial-shift, TWA area samples. Short-term, task-based personal air samples were collected for ketones and aldehydes.

During the November 2006 survey, NIOSH investigators collected diacetyl samples using both the NIOSH Method 2557 [NIOSH 2003a] and the modified OSHA Method PV2118 [OSHA 2006]. After the November 2006 visit, a laboratory investigation indicated that the NIOSH Method 2557 for diacetyl is affected by relative humidity, resulting in underestimation of true concentrations. Subsequent studies in laboratory, chamber, and field conditions have confirmed this phenomenon [NIOSH 2003a; Ashley et al. 2008]. In the July 2007 survey, NIOSH investigators collected diacetyl air samples using the modified OSHA Method PV2118. This method differs from the OSHA Method PV2118 [OSHA 2006] only in that the sample is collected on larger silica gel sorbent tubes (400mg/200mg versus 150mg/75mg). Because some of the diacetyl air samples collected using the modified OSHA Method PV2118 from November 2006 exhibited breakthrough of the front tube, sampling volumes were reduced for the July survey.

For statistical analyses, NIOSH investigators assigned sampling results below detectable limits a value of one-half of the minimum detectable concentration in air. However, in a letter dated June 4, 2007 (Appendix I-B), individual results below the limit of the detection were reported as such. Details on the industrial hygiene sampling methods used during the industrial hygiene survey are provided in Tables 1 and 2 and Appendix I-C.

Engineering Control Evaluation

The following engineering control evaluation methods are summarized from the NIOSH report, In-depth Survey Report: Evaluation of Engineering Controls for the Mixing of Flavoring Chemicals at Gold Coast Ingredients, Inc., Commerce, CA (Appendix II-B).

During the NIOSH technical assistance visit from November 14–16, 2006, NIOSH engineers performed a walkthrough of the plant to review production processes and plan for the engineering control evaluation. Following this walkthrough, interim recommendations on the design and implementation of engineering controls were provided to the company in a letter, dated February 7, 2007 (Appendix II-A).

During May to June 2007, the company installed five bench-top (back-draft slotted) ventilation hoods (Figure 2) and three ventilated booth-type hoods (Figure 3) in the liquid production room (Figure 5). The bench-top (back-draft slotted) hoods control worker exposure during small batch mixing, weighing, and pouring activities. The booth-type hoods permit rolling-in of large tanks (kettles) which allows the hood to collect chemical vapors when the worker is pouring flavor ingredients into large tanks and to contain evaporative losses when the batch is mixed. A third exhaust hood designed to control vapors from the largest mixer was partially installed but was not operational during the survey.

During July 9–12, 2007, NIOSH investigators returned for an engineering control evaluation of the recently installed hoods in the liquid production room. A variety of methods were used to evaluate the local exhaust ventilation system including hood velocity measurements, airflow visualization, tracer gas capture, control on/off, and exhaust re-entrainment tests. Brief details of each method can be found in Tables 3 and 4, with a more thorough explanation in Appendix II-B

Medical Evaluation

Participation and Demographics

October–November 2006: Of 47 workers employed at the plant, 41 (87%) participated in the medical survey. Among participants, 61% were Hispanic, 24% Caucasian, 12% Asian, and 2% African American. Sixty-eight percent were male; the mean age was 38 years (range: 19-68). The median age of production workers was 35 years; median age for all other workers was 36 years. The median tenure for production workers was 1.3 years compared to 1.9 years for all other workers. Twenty-seven (66%) participants were never-smokers; 2 (17%) production workers were current or former smokers; 12 (41%) other workers were current or former smokers.

March 2007: Of 46 workers employed at the plant, 37 (80%) participated in the medical survey. Thirty-four workers participated for a second time, and 3 participants participated for the first time.

Work History

October–November 2006: Among the 41 participants, four workers reported previously working for other flavoring plants in the past.

Fourteen workers reported current or past work in the production room. Of these workers, 13 reported working four to eight hours (or more) per day in the production room. All 14 workers reported mixing or pouring flavoring chemicals. Four reported handling diacetyl on a daily basis; 3 reported handling diacetyl two to three times per week; 2 reported handling diacetyl two to three times per month, 1 reported handling diacetyl less than once a month, and 4 reported not handling diacetyl.

Fifteen workers reported current or past work in the lab/QC. Thirteen of these workers reported they mixed or poured flavoring chemicals, including diacetyl. Four reported handling diacetyl on a daily basis; 4 reported handling diacetyl two to three times per week; 4 reported handling diacetyl two to three times a month, and 1 reported handling diacetyl less than once a month.

Twenty-six workers reported that they currently enter the production room regularly as part of another job. Fourteen reported entering the production room on a daily basis, 9 reported

two to three times a week, 1 reported two to three times a month, and 2 reported entering the production room less than once a month.

Worker Symptoms

The percentage of workers reporting post-hire eye and nasal irritation was high in all work areas (Table 5). Among all workers, 46% and 66% reported post-hire nasal and eye symptoms, respectively. Office workers (69%) and warehouse/other workers (60%) were the most likely to report post-hire nasal irritation. Post-hire nasal irritation was statistically more prevalent among current non-production workers (59%) compared to current production workers (17%) (p-value=0.02). Over 80% of current lab/QC workers and more than 90% of current production workers reported post-hire eye symptoms. Post-hire eye irritation was significantly more prevalent among current production workers (92%) compared to current non-production workers (55%) (p-value=0.03). Post-hire skin rash or skin problems were most common in 3 of 12 (25%) production workers, followed by 1 of 5 (20%) warehouse/other workers.

Seventeen workers (41%) reported that chemicals in the plant made them cough or feel short of breath. These chemicals included acetaldehyde, acetoin, benzaldehyde, capsicum, and diacetyl. Some workers did not know the names of the chemicals, or could not determine which chemicals specifically bothered them. Chemicals reported by the workers to cause both eye and nasal irritation included acetaldehyde, acetoin, benzaldehyde, capsicum, and diacetyl.

Table 6 shows worker symptoms, medical conditions, and spirometry (lung function) results by work history for ever- versus never-production workers, ever- versus never-flavoring-exposed workers, and ever- versus never-lab/QC workers. A persistent cough was present in 1 of 14 (7%) ever-production workers and 1 of 27 (4%) never-production workers. Shortness of breath when hurrying on level ground or walking up a slight hill was present in 3 of 14 (21%) ever-production workers and 5 of 27 (18%) never-production workers. Persistent trouble breathing in the last 12 months was found in 1 of 14 (7%) ever-production workers and none of 27 (0%) never-production workers.

Prevalence rate ratios are shown in Tables 7–9 for all workers,

for ever-production workers, and for never-production workers, respectively, for selected respiratory symptoms and conditions in comparison with NHANES III data [CDC 1996]. The analyzed population of 36 non-Asian workers and its subpopulations of 14 ever-production workers and 22 never-production workers were small and none of the rate ratios were statistically significant.

Spirometry Results

October–November 2006

Three of 41 tested workers had abnormal (or borderline abnormal) spirometry results. One worker, who works in the lab/QC, had mild restriction. Two (Workers A and B) of 14 participants who had ever worked in flavoring production at the plant were found to have spirometry indicative of obstruction. Worker A had severe fixed obstruction (FEV_1 17.9% predicted, FEV_1/FVC ratio 37.4%). Worker B had borderline obstruction (normal FEV_1 and FVC but low FEV_1/FVC ratio).

March 2007

Among the 34 workers tested a second time, one worker (Worker B) experienced a substantial drop in FEV_1 (Table 10). This asymptomatic worker, who previously had borderline airways obstruction, now had mild fixed airways obstruction after a 1-liter (25%) decline in FEV_1. Among 3 newly hired workers who were tested for the first time, we identified one worker with borderline airways obstruction.

Combined October/November 2006 and March 2007 Surveys

Forty-four workers completed at least one survey. The results from the most recent spirometry test showed one worker (Worker A) with severe airways obstruction and one worker (Worker B) with mild airways obstruction. Among workers less than 50 years of age, the prevalence of severe airways obstruction was 2.7% (1 of 37) compared to the expected prevalence of 0.1% based on NHANES III data (Table 11).

In Interim Report 1 (Appendix III-B), we provided summaries of Worker A and Worker B. Below are updated summaries, included here with written consents, of each of these workers.

Worker A

In 1995, a Spanish-speaking, 26-year-old male with no history of smoking or asthma developed shortness of breath one year

after beginning employment as a flavor compounder. Three years later in 1998, he developed a chronic cough. In his first six years, his job involved adding diacetyl and other ingredients to formulate powder flavorings; monitoring blending operations; and packaging finished product into boxes. His workplace lacked effective exposure controls including local exhaust ventilation and a comprehensive respiratory protection program. From 1995 to 1999, he wore an N-95 filtering facepiece and then, until leaving production work, he wore a full-facepiece, negative-pressure, air-purifying respirator. He reported that neither respirator was fit-tested. Due to respiratory symptoms, he was moved to liquid flavoring production sometime during 2000 and in April 2006 to warehouse work that involved entering the production area daily. He was evaluated by his personal physician who diagnosed chronic rhinitis in 2003 and acute bronchitis in 2004. In March 2005, his spirometry showed severe obstructive lung disease (FEV_1 20% predicted, FEV_1/FVC ratio 47%) without bronchodilator response. In May 2005, a pulmonologist diagnosed bronchiectasis of unknown etiology based on high-resolution computerized tomography (HRCT) scan of the chest. The worker was hospitalized on two occasions for his lung condition. Screening spirometry by NIOSH in October 2006 showed an FEV_1 of 17.9% predicted and a FEV_1/FVC ratio of 37.4% without bronchodilator response. Follow-up testing by NIOSH in March 2007 showed an FEV_1 of 20.7% predicted and an FEV_1/FVC ratio of 35.6% without bronchodilator response. He was diagnosed with bronchiolitis obliterans and has been placed off work while being evaluated for disability.

Worker B

In 2007, a Spanish-speaking, 25-year-old male with no history of asthma, bronchitis, or respiratory disease developed asymptomatic fixed obstructive lung disease two years after beginning work as a flavor compounder. He was a former smoker with a two-pack-year smoking history. He originally worked in liquid flavoring production. After approximately five months, he was transferred to powder flavoring production for 3 months and then returned to liquid flavoring production in December 2005. He started wearing a full-facepiece respirator sometime in 2005, but that was not fit-tested until January 2007. Screening spirometry by NIOSH in October 2006 showed borderline airways obstruction with a normal FEV_1 (86.5% of predicted) and FVC (113.5% of predicted) but a decreased FEV_1/FVC ratio (64.4%). By a follow-up NIOSH survey in March 2007, he had developed mild fixed airways

obstruction with a low FEV_1 (64.5% of predicted) and a low FEV_1/FVC ratio (51.3%) without bronchodilator response. Over the four and a half month period between screening spirometries, his FEV_1 dropped more than 1 liter (25% decline). He denied any shortness of breath, cough, or wheeze. He was moved to a warehouse job in the plant and was evaluated at a university occupational health clinic where a HRCT chest scan showed air-trapping on the expiratory view. He was diagnosed with asymptomatic bronchiolitis obliterans and continues to work in the warehouse.

Reported respirator usage

October–November 2006 Initial Medical Survey

Of the 14 workers with current or past work in the production rooms, 5 reported using respirators or masks all the time when in the production rooms, and 9 reported wearing a respirator or mask some of the time when in the production rooms. Among the 23 current production and lab/QC workers, 18 reported using respirators or masks in the production rooms or laboratory. One worker reported being qualitatively fit-tested for a respirator. No quantitative fit testing had been done.

Respirator use observations

October–November 2006 Initial Medical Survey

At the time of this survey, management's policy was to require respirator use with acetaldehyde, acetic acid, acetoin, benzaldehyde, and/or diacetyl use. Respirators were qualitatively fit-tested with isoamyl acetate (banana oil). No specific area existed for storage of respirators. During the initial walkthrough of the plant, we noted workers in the production areas wearing various types of respirators, including full-facepiece, half-facepiece, and N-95 filtering facepiece respirators (all NIOSH-certified). The full-facepiece or half-facepiece respirators were fitted with organic vapor cartridges, sometimes without particulate filters. During some tasks (such as pouring of liquid ingredients in the pre-production corridor), we observed some production workers wearing respirators while their co-workers performing the same task did not wear respirators. During the second walkthrough, production had ceased for the day. All of the workers performing cleaning activities in the production areas wore half-facepiece or full-facepiece respirators fitted with organic vapor cartridges, but not always with particulate filters. During the medical survey, we gave the company guidance about their respiratory protection program. Cal/OSHA was onsite during the closing meeting where we also

discussed the need for workers to wear appropriate respiratory protection and be quantitatively fit-tested.

November 2006 Initial Industrial Hygiene Survey (Appendix I-C)
During this survey, production workers generally wore respirators at all times in the liquid and powder production areas. Respirator use included both half-facepiece cartridge respirators and full-facepiece cartridge respirators with organic vapor and P-100 cartridges, and workers had been qualitatively fit-tested. During conversations with workers, they seemed uncertain about how often to change-out respirator cartridges (Appendix I-A). Respirators were stored in the production areas. NIOSH industrial hygienists provided specific guidance to management and workers on respirator use and storage.

March 2007 Follow-up Medical Survey
During the walkthrough, no production activities were occurring. Workers in the production rooms wore full-facepiece respirators fitted with organic vapor cartridges, but not always with particulate protection. All the current production workers, except for one production worker and the production manager, had been quantitatively fit tested for full-facepiece respirators. Unused respirators were stored in a specific location outside the powder production room in the pre-production corridor.

July 2007 Industrial Hygiene Follow-up Survey (Appendix I-C)
At the time of this survey, the respiratory protection program was notably improved. Respirators had a specific storage location outside the powder production area in the pre-production corridor. Management indicated that cartridges were changed after approximately eight hours of use and had stored used cartridges to confirm this schedule. New cartridges were visibly available, and employee use was more consistent. Management reported that production workers had been quantitatively fit-tested and trained. Observations suggested that production workers wore respirators more frequently and appropriately than was the case during the previous industrial hygiene survey. There were still some individuals (e.g., QC workers and management officials) who periodically entered the production areas without respiratory protection.

Industrial Hygiene Evaluation

The following results are summarized from the NIOSH report, Evaluating Occupational Exposures and Work Practices at Gold Coast Ingredients, Inc., Commerce, CA (Appendix I-C). Tables 12–17 show results for 8-hour TWA and task-based sampling (by work area) from the November 2006 industrial hygiene survey. Tables 18–21 show results for 2-hour TWA and task-based sampling (by work area) from the July 2007 industrial hygiene survey.

Temperature and relative humidity

November 2006 survey

Outdoor air temperatures ranged from 56 degrees Fahrenheit (°F) to 87°F. No indoor air temperatures or relative humidity measurements were collected.

July 2007 survey

Indoor air temperatures in the facility ranged from 71°F to 90°F. During the two days of sampling, the relative humidity ranged from 28% to 78% in the powder production room, 33% to 63% in the liquid production room, 23% to 65% in the spray-drying room, 35% to 55% in the pre-production corridor, and 28% to 53% in the distribution warehouse.

Ketones (Diacetyl and Acetoin)

Diacetyl

November 2006 survey

Diacetyl area and personal air samples collected on the same day in the work areas were not significantly different than one another (p-value=0.384); therefore, personal and area samples are presented together in Tables 12–17.

In an analysis limited to samples analyzed according to the modified OSHA Method PV2118, the mean 8-hour air TWA concentration for diacetyl was highest in the liquid production room (0.46 ppm), followed by the powder production room (0.34 ppm), pre-production corridor (0.21 ppm), and quality control room (0.07 ppm) (Table 13). The spray-drying room was not sampled because it was not in operation during the site visit.

In the pre-production corridor, a task-based personal air sample measured a diacetyl air concentration of 11.04 ppm (NIOSH

Method 2557) when a worker (in a full-facepiece respirator) was pouring diacetyl from a 55-gallon drum into multiple 5-gallon containers over a 10-minute period (Table 17).

July 2007 survey

Mean work-area-specific 2-hour TWA concentration of diacetyl was highest in the liquid production room (0.529 ppm), followed by the powder production room (0.483 ppm), pre-production corridor (0.098 ppm), and distribution warehouse (0.041 ppm) (Table 19). The highest single 2-hour TWA concentration of diacetyl (6.33 ppm) was observed in the spray-drying room while a recipe with diacetyl was being encapsulated.

Packaging and scooping powder formulations in the powder and liquid production rooms resulted in some of the highest personal task-based diacetyl air samples (4.75 ppm, 4.84 ppm, 9.32 ppm, 10.05 ppm, and 17.38 ppm) (Table 21). The two highest measurements occurred while packaging butter-flavored powder under a ventilated hood in the liquid production room. The highest concentration (17.38 ppm) was measured over an 8-minute period while a worker (wearing a respirator) scooped butter-flavored powder from a large metal container and packaged it into smaller containers inside a newly installed booth-type ventilation hood. The 10.05 ppm diacetyl concentration was measured during a 10-minute period while a worker (wearing a respirator) also packaged butter-flavored powder inside a ventilated booth-type hood. The 9.32 ppm diacetyl air concentration was measured over a 1-hour period when a worker (wearing a respirator) scooped butter-flavored powder into a sifter (above his head). During this process, the worker reached deeply into the metal grinder vat to completely remove the butter-flavored powder. The 4.84 ppm diacetyl concentration was measured over 17 minutes while a worker (wearing a respirator) worked under a bench-top hood preparing a confectionery flavor which involved pouring ingredients into a mixer followed by mixing, packaging, and taking a sample for quality control. The 4.75 ppm diacetyl concentration was measured over 33 minutes while a worker packaged a dairy-flavored powder into smaller containers in the powder production room with no exhaust hood.

Acetoin

November 2006 survey

Mean work-area-specific 8-hour TWA concentration of acetoin was

highest in the liquid production room (0.15 ppm) followed by the powder production room (0.09 ppm), quality control room (0.07), and pre-production corridor (0.07 ppm) (Table 13).

The highest personal task-based acetoin air concentration (1.05 ppm) was measured over a 61-minute period in the liquid production room during the mixing and pouring of a butter flavor (Table 17).

July 2007 survey
Mean work-area-specific 2-hour TWA air concentration of acetoin was highest in the spray- drying room (0.20 ppm) followed by the powder production room (0.163 ppm), pre-production corridor (0.077 ppm), and liquid production room (0.07 ppm) (Table 19).

The highest personal task-based acetoin air concentration (2.78 ppm) was measured in the powder production room during the packaging of a dairy-flavored powder into boxes over a 33-minute period (Table 21).

Aldehydes

For both industrial hygiene surveys, the highest measured aldehyde concentration was for acetaldehyde (Tables 12, 14, 17, 18, 20, and 21) which did not exceed the Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) of 200 ppm for an 8-hour TWA (Table 22).

November 2006 survey
Mean work-area-specific 8-hour air TWA acetaldehyde concentration was highest in the powder production room (0.14 ppm), followed by the liquid production room (0.07 ppm) and pre-production corridor (0.07 ppm), and quality control room (0.06 ppm) (Table 14).

An acetaldehyde air concentration of 0.19 ppm was measured over a 53-minute period in the liquid production room when a worker was pouring and mixing ingredients for a fruit flavor (Table 17).

July 2007 survey
Mean work-area-specific 2-hour TWA air concentration of acetaldehyde was highest in the spray-drying room (0.44 ppm) followed by the powder production room (0.343 ppm), liquid production room (0.273 ppm), pre-production corridor (0.029

ppm), and distribution warehouse (0.014 ppm) (Table 20).

The highest personal task-based acetaldehyde air concentration (4.02 ppm) was measured over a 33-minute period in the powder production room when a worker was packaging a dairy-flavored powder into boxes (Table 21).

Organic Acids

November 2006 survey

NIOSH investigators collected acetic acid, butyric acid, and propionic acid personal 8-hour TWA samples in production areas and areas samples throughout the facility. Mean work-area-specific 8-hour air TWA concentrations of organic acids were highest in the powder production room: acetic acid (0.75 ppm), butyric acid (0.10 ppm), and propionic acid (0.12 ppm) (Table 15).

While a worker poured and mixed ingredients during a 61-minute period for a butter flavor batch in the liquid production, task-based acetic acid was measured at 1.93 ppm, butyric acid at 1.20 ppm, and propionic acid at 1.43 ppm (Table 17).

Phosphoric Acid

November 2006 survey

Phosphoric acid 8-hour air TWA concentrations were below the analytical limit of detection and the NIOSH and OSHA occupational exposure limits (Table 22).

Respirable and Total Dusts

November 2006 survey

The highest mean 8-hour TWA concentrations of respirable and total dust were measured in the powder production room: respirable dust (0.26 mg/m^3), total dust (1.28 mg/m^3) (Table 16). The samples were all below established OSHA exposure limits (Table 22).

Real-time dust concentrations averaged over 1-minute periods were continuously logged one day in the powder production room (Figure 6). The dust concentrations were highly variable with 1-minute average concentrations ranging from around 0.1 to 1.6 mg/m^3. During some time-periods, increasing dust concentrations corresponded with rising VOC concentrations. This suggests that some product formulations released high quantities of both dusts

and VOCs. NIOSH investigators also observed times when VOC concentrations increased without increases in dust concentrations, which may correspond to liquid pouring prior to blending.

Volatile Organic Compounds

November 2006 survey

Figures 7–9 illustrate real-time concentrations of VOCs measured during the November 2006 survey. They are presented as ppm isobutylene equivalent concentrations in the pre-production corridor, liquid production room, and powder production room, respectively. In all three work areas, concentrations were highly variable and reflect the diversity of batches and their ingredients. The most variable and highest peak concentration (120.4 ppm) was observed in the liquid production room (Figure 8). VOC peaks in the liquid production room or the powder production room did not correspond to VOC peaks in the pre-production corridor. (Such correspondence, had it been observed, would have indicated possible migration of VOCs.)

November 2006 and July 2007 surveys

NIOSH investigators identified 191 compounds in the thermal desorption sample tubes. Table 23 lists the 30 most abundant compounds identified during each survey in rank order of abundance. A complete list can be found in Appendix I-C.

Engineering Control Evaluation

The following results are summarized from the February 7, 2007 NIOSH letter (Appendix II-A).

Ventilation / Air Movement

November 2006 survey

In the liquid production room, NIOSH investigators observed a combination of general exhaust and supply ventilation systems located on the ceiling of the room (Figure 10). Two air exhaust fans (EF), EF-1 and EF-2, were exhausting air at a combined flow rate of 980 cubic feet per minute (cfm) and one air supply fan (SF), SF-1, was supplying air at a rate of 1300 cfm. Three exhaust fans (EF-3, EF-4, and EF-5) were not moving air at all; one had a duct that was disconnected above the ceiling.

The fume canopy exhaust hood over Mixing Tanks 3 and 4 (Figure

10) were exhausting air when the fan was activated. EF-6 over Tank 3 had a flow rate of 950 cfm. NIOSH investigators did not measure the exhaust flow rate of EF-7 located over Tank 4 because the tank was in the way.

A smoke tracer test showed that the liquid production room was generally under negative pressure with respect to the pre-production corridor. However, this was dependent on the operation of the canopy hood over Tanks 3 and 4 (Figure 10). When this exhaust fan was on, the overall exhaust flow rate was higher than the measured supply air flow rate. When this fan was off, the measured supply flow rate was higher than the exhaust, potentially creating positive pressure with respect to the pre-production corridor.

No powered air supply was provided to the powder production room. Airflow into the room came from infiltration from the pre-production corridor through the 10-foot x 10-foot door opening (covered by a plastic curtain) and an approximately 15-inch x 15-inch vent opening located in the wall (about 11 feet above the floor) which was ducted to the pre-production corridor. Two local exhaust ventilation systems were installed in the powder production room: a canopy hood over the smaller ribbon blender and a slotted exhaust hood over the larger ribbon blender.

The following results are summarized from the NIOSH report, In-depth Survey Report: Evaluation of Engineering Controls for the Mixing of Flavoring Chemicals at Gold Coast Ingredients, Inc., Commerce, CA (Appendix II-B).

July 2007 survey

Hood Velocity Measurements

Table 24 lists the average air velocity measured across the face of each hood. Average face velocities for all bench-top hoods were above the recommended capture velocity of 100 feet per minute (fpm) with a range of 164 to 205 fpm. The velocities were fairly uniform across the opening of each hood face. Average face velocities for the booth-type hoods were lower than the bench-top hoods and ranged from 69 fpm to 80 fpm. Slot velocities were generally uniform across all slots for every hood and ranged from 1030 fpm to 2800 fpm.

Airflow Visualization Test

The smoke tests showed good capture for all bench-type ventilated workstation hoods. Smoke was generally captured directly and quickly when released in the interior of the hood and along the perimeter. However, turbulence due to cross drafts caused some leakage when testing Hoods 1, 5, and 9 in the liquid production room (Figure 5). The turbulence and swirling around these hoods were likely due to the large amount of make-up air entering the room through the door to the pre-production corridor. In addition, smoke tests showed that the use of the wall-mounted area fan located in the corner of the room resulted in substantial performance degradation for Hood 1.

The booth-type hoods also showed good capture, although with generally more leakage along the outside perimeter of the hood. These leakages were likely due to cross-draft turbulence and lower capture velocities at the face of these hoods than at the bench-top hoods.

Tracer Gas Capture Test

Quantitative collection efficiencies ranged from 89–100% for all hoods under various test conditions (Table 25). NIOSH investigators conducted multiple tests on Hood 1 because it was more likely to be affected by cross drafts than other hoods due to its proximity to the room opening (where makeup air was entering the room) (Figure 5). NIOSH investigators used a sulfur hexafluoride (SF_6) ejector source (Figure 11) placed at various locations in the hood (see Table 25). The lowest capture efficiency was observed when the source was located on the bench-top outside the side baffle nearest to the room opening.

In addition, NIOSH investigators performed a tracer-gas test with and without a mannequin in front of Hood 9 (Figure 11) to assess the effect of the body wake on contaminant capture efficiency. The capture efficiencies with and without the mannequin were both greater than 98%. This test indicated that the presence of the mannequin did not have an appreciable effect on the capture efficiency during this evaluation.

Control On/Off Test

NIOSH investigators observed a reduction in exposure during pouring and whisking activities when the local exhaust ventilation

system was activated (Figure 12 a, b, and c). They conducted three paired control on/control off tests using bench-top Hood 9 for two tests and bench-top Hood 2 for one test. When the ventilation system was activated, the task-based average VOC air concentration was reduced by 96% for Test 1, 93% for Test 2, and 90% for Test 3 (Figure 13).

VOC concentrations showed high variability during the control off tests due to the effects of worker activities and turbulent room drafts. This was greatly reduced when the control was turned on. However, as Figure 12 indicates, a few high exposures instantaneously existed when the control was on. These concentration spikes were noted when the operator would pick up the 5-gallon bucket and move the alcohol near the monitor probe, which was below the breathing zone. Once the pour started, the concentration dropped down to background level.

Exhaust Re-entrainment Evaluation

NIOSH investigators examined the blower/discharge configuration for each hood located on the roof of the facility. The blower for each hood exhaust was connected to an exhaust duct that extended off the deck of the roof between 22–40 inches. The exhaust duct openings were 20–24 inches in diameter and were angled 90 degrees to exhaust air parallel to the roof line (Figure 14).

The centerline velocity in the exhaust discharge stream ranged from 2100 to 3250 fpm (Table 26). The smoke-release test showed that under certain wind conditions, the exhaust could re-enter the building through a roof vent opening. Given the variability of wind fields, the amount of exhaust which can be re-entrained is difficult to predict.

We found one current and one former production worker who had fixed airways obstruction. The most severely affected worker is unable to wear a respirator due to respiratory symptoms and had been transferred to a job with less exposure to flavoring chemicals. His symptoms of shortness of breath and cough started while he worked in the powder production room and continued to progress when he was transferred to liquid production before being relocated to the warehouse. During our second medical survey, we identified the second worker who had a large drop in lung function (greater than one liter) over the 4.5-month interval between spirometry testing. He also worked in powder and liquid production with the majority of his employment in liquid production. He denied shortness of breath, cough, or wheeze during both medical surveys and remains asymptomatic.

We are not aware of reports of fixed obstructive lung disease in laboratory or quality control workers at this or other flavoring manufacturing plants. However, spirometry testing did identify one lab/QC worker at this plant with a restrictive abnormality but no other physiologic testing of this worker was done to possibly further elucidate the nature of this abnormality. Individual cases of possible flavoring-related respiratory impairment with restriction have occurred in the microwave popcorn industry without explanation or alternate diagnosis [Alkpinar-Elci et al. 2004; NIOSH 2003c, 2006]. Although it is likely that diacetyl exposure contributed to the occurrence of fixed airways disease in these facilities, whether restrictive abnormalities are related to diacetyl or other flavoring chemical exposures remains unclear. Longitudinal follow-up and/or studies of larger populations may clarify whether cases of restriction are coincidental, a stage of flavoring-related abnormalities, or a less common response to flavoring exposure.

Because symptoms of bronchiolitis obliterans, such as shortness of breath, are progressive and often not initially noticed by the worker, spirometry is an essential part of the medical surveillance program implemented at this plant. Workers with symptoms or large declines in lung function (FEV_1 drops of 10% or more) need to be restricted from exposure to flavoring chemicals or ingredients until medically evaluated for appropriate work restrictions. If the evaluating occupational or pulmonary physician recommends placement in the warehouse, the physician needs to be sure that the warehouse is free of flavoring exposures or, if it is not free of such exposure, that the worker can safely use appropriate respiratory protection. At the time of the NIOSH industrial

hygiene survey in July 2007, the distribution warehouse had measurable concentrations of diacetyl. NIOSH investigators did not sample the finished products warehouse; however, this area should be sampled for flavoring exposures. If sampling shows measurable diacetyl in the finished products warehouse, respiratory protection would also be warranted in this area, at least until a safe level is established.

The California Department of Public Health, with assistance from NIOSH, developed guidelines for medical surveillance for flavoring-related lung disease among flavoring manufacturing workers in California [CDPH 2007]. If a worker is identified with a flavoring-related lung disease, the guidelines recommend that workers whose job tasks pose similar or greater risk undergo spirometry testing every 3 months. In this plant, we recommend 3-month interval spirometry testing for all production workers, lab/QC workers, and any other workers who enter the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse. The spirometry testing interval may be reevaluated after achieving all of the following: 1) modifications are made to the bench-top and booth-type hoods in the liquid production room (see recommendations below); 2) engineering controls are installed and evaluated in the powder production room and spray-drying areas; 3) industrial hygiene sampling shows that worker exposures to flavoring chemicals have decreased; and 4) no further cases of fixed airways obstruction or large declines in lung function (i.e., >10% decline in FEV_1) occur in workers at this plant.

Spirometry, however, will lead only to secondary prevention (early disease detection followed by activities to prevent progression) unless it is part of a population-based surveillance program in which work-related risks are identified and preventive interventions are undertaken and evaluated for effectiveness in preventing flavoring-related lung disease (primary prevention). The two affected workers in this plant manifested their disease while working in flavored powder and liquid flavor production. At this plant, task-based air sampling done by NIOSH investigators demonstrated that the highest exposures to diacetyl occurred during the following activities: 1) pouring liquid diacetyl; 2) scooping and sifting flavored powder products; 3) packaging flavored powder products; and 4) adding ingredients into flavor formulations.

Although we know that diacetyl, as a single agent, is associated with lung disease in experimentally exposed animals and in diacetyl manufacture, we do not know if exposure to other flavoring chemicals contributed to the development of disease in the workers at this plant. Many volatile chemicals used to make flavorings, such as acetoin [NIOSH 2007a], acetaldehyde [NIOSH 2005, 2007a], benzaldehyde [NIOSH 2007a], and acetic acid [NIOSH 2005, 2007a] are highly irritating to the eyes and respiratory tract. Little is known about the potential of these chemicals to cause lung disease alone or as mixed exposures. In one case cluster of flavoring manufacturing workers with fixed obstructive lung disease consistent with bronchiolitis obliterans, acetaldehyde exposure was suspected as a cause [Lockey et al. 2002]. A spill of acetic acid has been reported to have caused an acute-onset obstructive airways disease known as reactive airways dysfunction syndrome [Kern 1991]. Acetaldehyde and acetic acid air measurements at this plant were below their respective OSHA PELs at the time of the NIOSH industrial hygiene surveys. OSHA PELs do not exist for acetoin, benzaldehyde, or diacetyl.

Air sampling by the modified OSHA Method PV2118 in this plant detected diacetyl in all the productions areas, the pre-production corridor, and the distribution warehouse [Appendix I-C]. The source of the diacetyl in the distribution warehouse is unknown, and this should be explored through subsequent investigations. As noted earlier, NIOSH investigators did not perform air sampling in the finished products warehouse; however, this area should be sampled in the future. Sampling in the spray-drying room indicated the highest 2-hour air TWA concentration during one formulation with diacetyl. Since limited sampling occurred in this area, spray-drying operations should be monitored in the future.

During both industrial hygiene surveys at this plant, diacetyl air measurements were higher in the liquid production room than the powder production room. In a Health Hazard Evaluation at a different flavoring manufacturing facility, NIOSH investigators observed higher diacetyl air concentrations during powder production activities [NIOSH 2007a]. At that facility, powder and liquid production occurred in adjacent areas of a single room; liquid production workers reported fewer symptoms than powder production workers and were not found to have airways obstruction [NIOSH 2007a]. Martyny et al. [2008] also found higher mean diacetyl air concentrations during powder operations than liquid operations when he and other investigators evaluated

16 flavor manufacturing facilities. In this facility, mean exposures were higher in the liquid production room during both site visits, although scooping, sifting, and packaging of flavored powder products occurred in the liquid production room during the second site visit, after the installation of engineering controls in that room. Exposures from both liquid and powder operations will vary dramatically at flavoring manufacturing facilities, depending upon the flavors formulated, engineering controls implemented, and work practices employed.

At this facility, measured diacetyl air concentrations were higher during the second industrial hygiene survey, after the installation of the local exhaust ventilation system in the liquid production room. There are some possible explanations for this finding [Appendices I-C and II-B]. First, the flavored products produced during the second industrial hygiene survey may have contained more diacetyl than those produced during the first survey. Second, during the follow-up industrial hygiene survey, 2-hour TWA samples were collected versus 8-hour TWA samples in the first survey. Although samples during both investigations were area TWA samples, the shorter duration samples may more accurately reflect peak exposures compared to longer duration samples. Third, deficiencies in the design and operation of the booth-type hoods during powder packaging activities may have compromised the performance of these hoods. During the packaging of diacetyl-containing powdered flavorings within the booth-type hoods, some activities extended beyond the booth envelope, potentially contaminating the production room air. When activities are conducted outside the booth envelope, hood function is marginalized, and chemicals may escape to other areas of the room, potentially exposing other workers. Additionally, the proximity switch (Figure 15) is mounted on the back of the booth and activates only when the mixing tank comes close to the face of the switch. If the powder packaging apparatus did not activate the proximity switch, then the hood would not have activated and would not have protected the workers [Appendices I-C and II-B].

When used properly, bench-top and booth-type hoods in the liquid production room are an effective engineering control. Bench-top hoods should be used during small-batch mixing, weighing, or pouring activities, while booth-type hoods should be used for large tank ventilation, packaging of flavored products, or redistributing or pouring diacetyl or other Flavor and Extract Manufacturers Association (FEMA) high-priority chemicals [FEMA 2004].

Engineering controls also need to be installed and evaluated in the powder production room and spray-drying areas. When the ribbon blenders or spray-drying units are in operation, diacetyl or other FEMA high-priority chemicals that have been added to the flavoring batch can volatilize, resulting in worker exposure. In fact, NIOSH investigators observed the highest 2-hour TWA diacetyl area air concentrations (6.33 ppm) in the spray-drying room during the operation of the spray dyer. Emptying flavored powder product from the ribbon blender or spray dryer may also result in worker exposure. A personal task-based diacetyl air concentration of 4.75 ppm was measured over a 33-minute period when a worker (wearing a respirator) discharged flavored powder product from the ribbon blender into boxes. A ventilated collar or some sort of continuous liner system would help reduce the release of product during the emptying of the ribbon blender. This concentration and the diacetyl concentrations measured during the operation of the spray dyer indicate the need for special attention during these operations.

In addition to engineering controls, workers who enter production areas (including the pre-production corridor) must wear quantitatively fit-tested, full-facepiece respirators (with NIOSH-certified organic vapor and particulate cartridges). Because the distribution warehouse had measurable diacetyl, we also recommend respirator use in this area. If further industrial hygiene sampling shows that the distribution warehouse is free of flavoring exposures, the use of respirators in this area may not be needed. Additionally, if sampling in the finished products warehouse shows measurable diacetyl, respirators would also be warranted in this area. Over the course of the NIOSH surveys, the plant's respiratory protection program improved significantly. Workers now use NIOSH-certified full-facepiece respirators with NIOSH-certified organic vapor and P-100 cartridges and are quantitatively fit-tested. It is important that the administrator of the respiratory protection program have adequate training and experience to run it and regularly evaluate its effectiveness. The respiratory protection program must include the following: 1) written policy; 2) change schedule for cartridges and filters; 3) pre-use medical evaluation; 4) pre-use and annual fit-testing and training; and 5) the establishment and implementation of procedures for proper respirator use (such as, prohibiting use with facial hair when this would impair the face seal, ensuring that users seal-check and inspect respirators prior to each use, ensuring proper cleaning, disinfection, maintenance of respirators, and

ensuring proper storage of respirators to protect respirators from damage, contamination, dust, sunlight, and extreme temperatures). In lieu of negative-pressure respirators, tight-fitting powered air-purifying respirators (PAPRs) with NIOSH-certified organic vapor and particulate cartridges are also an option for increased worker comfort; however, they also need to be fit-tested in the negative pressure mode.

We do not know how low volatile flavoring concentrations have to be to fully protect the health of exposed workers. In fact, intermittent high exposures, as occurred in the production areas and the pre-production corridor, may be dangerous to the workers even when exposures averaged over a typical eight-hour work shift are low. For this reason, we suggest, to the extent feasible, the potential for peak exposures be eliminated. Packaging of finished product and pouring, redistributing, or handling of diacetyl and other FEMA high-priority chemicals [FEMA 2004] should be done in the exhaust hoods until effective engineering controls are implemented and evaluated for the powder production processes. Although the engineering survey indicated good overall performance of the bench-top and booth-type hoods in the liquid production room when used properly [Appendix II-B], it is crucial that workers are educated on the proper function and use of the hoods. Strict adherence to a formal respiratory protection program and a medical surveillance program is required to protect workers.

Some limitations existed in our evaluation of this plant. First, the small number of workers prevented us from doing more sophisticated statistical analyses of the questionnaire data. Additionally if affected workers had been more likely than unaffected workers to have left employment at the plant prior to our medical survey, this would have resulted in underestimation of health effects in the workforce because the remaining workers would be generally healthier. Similarly, transfer of workers from high-risk to low-risk areas of the plant affected some of our findings. The two current workers with fixed obstructive lung disease consistent with bronchiolitis obliterans developed symptoms and/or disease while working in the production area. One of these workers had been transferred to the warehouse (prior to the NIOSH medical survey) because of his worsening symptoms and declining lung function. In some of our analyses (i.e., those shown in Table 5), his symptoms were included in those of a current nonproduction worker group, even though he had initially become affected while working in production.

Another limitation is the difficulty in interpreting air concentration measurements in the absence of occupational exposure limits for many chemicals used in flavoring manufacturing. While the U.S. Food and Drug Administration approves flavorings for use in foods with the designation of "generally recognized as safe" (GRAS) [FDA 2006], this designation only protects the consumer ingesting flavorings in food products. The GRAS designation is not designed to protect flavoring manufacturing workers from adverse health effects associated with direct skin contact or inhalation of flavoring chemicals. Safe air exposure levels for diacetyl and many other flavoring chemicals are not yet established. FEMA has identified 34 "high-priority" and 49 "low-priority" substances that may pose respiratory hazards in the flavor manufacturing workplace [FEMA 2004]. Until more is known about the potential toxicity of flavoring chemicals, it is important to minimize exposures during their use.

Lastly, performing an exposure assessment at this plant and other flavoring manufacturing plants is difficult because of the wide diversity in batch operations and recipes from plant to plant. Due to the diversity of batch operations and recipe formulations, exposure concentrations observed at this and other flavoring manufacturing facilities exhibit great variability. Given this known variability, it is unclear whether the exposures observed would be helpful to assess quantitative relationships for dose response. Information from industrial hygiene air sampling and medical surveys at food production plants with less process variability may be more helpful to quantify risk from exposure to flavoring chemicals.

Conclusions

Among the small number of workers who have made flavorings at this plant, we identified two workers with fixed airways obstruction. One worker was very symptomatic when we identified him, while the other worker was asymptomatic and has remained symptom-free. Although the two workers' disease arose during their flavoring production employment, we found that, as a group, current production workers did not have excess chest symptoms compared to other workers. Spiromety was key in identifying both affected workers. Workers with symptoms or interval spirometry declines in their FEV_1 of 10% or more need to be removed from exposure to flavoring chemicals or ingredients, at least until medically evaluated.

Measurements in this report indicate that exposure to diacetyl is possible in the pre-production corridor and distribution warehouse. Other areas, including the finished products warehouse, need to be evaluated. Scooping, sifting, and packaging flavored powders, as well as pouring diacetyl and adding ingredients into flavor formulations, were found to be high-exposure activities and should only be done under the exhaust hoods in the liquid production room until engineering controls have been implemented and evaluated in the other production areas. Although the bench-top and booth-type hoods in the liquid production room are effective controls when maintained and used properly, respiratory protection is still warranted in all production areas, in the liquid production room, in the pre-production corridor, and in the distribution warehouse. Respiratory protection may also be warranted in the finished products warehouse. Ongoing industrial hygiene sampling to monitor air concentrations of flavoring chemicals in the plant is recommended.

RECOMMENDATIONS

Many of the following recommendations were provided in previous communications from NIOSH. To enhance the comprehensiveness of this report, they are included here.

A. Engineering Controls:

1. Install engineering controls in the spray-drying areas and powder production room. These controls should address any potential sources of exposure, including those documented in the letter from NIOSH, dated February 7, 2007 (Appendix II-A). Use an experienced industrial ventilation engineer in the design of these engineering controls.
2. Check all operations being conducted in the booth-type hoods to evaluate whether the worker is being adequately protected (such as during packaging of powder or liquid flavorings). Ensure that workers use proper techniques and that the control system allows for activation of the exhaust fan when performing these tasks.
3. Re-design the proximity switch in the bench-top and booth-type hoods to insure ventilation systems are on when workers perform tasks inside the hood in the liquid production room. Add a fan operational status light (on/off) to each hood to provide an indication to the worker that the hood is activated. Train workers on the new fan indication system so that they understand what the light(s) mean and what to look for before they begin work.
4. Install hood static pressure gauges on each booth-type hood and bench-top hood to provide information on hood performance. Place an indelible mark on each gauge indicating optimal static pressure. Check and record pressure reading as a part of routine preventative maintenance schedule.
5. Ensure adequate hood performance using hood static pressure, smoke visualization testing, and hood slot/face velocity using an anemometer. These system evaluation tasks must become part of a routine maintenance schedule to check system performance.
6. Extend the bench-top hood side baffles to the edge of the bench. This can be done using flexible strip curtains if side accessibility or interference is a concern.

7. Discontinue the use of floor fans and wall-mounted fans as they can reduce hood performance by creating drafts within the room. Consider using ceiling-mounted supply registers to provide more uniform and lower velocity cooling and air movement in the production rooms.
8. Consider upgrading hood and duct materials to higher gauge (thicker) galvanized steel when appropriate. This will improve the system's ability to withstand the wear and tear of ordinary use.
9. Consider reworking the roof-top exhaust stack design to ensure that hood exhaust is effectively discharged. This would include changing the design to a vertical stack with a discharge velocity of between 2000–3000 fpm and the addition of a stack rain drain [ASHRAE 2007].
10. Ensure laboratory and quality control room hoods exhaust outside the plant. Require laboratory and quality control room staff to perform all open handling of flavoring ingredients and mixtures within laboratory fume hoods.
11. Perform industrial hygiene air sampling and repeat air sampling regularly to ensure effectiveness of controls is maintained. Include the distribution warehouse and the finished products warehouse in the sampling plan.

B. Work Practices:

1. Avoid open pouring, measuring, and transferring of FEMA high-priority flavoring chemicals [FEMA 2004] in the pre-production corridor and warehouse areas. For large pour and weigh-out activities, use the large ventilated, booth-type hoods in the liquid production room.
2. Add diacetyl and other FEMA high-priority chemicals [FEMA 2004] into a batch last, when possible, to limit their volatization.
3. Train employees on how to use the engineering control hoods properly; provide guidance on proper usage and good work practices such as not filling up the bench-top hoods with non-essential items. Worker training should also include a discussion of the proper use of booth-type hoods such as proper orientation of worker and contaminants (e.g. worker should not get between the source of exposure and the exhaust hood).

4. Avoid removing containers packaged with a flavor containing diacetyl or other FEMA high- priority chemicals [FEMA 2004] or product from the ventilated booth until the containers are closed entirely. These containers should be labeled to alert workers and downstream users that the product contains diacetyl or other FEMA high-priority chemicals.
5. Keep containers of flavoring chemicals and ingredients sealed when not in use to limit emissions of chemical vapors.
6. Utilize cold water washes and cold storage of chemicals when feasible to limit emissions of chemical vapors.
7. Clean spills promptly to limit emissions of chemical vapors.
8. Wear personal protection equipment including respirators that provide protection against both organic vapors and particulates and eye and skin protection when cleaning up spills or washing empty containers of flavoring chemicals or ingredients.

C. Respiratory Protection:

1. Continue to require mandatory respirator use (with NIOSH-certified organic vapor and particulate cartridges) for all production workers, distribution warehouse workers, and other workers who enter the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse. If further industrial hygiene sampling shows that the distribution warehouse is free of flavoring exposures, use of respirators in this area may not be needed. The finished products warehouse was not sampled; however, if industrial hygiene sampling detects diacetyl in this area, respiratory protection would be warranted in this area.
2. Relocate the respirator storage and cartridge re-load area from outside the powder production room (in the pre-production corridor) to an alternate area with known lower exposures.
3. Restrict access to the pre-production corridor, liquid production room, powder production room, spray-drying areas, and distribution warehouse to only employees that need to be there.

4. Ensure workers have been properly quantitatively fit-tested with respirators.

5. In accordance with Cal/OSHA direction, "full-facepiece respirators fit-tested with an approved quantitative method are needed as minimal protection for employees exposed to flavoring ingredients in this industry. All employees entering flavor formulation areas or unprotected areas (e.g., packaging areas) must wear respirators" (FISHEP correspondence from K. Howard, dated October 13, 2006). Employees should continue to use NIOSH-certified full-facepiece respirators with NIOSH-certified organic vapor and particulate cartridges. A tight-fitting PAPR (with NIOSH-certified organic vapor and particulate cartridges) is also an option for increased worker comfort. Information about respirators is available at the NIOSH website (http://www.cdc.gov/niosh/npptl/topics/respirators/ and http://www.cdc.gov/niosh/docs/2005-100/default.html).

6. The respiratory protection program must include the following:

   a. Written policy.

   b. Change-out schedule for cartridges and filters.

   c. Pre-use medical evaluation.

   d. Pre-use and annual fit-testing and training.

   e. Establishment and implementation of procedures for proper respirator use (such as, prohibiting use with facial hair when this would impair the seal, ensuring user seal-check and inspection of respirators prior to each use, ensuring proper cleaning, disinfection, and maintenance of respirators, and ensuring proper storage of respirators to protect respirators from damage, contamination, dust, sunlight, and extreme temperatures).

Details about the Cal/OSHA Respiratory Protection Standard can be found at http://www.dir.ca.gov/title8/5144.html. OSHA's Respiratory Protection Standard is available at http://www.osha.gov/SLTC/respiratoryprotection/index.html.

D. Eye and Skin Protection:

1. Enforce the use of eye and skin protection in the laboratory, quality control room, and production areas. Full-facepiece respirators provide eye protection.

E. Hazard Communication:

1. Ensure that workers understand the hazards associated with flavoring chemicals and how to protect themselves. The California Code of Regulations, Title 8, Section 5194, Hazard Communication, is available at http://www.dir.ca.gov/title8/5194b.html. OSHA's Hazard Communication Standard, also known as the "Right to Know Law" (29 CFR 1910.1200) requires that employees are informed and trained of potential work hazards and associated safe practices, procedures, and protective measures. The elements of the Hazard Communication Program include:
   a. Preparing a written Hazard Communication Program that includes an inventory of all hazardous chemicals used.
   b. Obtaining material safety data sheets (MSDSs) for each hazardous chemical used.
   c. Displaying appropriate facility placards and warnings signs.
   d. Preparing a hazardous communication training plan.
   e. Providing training to employees who are potentially exposed to hazardous chemicals.

F. Medical Surveillance:

1. Perform pre-placement spirometry testing on all new production workers, laboratory/quality control workers, and any other workers who enter the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse.
2. Perform spirometry every 3 months on all production workers, laboratory/quality control workers, and any other workers who enter the pre-production corridor, liquid production room, powder production room, spray-drying areas, or distribution warehouse. Additionally, workers with FEV_1 falls of 10% or more should be removed from exposure to flavoring chemicals or ingredients until medically evaluated for appropriate medical restrictions. Workers with persistent symptoms such as shortness of breath, wheezing, or cough should also be removed from exposure to flavoring chemicals or ingredients until

medically evaluated for appropriate medical restrictions. With assistance from NIOSH, the California Department of Public Health developed guidelines for medical surveillance for flavoring-related lung disease among flavoring manufacturing workers in California [CDPH 2007]. These guidelines are available at http://ww2.cdph.ca.gov/programs/ohb/Pages/New.aspx#flavorings.

3. Provide workers with information sheets regarding flavoring-related lung disease to take to their healthcare providers. Informational handouts are available at the California Department of Public Health website (http://www.dhs.ca.gov/ohb/flavorings.htm) and NIOSH's website (http://www.cdc.gov/niosh/topics/flavorings/).

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Table 1. Industrial hygiene air sampling methods for November 2006 industrial hygiene survey.

Type	Analysis Method	Media	Analytes	Personal (P) / Area (A) Samples	Objective	Flow Rate (L/min)	Sample Duration (minutes)
Aldehydes	EPA TO-11A	Sorbent tube (dinitrophenylhydrazine-treated silica gel) 150/300 mg)	2-Furaldehyde Acetaldehyde Benzaldehyde Isovaleraldehyde Propionaldehyde	P, A	8-hour TWA	0.1	300
Aldehydes	EPA TO-11A	Sorbent tube (dinitrophenylhydrazine-treated silica gel) 150/300 mg)	2-Furaldehyde Acetaldehyde Benzaldehyde Isovaleraldehyde Propionaldehyde	P	Task-based	0.2	15-60
Organic acids	Draft NIOSH NMAM 5048	Sorbent tube (silica gel 200mg/400mg)	Acetic acid Butyric acid Propionic acid	P, A	8-hour TWA	0.2	480
Organic acids	Draft NIOSH NMAM 5048	Sorbent tube (silica gel 200mg/400mg)	Acetic acid Butyric acid Propionic acid	P	Task-based	0.2	15-60
Inorganic acid	NIOSH NMAM 7903	Sorbent tube (silica gel 200mg/400mg)	Phosphoric acid	A	8-hour TWA	0.2	480
Ketone compounds	Modified OSHA PV2118	Sorbent tube (silica gel 200mg/400mg)	Diacetyl	A	8-hour TWA	0.1	480
Ketone compounds	NIOSH NMAM 2557/2558	Sorbent tube (carbon sorbent sieve 75mg/150mg)	Diacetyl Acetoin	P, A	8-hour TWA	0.1	480
Ketone compounds	NIOSH NMAM 2557/2558	Sorbent tube (carbon sorbent sieve 75mg/150mg)	Diacetyl Acetoin	P	Task-based	0.2	15-60
Volatile organic compounds	NIOSH NMAM 2549	Thermal desorption tubes	Varied based on thermal desorption tubes	A	2-hour TWA	0.1	60
Real-time volatile organic compounds	Direct-reading instrument (Rae Systems, Inc., Sunnyvale, CA)	MiniRAE 2000 PID or ToxiRAE PID	Volatile organic compounds	P, A	Continuous measurements	-	-
Real-time dust	Direct-reading instrument (Thermo Electron Corporation, Franklin, MA)	Photometric meter, PersonalDataRAM® pDR-1000AN/1200	Total dust	A	Continuous measurements	-	-
Respirable dust	NIOSH NMAM 0600	37-mm PVC filter, BGI® cyclone	Respirable dust	P, A	8-hour TWA	4.2	240
Total dust	NIOSH NMAM 0500	37-mm PVC filter, open-face filter cassette	Total dust	A	8-hour TWA	1.5	240

Table adapted from Appendix I-C. EPA: Environmental Protection Agency; TWA: time-weighted average; NIOSH: National Institute for Occupational Safety and Health; NMAM: NIOSH Manual of Analytical Methods; OSHA: Occupational Safety and Health Administration, PID: photoionization detector; PVC: polyvinyl chloride.

Table 2. Industrial hygiene air sampling methods for July 2007 industrial hygiene survey.

Type	Analysis Method	Media	Analytes	Personal (P) / Area (A) Samples	Objective	Flow Rate (L/min)	Sample Duration (minute)
Aldehydes	EPA TO-11A	Sorbent tube (dinitrophenylhydrazine-treated silica gel) 150/300 mg)	2-Furaldehyde Acetaldehyde Benzaldehyde Isovaleraldehyde Propionaldehyde	A	2-hour TWA	0.2	120
Aldehydes	EPA TO-11A	Sorbent tube (dinitrophenylhydrazine-treated silica gel) 150/300 mg)	2-Furaldehyde Acetaldehyde Benzaldehyde Isovaleraldehyde Propionaldehyde	P	Task-based	0.2	15-60
Ketones	Modified OSHA PV2118	Sorbent tube (silica gel 200mg/400mg)	Diacetyl Acetoin	A	2-hour TWA	0.05	120
Ketones	Modified OSHA PV2118	Sorbent tube (silica gel 200mg/400mg)	Diacetyl Acetoin	P	Task-based	0.05	15-60
Temperature and relative humidity	Direct-reading Instrument (Onset Computer Corporation, Bourne, MA)	HOBO Pro Model H08-032-08 temperature and humidity data loggers	Temperature Relative humidity	A	Continuous measurements	-	-

Table adapted from Appendix I-C. EPA: Environmental Protection Agency; TWA: time-weighted average; OSHA: Occupational Safety and Health Administration.

Table 3. Engineering controls evaluation methods used during November 2006 survey.

Method	Objective	Equipment	Procedure Used
Airflow at ventilation registers	Measure air volume flowing through registers	Accubalance air capture hood (TSI Inc., Shoreview, MN)	An Accubalance air capture hood was held up to the air registers and direct supply or exhaust airflow rate on the digital display was read.
Smoke tracer test	Determine airflow direction	Wizard Stick (Zero Toys, Concord, MA)	Smoke was released in various locations in the plant to determine direction of air flow.

Table adapted from Appendix II-A.

Table 4. Engineering controls evaluation methods used during the July 2007 survey.

Method	Objective	Equipment	Procedure used
Hood velocity measurement	Evaluate containment capture velocity at hood face	Velocicalc Plus Model 8388 thermal anemometer (TSI Incorporated, St. Paul, MN)	The opening of the hood was divided into equal grids of approximately 1 square foot (Figure 16). Velocity was measured at the center of each grid over a 5-second period.
Airflow visualization test	Qualitatively evaluate hood capture effectiveness	Rosco fog machine model 1500 (Rosco Laboratories, Inc., Stamford, CT) Tracer gas/smoke, sulfur hexafluoride (SF_6)	Smoke (SF_6) was released inside the hood. The hood was considered marginal if it took greater than 15-30 seconds to clear the smoke from the hood or smoke escaped into the room. Smoke was released at the edge of the hood to evaluate the cross drafts on the hood. Smoke was injected into the base of a 5-gallon bucket to allow for the observation of contaminant capture during the simulation of bench-top pour activities.
Tracer gas capture test	Qualitatively evaluate contaminant capture of hood	FMA 5518 mass flow controller (Omega Engineering Inc., Stamford, CT) Tracer gas/smoke, sulfur hexafluoride (SF_6), 10% SF_6 Balance Air Copper, tygon, and PTFE tubing AirCon 2 high volume air sampler (Gilian Instrument Corporation, West Caldwell, NJ) Carbon-Cap 150 activated carbon/ HEPA filter (Whatman Specialty Products, Inc., Florham Park, NJ) MIRAN 205B Sapphire portable ambient air analyzer (Thermo Environmental Instruments, Franklin, MA) USB 12-bit analog and digital I/O module (Measurement Computing Corporation, Norton, MA) Laptop computer	For ventilated booth-type hoods, evaporation of chemicals was stimulated using an area source consisting of a copper tubing coil perforated with uniformly spaced 1/16 inch diameter holes. The coil delivered low momentum tracer gas distributed across the surface of the mixing tank cross section (Figure 17). The tracer gas was measured in the exhaust duct at a location above the hood and below the roof. Hood exhaust air was drawn through a ¼ inch diameter sample probe constructed from copper tubing with 3/64 inch diameter holes spread evenly across the duct. The probes were mounted perpendicular to the airflow inside the hood exhaust hood. An AirCon 2 high-volume air sampler was used to draw air from the probe through tygon tubing at a flow rate of approximately 15 liters per minute. The air was routed through a Caron-Cap 150 activated carbon/HEPA filter to remove dust and volatile compounds before being routed to the analyzer. Exhaust from the analyzer was routed to an adjacent hood exhaust to minimize the possibility of contaminating the liquid production room with SF_6. Real-time SF_6 concentration was collected from the air analyzer onto a laptop computer through a USB 12-bit analog and digital I/O module.
Control on/off test	Evaluate hood during normal work tasks with exhaust fan on and off	MiniRAE 2000 (RAE Systems, San Jose, CA) PID Ethanol	A PID was placed on a NIOSH investigator during weighing, pouring, and whisking of ethanol while the hood ventilation system was turned on and off. Each task lasted approximately 3 minutes and 30 seconds. There were three paired trials with the control on and off.
Exhaust re-entrainment test	Measure air velocities from exhaust stack on roof	Rosco Fog Generator Smoke 1500 (Rosco Laboratories, Inc., Stamford, CT) Velocicalc Plus Model 8388 thermal anemometer (TSI incorporated, St. Paul, MN)	Smoke was released within each hood in the liquid production room. A NIOSH investigator and an employee of Gold Coast Ingredient, Inc. observed the movement of the smoke following the emission of the air through the exhaust discharge stack. Air velocity measurements were taken at the center of the exhaust stack to evaluate the discharge velocity of the hood.

Table adapted from Appendix II-B. SF_6: sulfur hexafluoride; PTFE: polytetrafluoroethylene; HEPA: high-efficiency particulate air; PID: photoionization detector; NIOSH: National Institute for Occupational Safety and Health.

Table 5. Prevalence of symptoms and medical conditions by current work area for 41 current workers, October-November 2006.

Health Outcome	Production (N=12)	Laboratory/ QC (N=11)	Warehouse/ Other (N=5)	Office (N=13)
Trouble breathing in last 12 months[1]	0	2 (18%)	2 (40%)	3 (23%)
-Always resolves[2]	0	0	0	1 (8%)
-Persists[3]	0	0	1 (20%)	0
Shortness of breath on exertion (hurrying or walking up hill)[4]	2 (17%)	0	2 (40%)	4 (31%)
Shortness of breath on exertion (walking with people of same age)[5]	0	0	2 (40%)	1 (8%)
Chronic cough[6]	0	0	1 (20%)	1 (8%)
Wheeze[7]	0	1 (9%)	1 (20%)	1 (8%)
Asthma-like symptoms[8]				
-1 or more yes responses	1 (8%)	4 (36%)	3 (60%)	3 (23%)
-3 or more yes responses	0	1 (9%)	3 (60%)	1 (8%)
Acute bronchitis[9]	0	1 (9%)	2 (40%)	2 (15%)
Diagnosed chronic bronchitis[10]	0	1 (9%)	2 (40%)	0
Pneumonia[11]	0	0	1 (20%)	1 (8%)
Diagnosed asthma[12]	0	2 (18%)	2 (40%)	0
Post-hire nasal irritation[13]	2 (17%)	5 (45%)	3 (60%)	9 (69%)
Post-hire eye irritation[14]	11 (92%)	9 (82%)	2 (40%)	5 (38%)
Post-hire onset skin rash[15]	3 (25%)	2 (18%)	1 (20%)	2 (15%)

Table adapted from Appendix III-B.

[1] During the last 12 months, have you had any trouble with your breathing?

[2] I have regular trouble with my breathing but it always gets completely better.

[3] My breathing is never quite right.

[4] Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?

[5] Do you get short of breath walking with people of your own age on level ground?

[6] Do you usually cough on most days for 3 consecutive months or more during the year?

[7] During the last 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?

[8] During the last four weeks: If you run, or climb stairs fast do you ever cough? If you run, or climb stairs fast do you ever wheeze? If you run, or climb stairs fast do you ever get tight in the chest? Is your sleep ever broken by difficulty breathing? Do you ever wake up in the morning with wheeze? Do you ever wake up in the morning with difficulty breathing? Do you ever wheeze if you are in a smoky room? Do you ever wheeze if you are in a very dusty place?

[9] Since you began working at this plant, have you ever had attacks of bronchitis?

[10] Have you ever had chronic bronchitis (confirmed by a doctor)?

[11] Since you began working at this plant have you ever had pneumonia?

[12] Have you ever had asthma (confirmed by a doctor)?

[13] 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)?

[14] 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?

[15] Since working at this plant, have you developed any new skin rash or skin problems?

Table 6. Prevalence of symptoms, medical conditions, and lung function abnormalities by work history for 41 current workers, October-November, 2006.

Health Outcome	Ever-Production (N=14)	Never-Production (N=27)	Flavoring-Exposed† (N=27)	Not Flavoring-Exposed (N=14)	Ever-Lab/QC (N=15)	Never-Lab/QC (N=26)
Trouble breathing in last 12 months[1] **-Always resolves[2]** **-Persists[3]**	1 (7%) 0 1 (7%)	6 (22%) 1 (4%) 0	2 (7%) 0 1 (4%)	5 (36%) 1 (7%) 0	3 (20%) 1 (7%) 0	4 (15%) 0 1 (4%)
Shortness of breath on exertion (hurrying or walking up hill)[4]	3 (21%)	5 (18%)	5 (19%)	3 (21%)	1 (7%)	7 (27%)
Shortness of breath on exertion (compared with people of same age)[5]	1 (7%)	2 (7%)	3 (11%)	0	0	3 (12%)
Chronic cough[6]	1 (7%)	1 (4%)	1 (4%)	1 (7%)	1 (7%)	2 (8%)
Wheeze[7]	0	3 (11%)	2 (7%)	1 (7%)	2 (13%)	1 (4%)
Asthma-like symptoms[8] **-1 or more yes responses** **-3 or more yes responses**	2 (14%) 1 (7%)	9 (33%) 4 (15%)	7 (26%) 4 (15%)	4 (29%) 1 (7%)	6 (40%) 2 (13%)	5 (19%) 3 (12%)
Acute bronchitis[9]	1 (7%)	4 (15%)	3 (11%)	2 (14%)	2 (13%)	3 (12%)
Diagnosed chronic bronchitis[10]	1 (7%)	2 (7%)	3 (11%)	0	1 (7%)	2 (8%)
Pneumonia[11]	1 (7%)	1 (4%)	1 (11%)	1 (7%)	1 (7%)	1 (4%)
Diagnosed asthma[12]	0	4 (15%)	2 (7%)	2 (14%)	2 (13%)	2 (8%)
Post-hire nasal irritation[13]	3 (21%)	16 (59%)	11 (41%)	8 (57%)	8 (53%)	11(42%)
Post-hire eye irritation[14]	13 (93%)	15 (55%)	17 (63%)	10 (71%)	10 (67%)	17(65%)
Post-hire skin rash[15]	3 (21%)	5 (18%)	6 (22%)	2 (14%)	2 (13%)	6 (23%)
Obstruction or mixed pattern on spirometry	1 (7%)	0	1 (4%)	0	0	1 (4%)
Borderline obstruction on spirometry	1 (7%)	0	1 (4%)	0	0	1 (4%)
Restriction on spirometry	0	1 (4%)	0	1 (7%)	1 (7%)	0

Table adapted from Appendix III-B. †Workers having entered the production area on a daily basis as part of a non-production job or with a history of ever working in production. 1-15: See Table 5 footnote for symptom questions.

Table 7. Prevalence ratios of observed to expected number of all workers with selected respiratory symptoms and conditions based on NHANES III data, adjusted for gender, race, age, and smoking categories, October - November 2006 survey.

Symptom/Condition	N†	Observed Number	Expected Number	Prevalence Ratio	CI‡
Shortness of breath on exertion[1]	36	8	5.7	1.4	0.7 – 2.8
Chronic cough[2]	36	2	2.1	1.0	0.3 – 3.5
Wheeze[3]	36	5	4.6	1.1	0.5 – 2.6
Ever diagnosed with chronic bronchitis[4]	36	3	1.2	2.5	0.9 – 7.5
Ever diagnosed with asthma[5]	36	3	1.9	1.6	0.5 – 4.6

Table adapted from Appendix III-B. †Total number of workers with demographic characteristics comparable to NHANES III data (Five Asians excluded due to no reference rates for Asians.) ‡CI: 95% confidence interval
[1]Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
[2]Do you usually cough on most days for 3 consecutive months or more during the year?
[3]During the last 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?
[4]Have you ever had chronic bronchitis (confirmed by a doctor)?
[5]Have you ever had asthma (confirmed by a doctor)?

Table 8. Prevalence ratios of observed to expected number of ever-production workers with selected respiratory symptoms and conditions based on NHANES III data, adjusted for gender, race, age, and smoking categories, October - November 2006 survey.

Symptom/Condition	N†	Observed Number	Expected Number	Prevalence Ratio	CI‡
Shortness of breath on exertion[1]	14	3	1.4	2.1	0.7 – 6.2
Chronic cough[2]	14	1	0.6	1.7	0.3 – 9.1
Wheeze[3]	14	0	1.4	-	-
Ever diagnosed with chronic bronchitis[4]	14	1	0.3	3.3	0.6 – 17.7
Ever diagnosed with asthma[5]	14	0	0.6	-	-

Table adapted from Appendix III-B. †Total number of workers. ‡CI: 95% confidence interval
[1]Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
[2]Do you usually cough on most days for 3 consecutive months or more during the year?
[3]During the last 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?
[4]Have you ever had chronic bronchitis (confirmed by a doctor)?
[5]Have you ever had asthma (confirmed by a doctor)?

Table 9. Prevalence ratios of observed to expected number of never-production workers with selected respiratory symptoms and conditions based on NHANES III data, adjusted for gender, race, age, and smoking categories, October - November 2006 survey.

Symptom/Condition	N†	Observed Number	Expected Number	Prevalence Ratio	CI‡
Shortness of breath on exertion[1]	22	5	4.3	1.2	0.5 – 2.7
Chronic cough[2]	22	1	1.4	0.7	0.1 – 3.9
Wheeze[3]	22	5	3.2	1.6	0.7 – 3.6
Ever diagnosed with chronic bronchitis[4]	22	2	0.8	2.5	0.6 – 8.6
Ever diagnosed with asthma[5]	22	3	1.3	2.3	0.8 – 6.6

Table from Appendix III-B. †Total number of workers with demographic characteristics comparable to NHANES III data. (Five Asians excluded due to no reference rates for Asians.) ‡CI: 95% confidence interval
[1]Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
[2]Do you usually cough on most days for 3 consecutive months or more during the year?
[3]During the last 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?
[4]Have you ever had chronic bronchitis (confirmed by a doctor)?
[5]Have you ever had asthma (confirmed by a doctor)?

Table 10. Longitudinal changes in FEV_1 and newly identified airways obstruction for 34 workers who had a second spirometry test during March 13-14, 2007.

Decline in FEV_1	Number of workers	Percent change in FEV_1	Number with newly identified airways obstruction
None	9	+0.8% to +15.6%	0
< 100 ml	13	-0.3% to -3.1%	0
≥ 100 ml to <200 ml	7	-3.2% to -4.3%	0
≥ 200 ml to <300 ml	4	-4.9% to -7.7%	0
≥ 300 ml to <1000 ml	0	-	-
> 1000 ml	1	-25.4%	1

Table adapted from Appendix III-B.

Table 11. Prevalence (percent) of airways obstruction on most recent spirometry test by age and severity and corresponding prevalence for the general population from NHANES III.

Severity grade of airways obstruction	FEV_1 % predicted	Age 17-49 (n=37)	Age 50-69 (n=7)	Total (N=44)
Mild	65% to lower limit of normal	1 (2.7%) *[2.7%]*	0 (0%) *[5.0%]*	1 (2.3%) *[3.3%]*
Moderate	40% to 64%	0 (0%) *[0.7%]*	0 (0%) *[4.4%]*	0 (0%) *[1.7%]*
Severe	< 40%	1 (2.7%) *[0.1%]*	0 (0%) *[1.8%]*	1 (2.3%) *[0.5%]*
Any	Less than lower limit of normal	2 (5.4%) *[3.5%]*	0 (0%) *[11.3%]*	2 (4.5%) *[5.5%]*

Table adapted from Appendix III-B. Note: Observed workforce percent prevalence shown within parenthesis; percent prevalences from NHANES III general population data shown within brackets. FEV_1: forced expiratory volume in the first second of exhalation.

Table 12. Eight-hour TWA analyte air concentrations[†], November 2006.

Analyte	n	Mean	STD	GM	GSD	Min	Max
Ketones (ppm)							
Acetoin	39	0.12	0.10	0.08	2.84	0.005	0.47
Diacetyl (MOSHA)[‡]	14	0.23	0.29	0.10	4.21	0.019	1.00
Diacetyl (NIOSH)[§]	39	0.19	0.35	0.04	6.64	0.001	1.71
Aldehyde (ppm)							
2-Furaldehyde	39	0.01	0.01	0.01	3.00	0.0002	0.06
Acetaldehyde	39	0.09	0.11	0.06	2.49	0.001	0.68
Benzaldehyde	39	0.05	0.03	0.04	2.43	0.001	0.11
Isovaleraldehyde	39	0.03	0.05	0.01	4.32	0.001	0.30
Propionaldehyde	39	0.03	0.02	0.02	2.32	0.002	0.08
Organic Acids (ppm)							
Acetic Acid	38	0.44	0.98	0.13	4.47	0.018	4.80
Butyric Acid	38	0.07	0.07	0.03	3.59	0.007	0.30
Propionic Acid	38	0.08	0.09	0.03	5.95	0.003	0.35
Dust (mg/m^3)							
Respirable Dust	24	0.17	0.18	0.11	2.55	0.032	0.73
Total Dust	15	0.47	0.49	0.25	3.42	0.034	1.47

Table adapted from Appendix I-C. [†]Area and personal samples are presented together. [‡]Diacetyl was collected and analyzed by the modified OSHA Method PV2118. [§]Diacetyl was collected and analyzed by the NIOSH Method 2557, which likely underestimates true exposure concentration. STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; ppm: parts per million; mg/m^3: milligram per cubic meter.

Table 13. Eight-hour TWA ketone air concentrations[†] by work area, November 2006.

Analyte	n	Mean (ppm)	STD	GM (ppm)	GSD	Min (ppm)	Max (ppm)
Powder production room							
Acetoin	12	0.09	0.58	0.08	1.79	0.035	0.19
Diacetyl (MOSHA)[‡]	3	0.34	0.28	0.17	6.38	0.020	0.52
Diacetyl (NIOSH)[§]	12	0.35	0.51	0.09	8.29	0.005	1.71
Liquid production room							
Acetoin	17	0.15	0.13	0.09	3.54	0.005	0.47
Diacetyl (MOSHA)[‡]	3	0.46	0.05	0.20	7.41	0.021	1.00
Diacetyl (NIOSH)[§]	17	0.14	0.27	0.03	6.64	0.001	1.05
Pre-production corridor							
Acetoin	3	0.07	0.06	0.04	5.22	0.006	0.11
Diacetyl (MOSHA)[‡]	2	0.21	0.20	0.16	3.20	0.068	0.35
Diacetyl (NIOSH)[§]	3	0.07	0.09	0.04	3.74	0.013	0.17
Quality control room							
Acetoin	3	0.07	0.05	0.05	2.98	0.015	0.12
Diacetyl (MOSHA)[‡]	3	0.07	0.06	0.05	2.29	0.028	0.13
Diacetyl (NIOSH)[§]	3	0.02	0.01	0.02	1.81	0.012	0.04
Office							
Acetoin	1	0.04	-	-	-	-	-
Diacetyl (MOSHA)[‡]	1	0.02	-	-	-	-	-
Diacetyl (NIOSH)[§]	1	0.003	-	-	-	-	-

Table adapted from Appendix I-C. Note: Three acetoin samples, 2 diacetyl (MOSHA) samples, and 3 diacetyl (NIOSH) samples from Table 12 are not in this table because the samples were not taken in the areas identified in this table. [†]Area and personal samples are presented together. [‡]Diacetyl was collected and analyzed by the modified OSHA Method PV2118. [§]Diacetyl was collected and analyzed by the NIOSH Method 2557, which likely underestimates true concentration. STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; ppm: parts per million.

Table 14. Eight-hour TWA aldehyde air concentrations† by work area, November 2006.

Analyte	n	Mean (ppm)	STD	GM (ppm)	GSD	Min (ppm)	Max (ppm)
Powder production room							
2-Furaldehyde	12	0.01	0.01	0.004	4.04	0.0002	0.04
Acetaldehyde	12	0.14	0.19	0.08	2.64	0.026	0.68
Benzaldehyde	12	0.03	0.01	0.03	1.50	0.012	0.07
Isovaleraldehyde	12	0.01	0.01	0.01	2.40	0.003	0.04
Propionaldehyde	12	0.03	0.02	0.02	2.63	0.003	0.06
Liquid production room							
2-Furaldehyde	17	0.01	0.01	0.01	1.89	0.002	0.03
Acetaldehyde	17	0.07	0.03	0.06	2.71	0.001	0.14
Benzaldehyde	17	0.07	0.02	0.07	1.46	0.035	0.11
Isovaleraldehyde	17	0.05	0.07	0.02	3.74	0.003	0.30
Propionaldehyde	17	0.02	0.01	0.02	2.16	0.002	0.05
Pre-production corridor							
2-Furaldehyde	3	0.02	0.03	0.01	3.87	0.005	0.05
Acetaldehyde	3	0.07	0.03	0.07	1.49	0.047	0.10
Benzaldehyde	3	0.03	0.01	0.03	1.26	0.023	0.04
Isovaleraldehyde	3	0.002	0.001	0.001	2.25	0.001	0.003
Propionaldehyde	3	0.02	0.02	0.02	2.44	0.007	0.04
Quality Control Room							
2-Furaldehyde	3	0.01	0.01	0.01	2.35	0.003	0.02
Acetaldehyde	3	0.06	0.04	0.05	2.08	0.024	0.10
Benzaldehyde	3	0.06	0.03	0.05	1.68	0.031	0.09
Isovaleraldehyde	3	0.003	0.002	0.002	2.05	0.001	0.005
Propionaldehyde	3	0.05	0.01	0.04	1.45	0.028	0.05
Office							
2-Furaldehyde	1	0.02	-	-	-	-	-
Acetaldehyde	1	0.04	-	-	-	-	-
Benzaldehyde	1	0.01	-	-	-	-	-
Isovaleraldehyde	1	0.01	-	-	-	-	-
Propionaldehyde	1	0.05	-	-	-	-	-

Table adapted from Appendix I-C. Note: Three samples of each aldehyde analyte from Table 12 are not in this table because the samples were not taken in the areas identified in this table. †Area and personal samples are presented together. STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; ppm: parts per million.

Table 15. Eight-hour TWA organic acid air concentrations† by work area, November 2006.

Analyte	n	Mean (ppm)	STD	GM (ppm)	GSD	Min (ppm)	Max (ppm)
Powder production room							
Acetic Acid	11	0.75	1.45	0.20	5.08	0.018	4.80
Butyric Acid	11	0.10	0.09	0.05	3.88	0.007	0.30
Propionic Acid	11	0.12	0.12	0.05	6.37	0.003	0.35
Liquid production room							
Acetic Acid	17	0.44	0.86	0.15	4.45	0.018	3.60
Butyric Acid	17	0.08	0.06	0.05	2.84	0.008	0.21
Propionic Acid	17	0.09	0.08	0.05	4.08	0.003	0.26
Pre-production corridor							
Acetic Acid	3	0.08	0.06	0.06	2.67	0.02	0.14
Butyric Acid	3	0.008	0.0004	0.008	1.05	0.007	0.008
Propionic Acid	3	0.003	0.0002	0.003	1.05	0.003	0.003
Quality control room							
Acetic Acid	3	0.09	0.08	0.07	2.94	0.020	0.17
Butyric Acid	3	0.008	0.0003	0.008	1.04	0.008	0.008
Propionic Acid	3	0.003	0.0001	0.003	1.04	0.003	0.003
Office							
Acetic Acid	1	0.02	-	-	-	-	-
Butyric Acid	1	0.007	-	-	-	-	-
Propionic Acid	1	0.003	-	-	-	-	-

Tables adapted from Appendix I-C. Note: Three samples of each organic acid analyte from Table 12 are not in this table because the samples were not taken in the areas identified in this table. †Area and personal samples are presented together. STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; ppm: parts per million.

Table 16. Eight-hour TWA dust air concentrations† by work area, November 2006.

Analyte	n	Mean (mg/m^3)	STD	GM (mg/m^3)	GSD	Min (mg/m^3)	Max (mg/m^3)
Powder production room							
Respirable Dust	12	0.26	0.22	0.19	2.40	0.038	0.73
Total Dust	3	1.28	0.21	1.26	1.18	1.058	1.47
Liquid production room							
Respirable Dust	3	0.14	0.84	0.11	2.32	0.043	0.18
Total Dust	3	0.61	0.35	0.52	2.11	0.224	0.91
Pre-production corridor							
Respirable Dust	3	0.11	0.08	0.09	2.46	0.034	0.20
Total Dust	3	0.26	0.15	0.22	2.13	0.095	0.39
Quality control room							
Respirable Dust	3	0.05	0.10	0.05	1.11	0.043	0.05
Total Dust	3	0.08	0.06	0.07	2.08	0.034	0.14
Office							
Respirable Dust	1	0.05	-	-	-	-	-

Table adapted from Appendix I-C. Note: Two respirable dust samples and 3 total dust samples from Table 12 are not in this table because the samples were not taken in the areas identified in this table. †Area and personal respirable dust samples are presented together. Total dust samples were collected only as area samples. STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; mg/m^3: milligram per cubic meter.

Table 17. Personal task-based sampling results, November 2006.

Task completed	Duration (minutes)	Analyte	ppm	Flavor
Powder production room				
Small pouring and mixing ingredients	15	Acetoin	0.18	Caramel flavor
Pouring and mixing ingredients	26	Acetoin	0.05	Powder mix
Pouring and mixing ingredients	26	Diacetyl (NIOSH)†	0.05	Powder mix
Small pouring and mixing ingredients	15	Diacetyl (NIOSH)†	1.58	Caramel flavor
Liquid production room				
Pouring and mixing ingredients	53	2-Furaldehyde	0.01	Fruit flavor
Pouring and mixing ingredients	53	Acetaldehyde	0.19	Fruit flavor
Pouring and mixing ingredients	53	Isovaleraldehyde	0.04	Fruit flavor
Pouring and mixing ingredients	53	Propionaldehyde	0.05	Fruit flavor
Pouring and mixing ingredients	61	Acetic acid	1.93	Butter flavor
Pouring and mixing ingredients	61	Butryic acid	1.20	Butter flavor
Pouring and mixing ingredients	61	Propionic acid	1.43	Butter flavor
Pouring and mixing ingredients	45	Acetoin	0.16	Butter flavor
Pouring and mixing ingredients	61	Acetoin	1.05	Butter flavor
Pouring and mixing ingredients	15	Acetoin	0.09	Butter flavor
Pouring and mixing ingredients	59	Acetoin	0.18	Caramel flavor
Pouring and mixing ingredients	55	Acetoin	0.50	Fruit flavor
Pouring and mixing ingredients	45	Diacetyl (NIOSH)†	0.04	Butter flavor
Pouring and mixing ingredients	61	Diacetyl (NIOSH)†	0.08	Butter flavor
Pouring and mixing ingredients	15	Diacetyl (NIOSH)†	0.09	Butter flavor
Pouring and mixing ingredients	59	Diacetyl (NIOSH)†	0.02	Caramel flavor
Pouring and mixing ingredients	55	Diacetyl (NIOSH)†	0.03	Fruit flavor
Pre-production corridor				
Pouring diacetyl from 55- to 5-gallon drum	10	Acetoin	0.14	Diacetyl transfer
Pouring diacetyl from 55- to 5-gallon drum	10	Diacetyl (NIOSH)†	11.04	Diacetyl transfer

Table adapted from Appendix I-C. †Diacetyl samples were collected/analyzed using NIOSH Method 2557 (NIOSH), which likely underestimates of true concentration. ppm: parts per million

Table 18. Two-hour TWA air concentrations†, July 2007.

Analyte	n	Mean (ppm)	STD	GM (ppm)	GSD	Min (ppm)	Max (ppm)
Ketones							
Acetoin	30	0.115	0.083	0.096	1.77	0.048	0.37
Diacetyl (MOSHA)‡	30	0.445	1.168	0.085	6.53	0.008	6.33
Aldehydes							
2-Furaldehyde	30	0.009	0.009	0.005	3.59	0.001	0.04
Acetaldehyde	30	0.22	0.513	0.045	5.19	0.006	2.57
Benzaldehyde	30	0.076	0.238	0.013	5.46	0.001	1.29
Isovaleraldehyde	30	0.076	0.149	0.011	7.49	0.001	0.43
Propionaldehyde	30	0.032	0.039	0.011	6.2	0.001	0.17

Table adapted from Appendix I-C. †Area samples, ‡Diacetyl and acetoin were collected/analyzed by the modified OSHA Method PV2118. STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; ppm: parts per million.

Table 19. Two-hour TWA ketone air concentrations† by work area, July 2007.

Analyte‡	n	Mean (ppm)	STD	GM (ppm)	GSD	Min (ppm)	Max (ppm)
Powder production room							
Acetoin	6	0.163	0.082	0.144	1.78	0.07	0.26
Diacetyl	6	0.483	0.572	0.288	2.97	0.10	1.58
Liquid production room							
Acetoin	6	0.07	0.009	0.07	1.137	0.058	0.09
Diacetyl	6	0.529	0.297	0.467	1.712	0.26	1.04
Pre-production corridor							
Acetoin	6	0.077	0.027	0.074	1.35	0.053	0.13
Diacetyl	6	0.098	0.151	0.031	5.13	0.009	0.38
Spray-drying room							
Acetoin	6	0.20	0.118	0.165	1.99	0.063	0.37
Diacetyl	6	1.07	2.578	0.048	11.5	0.011	6.33
Distribution warehouse							
Acetoin	6	0.067	0.01	0.066	1.18	0.048	0.08
Diacetyl	6	0.041	0.053	0.023	3.12	0.008	0.14

Table adapted from Appendix I-C). †Area samples, ‡Samples collected/analyzed using modified OSHA Method PV2118 for diacetyl and acetoin. STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; ppm: parts per million.

Table 20. Two-hour TWA aldehyde air concentrations† by work area, July 2007.

Analyte	n	Mean (ppm)	STD	GM	GSD	Min (ppm)	Max (ppm)
Powder production room							
2-Furaldehyde	6	0.008	0.007	0.004	3.76	0.001	0.02
Acetaldehyde	6	0.343	0.45	0.112	5.95	0.015	1.02
Benzaldehyde	6	0.034	0.055	0.017	2.98	0.007	0.15
Isovaleraldehyde	6	0.013	0.055	0.012	1.52	0.006	0.02
Propionaldehyde	6	0.080	0.056	0.061	2.48	0.012	0.17
Liquid production room							
2-Furaldehyde	6	0.007	0.004	0.006	1.67	0.004	0.01
Acetaldehyde	6	0.273	0.245	0.17	3.32	0.031	0.69
Benzaldehyde	6	0.295	0.498	0.09	5.49	0.016	1.29
Isovaleraldehyde	6	0.011	0.005	0.01	1.71	0.004	0.02
Propionaldehyde	6	0.031	0.027	0.02	5.65	0.001	0.06
Pre-production corridor							
2-Furaldehyde	6	0.012	0.015	0.005	4.99	0.001	0.04
Acetaldehyde	6	0.029	0.018	0.024	2.16	0.006	0.05
Benzaldehyde	6	0.012	0.005	0.012	1.51	0.007	0.02
Isovaleraldehyde	6	0.006	0.004	0.004	3.36	0.001	0.01
Propionaldehyde	6	0.011	0.016	0.003	6.60	0.001	0.04
Spray-drying room							
2-Furaldehyde	6	0.01	0.01	0.007	2.40	0.003	0.03
Acetaldehyde	6	0.44	1.042	0.032	8.74	0.008	2.57
Benzaldehyde	6	0.03	0.07	0.005	7.21	0.001	0.18
Isovaleraldehyde	6	0.35	0.131	0.309	1.88	0.086	0.43
Propionaldehyde	6	0.02	0.023	0.010	5.03	0.001	0.05
Distribution warehouse							
2-Furaldehyde	6	0.007	0.010	0.002	5.75	0.001	0.02
Acetaldehyde	6	0.014	0.007	0.013	1.56	0.008	0.03
Benzaldehyde	6	0.004	0.003	0.003	2.53	0.001	0.01
Isovaleraldehyde	6	0.002	0.002	0.001	2.48	0.001	0.01
Propionaldehyde	6	0.016	0.017	0.007	5.66	0.001	0.04

Table adapted from Appendix I-C. †Area samples, STD: standard deviation; GM: geometric mean; GSD: geometric standard deviation; n: number of samples; ppm: parts per million

Table 21. Personal task-based sampling results, July 2007.

Task Description	Duration (minutes)	Analyte	ppm	Batch Flavor
Powder production room				
Packaging powder product into boxes	33	2-Furaldehyde	0.04	Dairy-flavored powder
Packaging powder product into boxes	33	Acetaldehyde	4.02	Dairy-flavored powder
Packaging powder product into boxes	33	Benzaldehyde	0.06	Dairy-flavored powder
Packaging powder product into boxes	33	Isovaleraldehyde	0.01	Dairy-flavored powder
Packaging powder product into boxes	33	Propionaldehyde	0.002	Dairy-flavored powder
Packaging powder product into boxes	33	Acetoin	2.78	Dairy-flavored powder
Bench-top liquid pouring, dumping substrate into mixer, mixing, packaging, taking a QC sample	17	Acetoin	0.12	Confectionery flavor
Packaging powder product into boxes	33	Diacetyl†	4.75	Dairy-flavored powder
Bench-top liquid pouring, dumping substrate into mixer, mixing, packaging, taking a QC sample	17	Diacetyl†	4.84	Confectionery flavor
Liquid production room				
Bench-top liquid pouring	12	2-Furaldehyde	0.004	Nut emulsion
Mixing into stand alone vessel	33	2-Furaldehyde	0.001	Tropical fruit flavor
Liquid pouring	12	Acetaldehyde	0.01	Nut emulsion
Mixing	33	Acetaldehyde	0.08	Tropical fruit flavor
Bench-top liquid pouring	12	Benzaldehyde	0.13	Nut emulsion
Mixing into stand alone vessel	33	Benzaldehyde	0.05	Tropical fruit flavor
Bench-top liquid pouring	12	Isovaleraldehyde	0.01	Nut emulsion
Bench-top liquid pouring	12	Propionaldehyde	0.004	Nut emulsion
Mixing into stand alone vessel	33	Propionaldehyde	0.02	Tropical fruit flavor
Bench-top pouring	12	Acetoin	0.17	Nut emulsion
Scooping butter from metal bin into boxes (under an exhaust hood); worker leaned into bin to remove all powder	8	Acetoin	0.59	Butter-flavored powder
Bench-top mixing	35	Acetoin	0.24	Wine flavor
Setting up boxes, moving equipment, scooping powder over head into a sifter	61	Acetoin	0.88	Butter-flavored powder
Cleaning grinder/sifter with hose	21	Acetoin	0.10	Butter-flavored powder
Pouring butter emulsion into 1-gallon bottles, cleaning drip pan for butter blending operation	33	Acetoin	0.06	Butter emulsion
Scooping out powder into smaller packages (under an exhaust hood)	10	Acetoin	0.72	Butter-flavored powder
Bench-top pouring	12	Diacetyl†	0.27	Nut emulsion
Scooping powder from metal bin into boxes (under an exhaust hood); worker leaned into bin to remove all powder	8	Diacetyl†	17.38	Butter-flavored powder
Bench-top mixing	35	Diacetyl†	0.65	Wine flavor
Setting up boxes, moving equipment, scooping powder over head into a sifter	61	Diacetyl†	9.32	Butter-flavored powder
Cleaning grinder/sifter (used for butter-flavored powder) with hose	21	Diacetyl†	0.53	Butter-flavored powder
Pouring powder emulsion into 1-gallon bottles, cleaning drip pan for butter blending operation	33	Diacetyl†	1.03	Butter emulsion
Scooping out powder into smaller packages (inside exhaust hood)	10	Diacetyl†	10.05	Butter-flavored powder
Spray-drying room				
Operating small spray dryer	99	Acetoin	0.14	Dried fruit flavor
Operating small spray dryer	99	Diacetyl†	0.11	Dried fruit flavor

Table adapted from Appendix I-C. †Collected/analyzed using modified OSHA Method PV2118 for diacetyl. ppm: parts per million.

Table 22. Occupational exposure limits for sampled analytes.

Chemical name	Occupational exposure limits					
	NIOSH Recommended Exposure Limit TWA	**NIOSH Recommended Exposure Limit** STEL	**NIOSH Recommended Exposure Limit** Ceiling	**OSHA Permissible Exposure Limit** TWA	**OSHA Permissible Exposure Limit** STEL	**OSHA Permissible Exposure Limit** Ceiling
2-Furaldehyde	-	-	-	5 ppm [A,]	-	-
Acetaldehyde	[C]	[C]	[C]	200 ppm	-	-
Acetic acid	10 ppm	15 ppm	-	10 ppm	-	-
Phosphoric acid	1 mg/m^3	3 mg/m^3	-	1 mg/m^3	-	-
Propionic acid	10 ppm	15 ppm	-	-	-	-
Respirable particulate	-	-	-	5 mg/m^3	-	-
Total particulate	-	-	-	15 mg/m^3	-	-

No NIOSH or OSHA occupational exposures limits have been established for acetoin, benzaldehyde, butyric acid, diacetyl, isovaleraldehyde, propionaldehyde, and total volatile organic compounds. [A] Skin notation; [C] NIOSH potential occupational carcinogen; ppm: parts per million; mg/m^3: milligram per cubic meter; TWA: time-weighted average; STEL: short-term exposure limit.

Table 23. The 30 most abundant compounds observed in thermal desorption tube samples in rank order of abundance for November 2006 and July 2007 industrial hygiene surveys.

November 2006 survey	July 2007 survey
Limonene	Limonene
Ethyl butyrate	Ethyl butyrate
Benzaldehyde	Benzaldehyde
$C_{10}H_{16}$ terpene, alpha-pinene	Ethyl acetate
Ethyl acetate	Isoamyl acetate (3-methyl-butyl acetate)
Isoamyl acetate (3-methyl-butyl acetate)	Propylene glycol
Butyl butyryl lactate	Diacetyl
Decamethylcyclopentasiloxane	Isovaleraldehyde (3-methylbutanal)
Ethyl propionate	Vanillin
p-Cymene	Ethyl isovalerate (ethyl 3-methyl butyrate)
$C_{10}H_{16}$ terpene, beta-pinene	$C_3H_4O_2$ isomer, methyl glyoxal
$C_{10}H_{16}$ terpene, myrcene	Ethyl propionate
Propylene glycol	Methyl amyl ketone
Methyl amyl ketone	Isovaleraldehyde propylene glycol acetal
Ethyl isovalerate (ethyl 3-methyl butyrate)	Trimethyl pyrazine
Ethyl caproate (hexanoate)	Amyl alcohol
Cinnamaldehyde	Ethyl 2-methyl butyrate
Gamma-Terpinene	$C_{10}H_{16}$ terpenes (such as thujene, sabinene, fenchene, phellandrene, etc.)
Diacetyl	p-Cymene
Toluene	Gamma-Terpinene
Diethylphthalate	$C_{10}H_{16}$ terpene, alpha-pinene
2-Methylbutyl acetate	Ethanol
Ethanol	Linalool
Isovaleraldehyde (3-methylbutanal)	Butyl butyryl lactate
Ethyl 2-methyl butyrate	p-Dichlorobenzene
$C_{10}H_{16}$ terpenes (such as thujene, sabinene, fenchene, phellandrene,etc.)	Ethyl phenyl acetate
Hexyl acetate	5-Methylfurfural
Isopropyl myristate	Sulfur dioxide
Pentane	Pentane
Acetic acid	Acetic acid

Table adapted from Appendix I-C.

Table 24. Hood face velocity and exhaust flow rate measurements in the liquid production Room, July 2007.

Hood number	Type	Average face velocity (fpm)	Standard deviation	Exhaust flow rate (cfm)
1	**Bench-top**	191	21	1663
2	**Bench-top**	164	14	1552
3	**Bench-top**	177	30	1560
5	**Bench-top**	205	26	1581
6	**Booth-type**	80	15	2045
7	**Booth-type**	73	21	2028
8	**Booth-type**	69	18	2806
9	**Bench-top**	189	38	1506

Table adapted from Appendix II-B. fpm: feet per minute; cfm: cubic feet per minute.

Table 25. Measured capture efficiencies of local exhaust ventilation systems in the liquid production room, based on quantitative tracer gas (SF_6) tests, July 2007.

Hood number (type)	Capture efficiency	Procedure used
Hood 1 (Bench-top)	89-97%	Test performed with the ejector source at various locations within the hood.
Hood 2 (Bench-top)	98%	Positioned the ejector source in the middle of the bench inside of the side baffle.
Hood 3 (Bench-top)	100%	Performed the test with mannequin in front of hood (Figure 11). Positioned the ejector source in the middle of the bench inside of the side baffle.
Hood 5 (Bench-top)	98%	Performed the test with mannequin in front of the hood. Positioned the ejector source in the middle of bench inside of the side baffle.
Hood 6 (Booth-type)	97%	Positioned the coiled dispersion tube (Figure 19) inside the mixing tank.
Hood 7 (Booth-type)	96%	Positioned the coiled dispersion tube inside the mixing tank.
Hood 8 (Booth-type)	98%	Positioned the coiled dispersion tube inside mixing the tank.
Hood 9 (Bench-top)	98-99%	Performed the test with and without the mannequin. Positioned the ejector source in the middle of bench inside of the side baffle.

Table adapted from Appendix II-B.

Table 26. Roof-top stack exhaust discharge characteristics, July 2007.

Hood number	Distance from base of exhaust opening to roof deck (inches)	Diameter of roof exhaust opening† (inches)	Exhaust outlet velocity (fpm)
1	22	20	3200
2	22	20	3250
3	22	20	3100
5	22	20	2100
6	40	24	2100
7	38	24	2500
8	39	24	2500
9	25	20	2500

Table adapted from Appendix II-B. †Several facility roof vent openings were situated 4-8 inches from the roof deck. fpm: feet per minute; cfm: cubic feet per minute.

Figure 1. Plant Layout

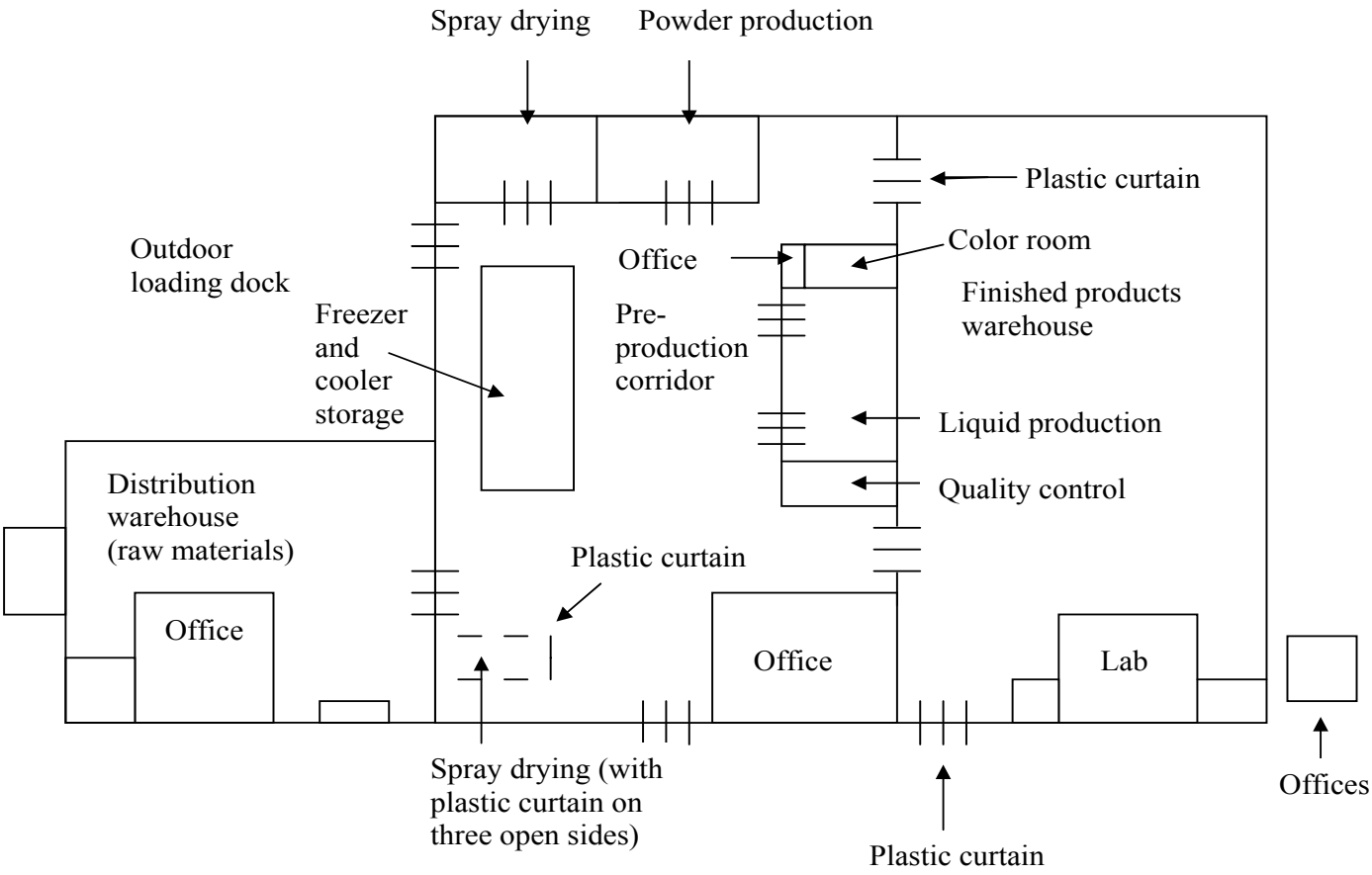

Figure adapted from Appendix III-C.

Figure 2. Bench-top exhaust hood workstations in liquid production area, July 2007.

Figure from Appendix II-B.

Figure 3. Ventilated booth-type exhaust hood in liquid production area, July 2007.

Figure from Appendix II-B.

Figure 4. Air sampling locations for area samples, November 2006 and July 2007.

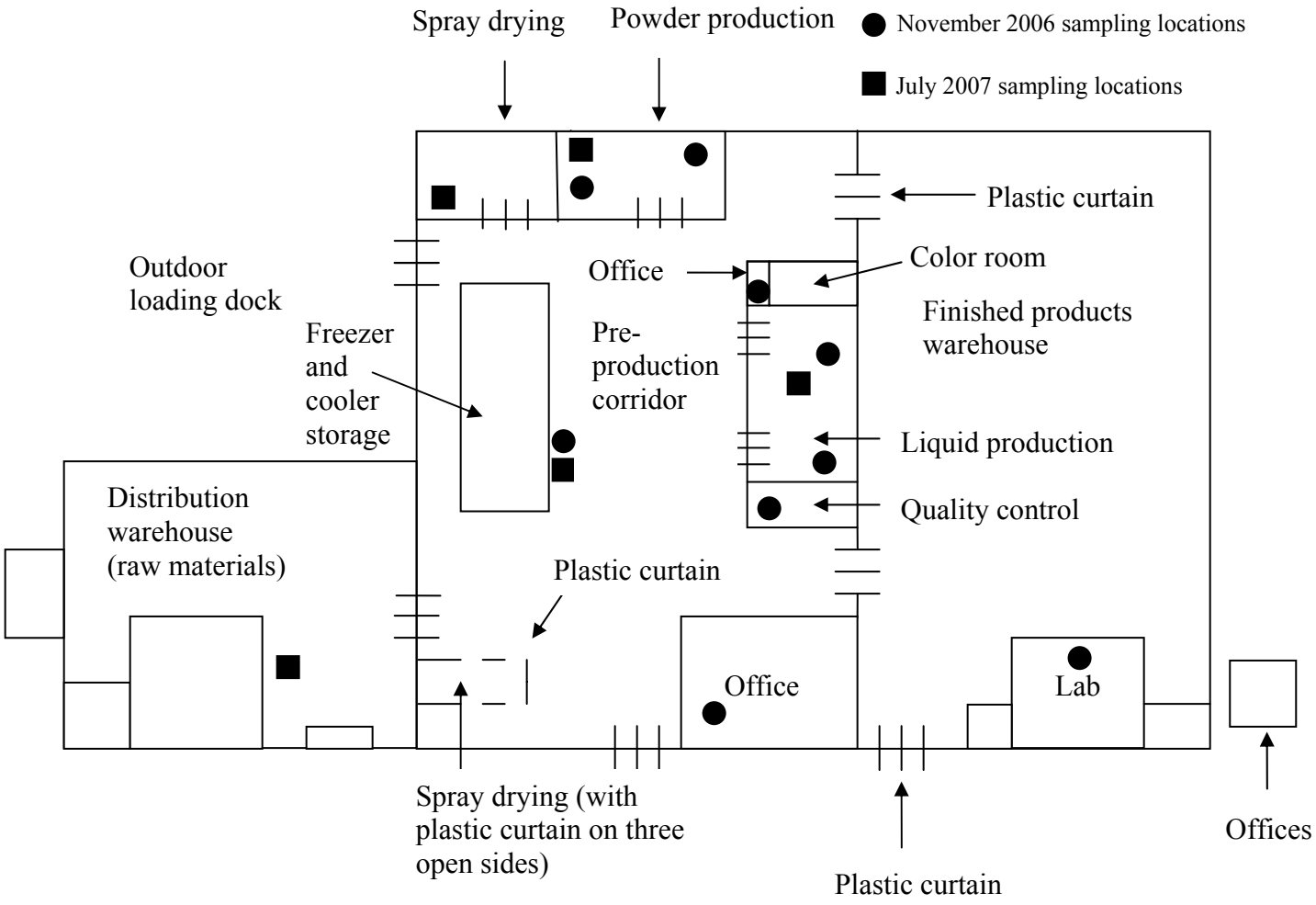

Figure adapted from Appendix I-C.

Figure 5. Layout of bench-top and booth-type hoods in the liquid production room, July 2007.

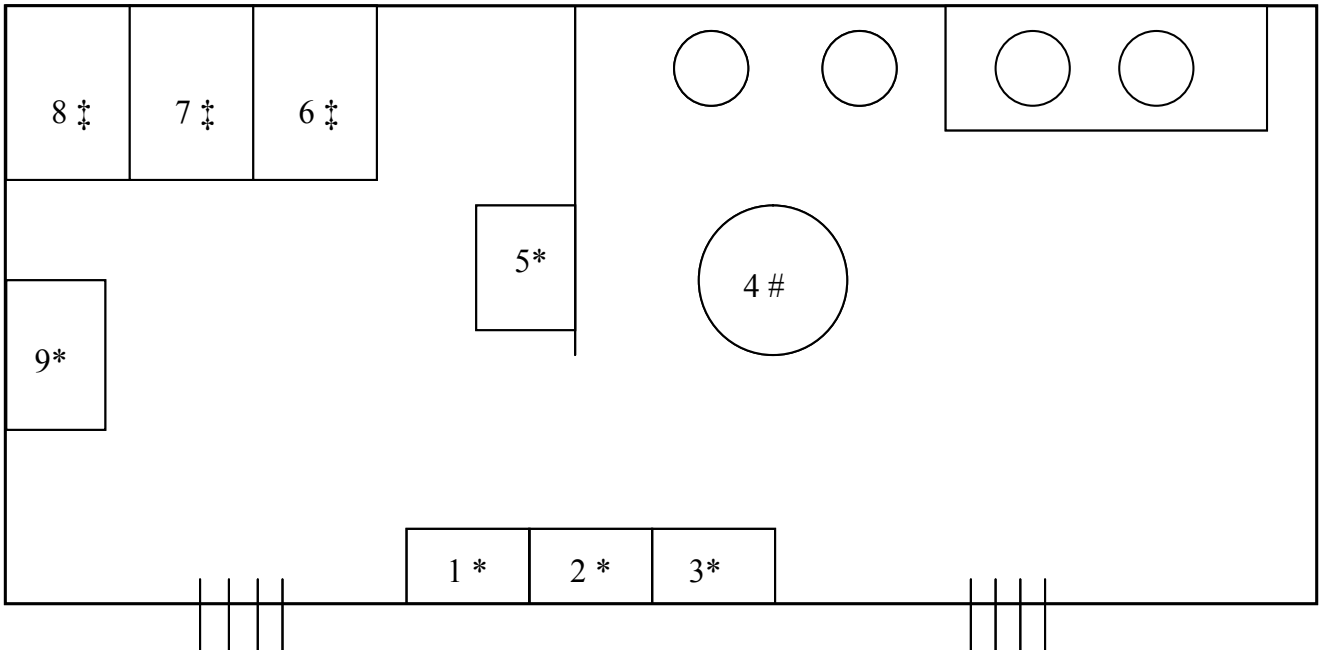

Figure from Appendix II-B. *Bench-top hoods, ‡Booth-type hoods, # Hood not installed at time of evaluation.

Figure 6. Real-time volatile organic compound (VOC) and total dust air concentrations in powder production room, November 2006.

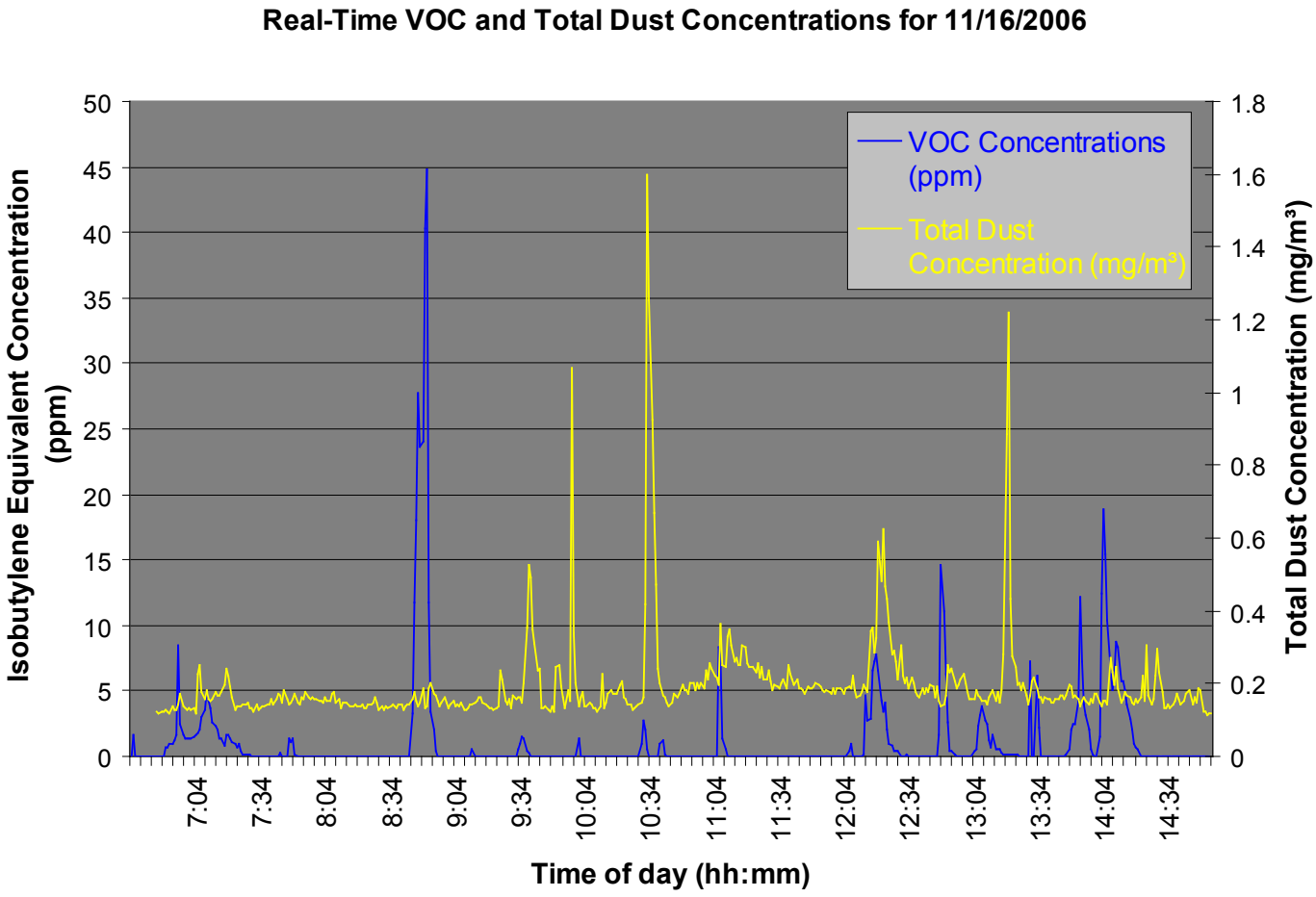

Figure from Appendix I-C. VOC: volatile organic compound, ppm: parts per million, mg/m^3: milligrams per cubic meter of air.

Figure 7. Real-time volatile organic compound air concentrations in the pre-production corridor, November 2006.

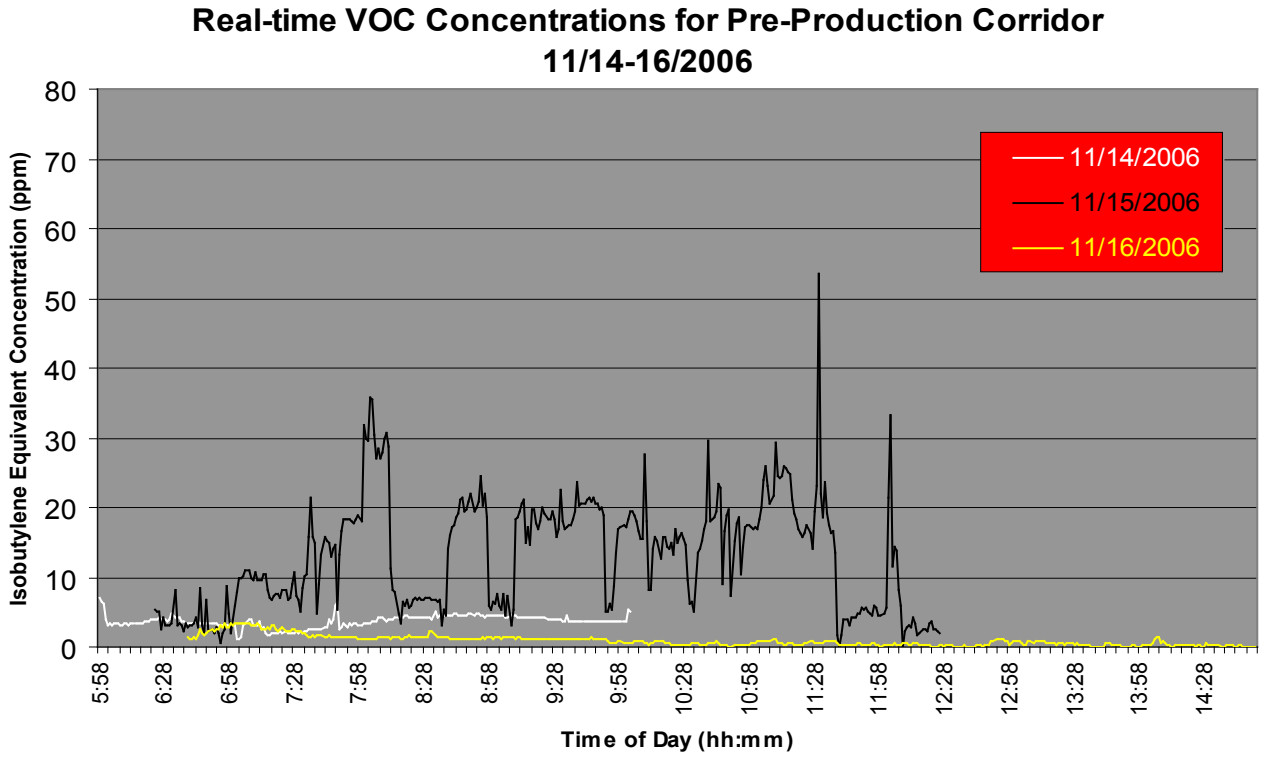

Figure from Appendix I-C. VOC: volatile organic compound, ppm: parts per million.

Figure 8. Real-time volatile organic compound air concentrations in the liquid production room, November 2006.

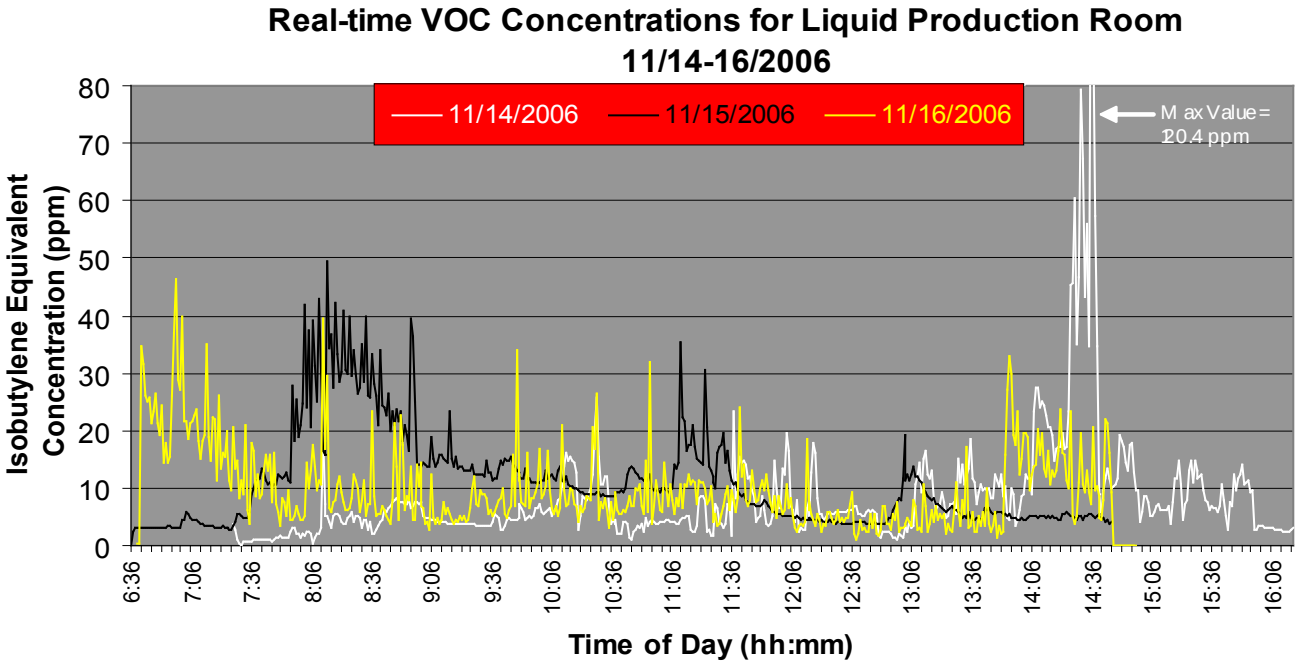

Figure from Appendix I-C. VOC: volatile organic compound, ppm: parts per million.

Figure 9. Real-time volatile organic compound air concentrations in the powder production room, November 2006.

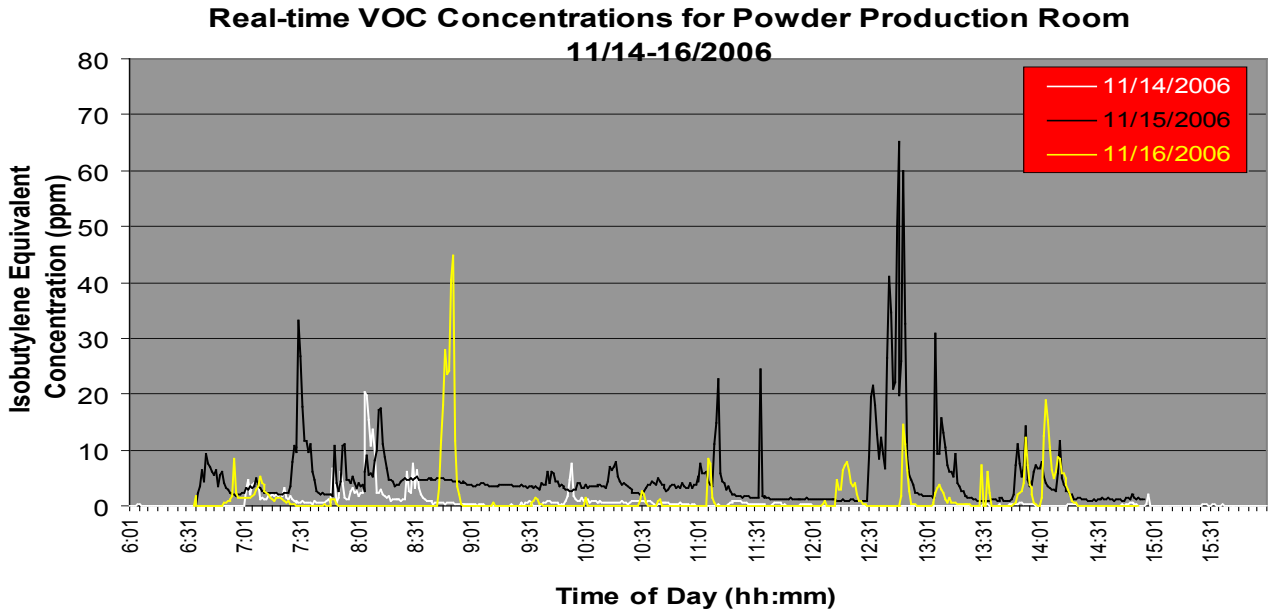

Figure from Appendix I-C. VOC: volatile organic compound, ppm: parts per million.

Figure 10. Liquid production room layout of exhaust fans and supply fans, November 2006.

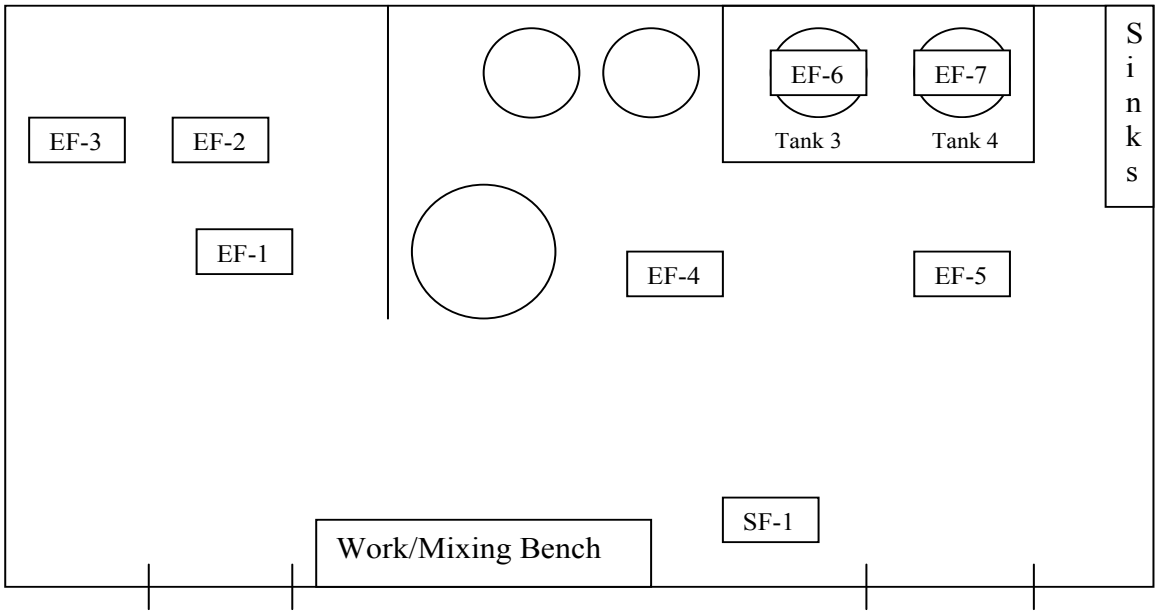

Figure adapted from Appendix I-C. EF: air exhaust fan, SF: air supply fan.

Figure 11. Sulfur hexafluoride (SF_6) ejector setup with mannequin, July 2007.

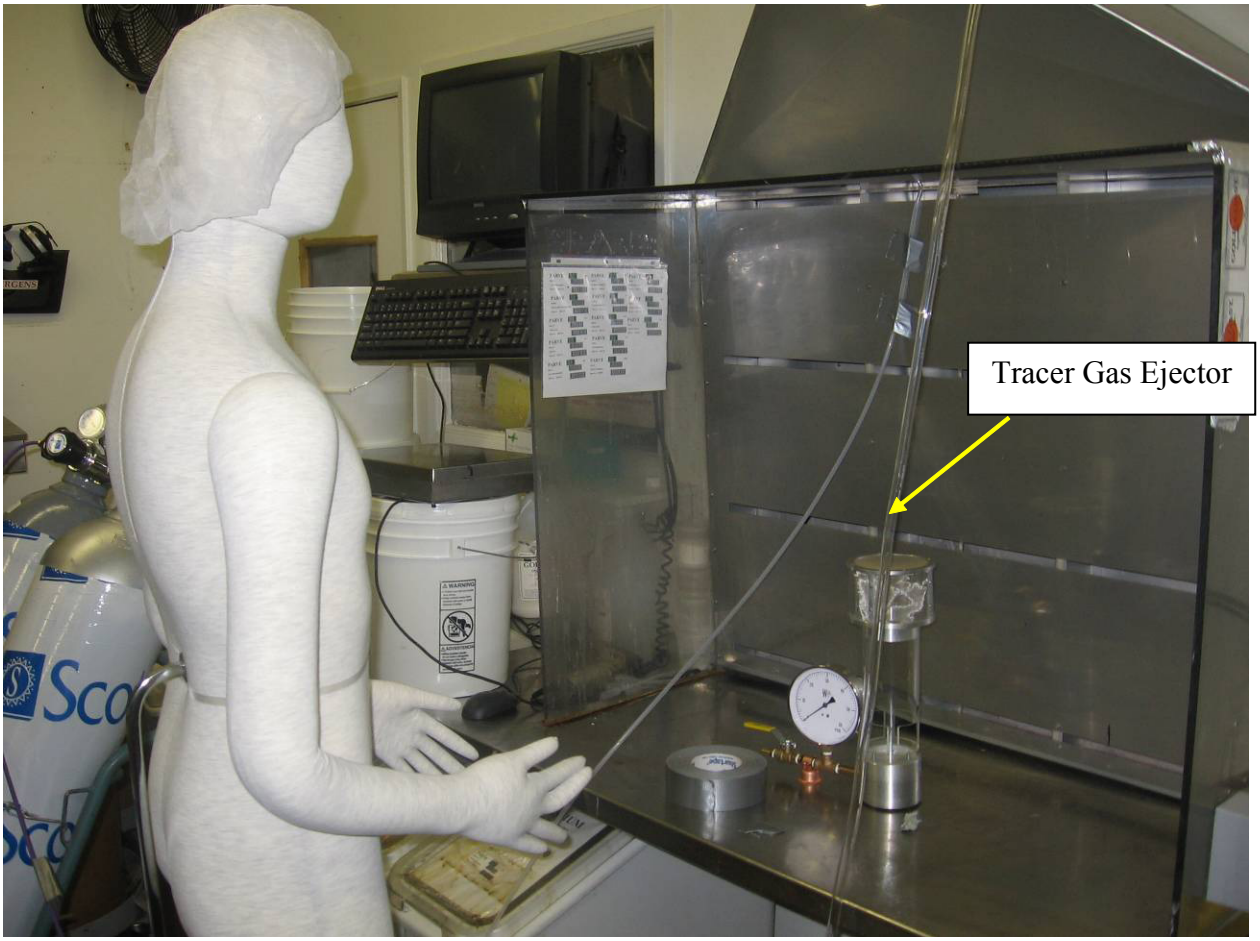

Figure from Appendix II-B.

Figure 12a. Real-time evaluation of bench-top exhaust hoods - Hood 9 control on/off, in the liquid production room, July 2007.

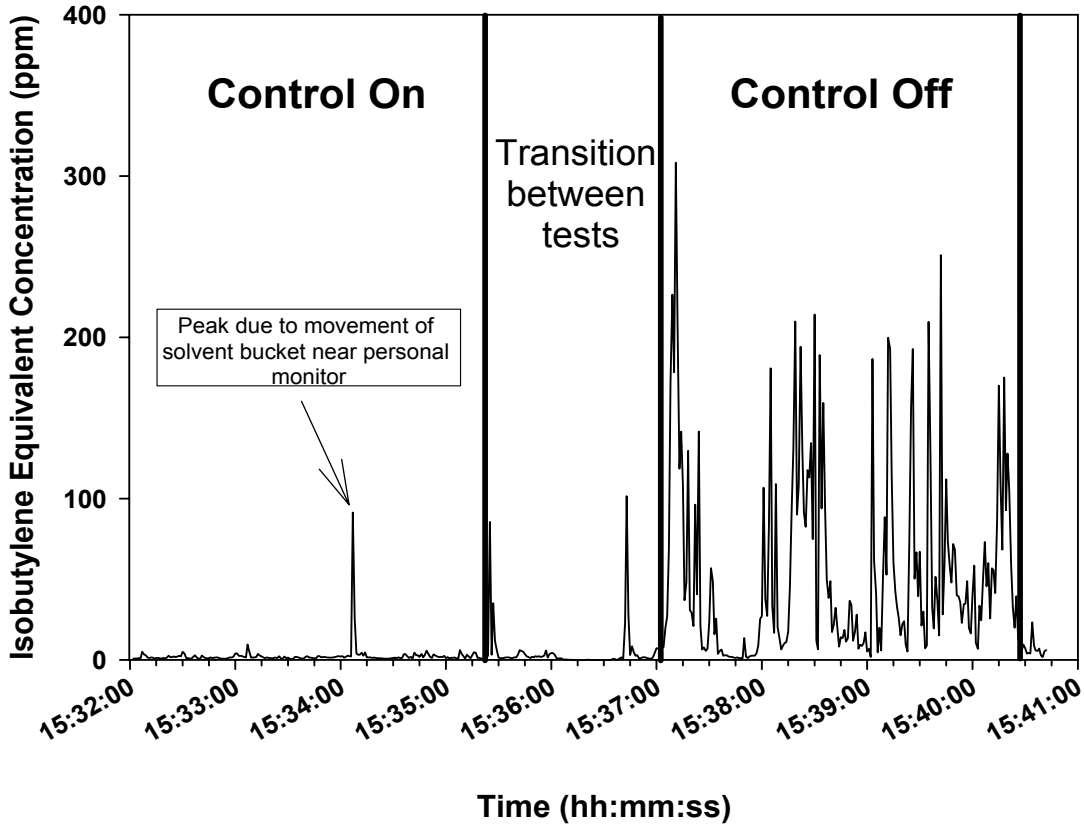

Figure from Appendix II-B.

Figure 12b. Real-time evaluation of bench-top exhaust hoods – Hood 9 control on/off, in the liquid production room, July 2007.

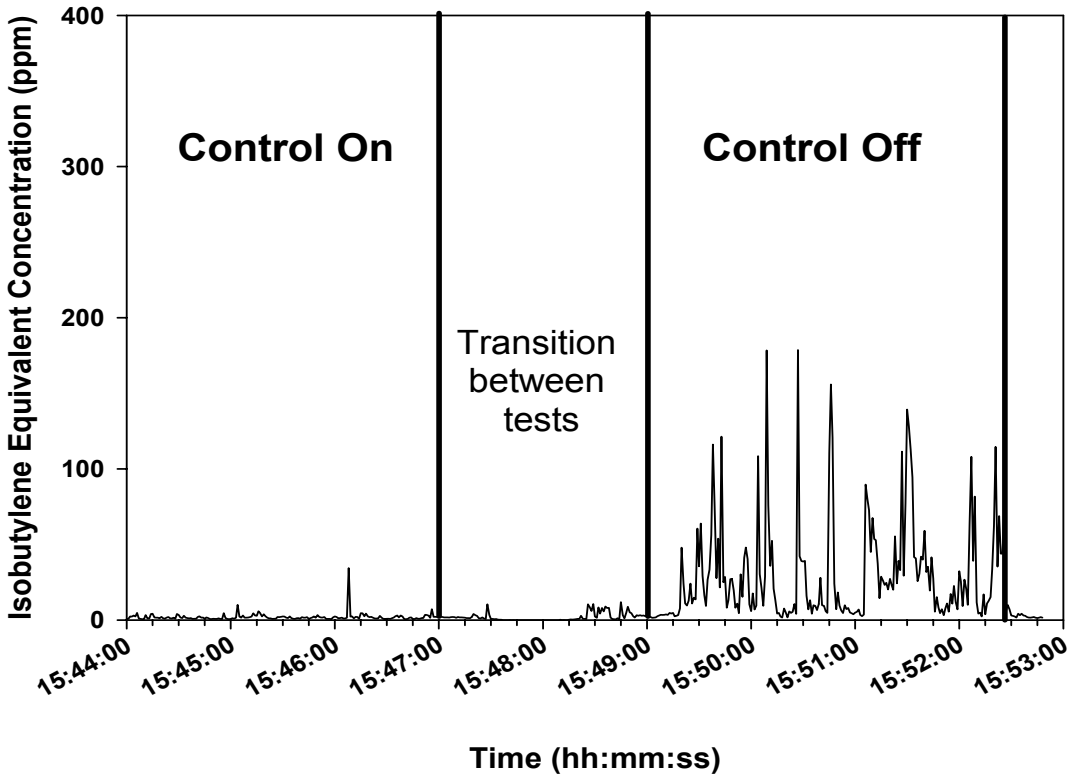

Figure from Appendix II-B.

Figure 12c. Real-time evaluation of bench-top exhaust hoods – Hood 2 control on/off, in the liquid production room, July 2007.

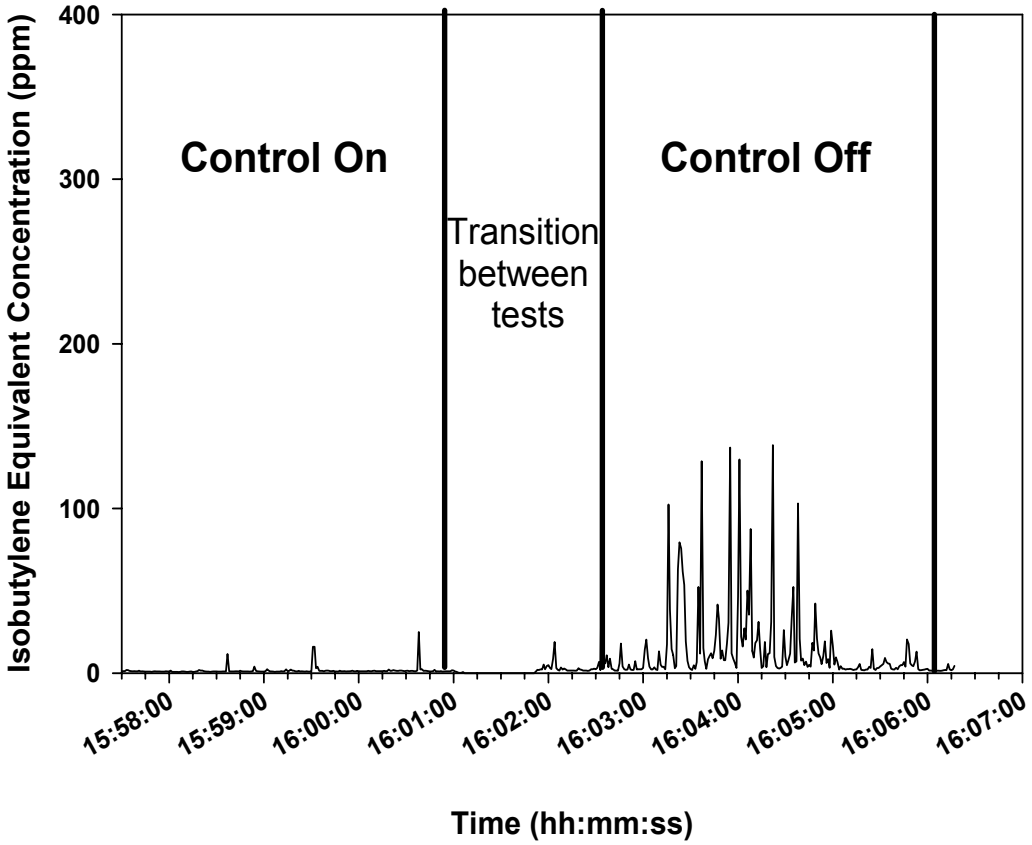

Figure from Appendix II-B.

Figure 13. Average concentrations and standard deviations for control on/off bench-top tests, July 2007.

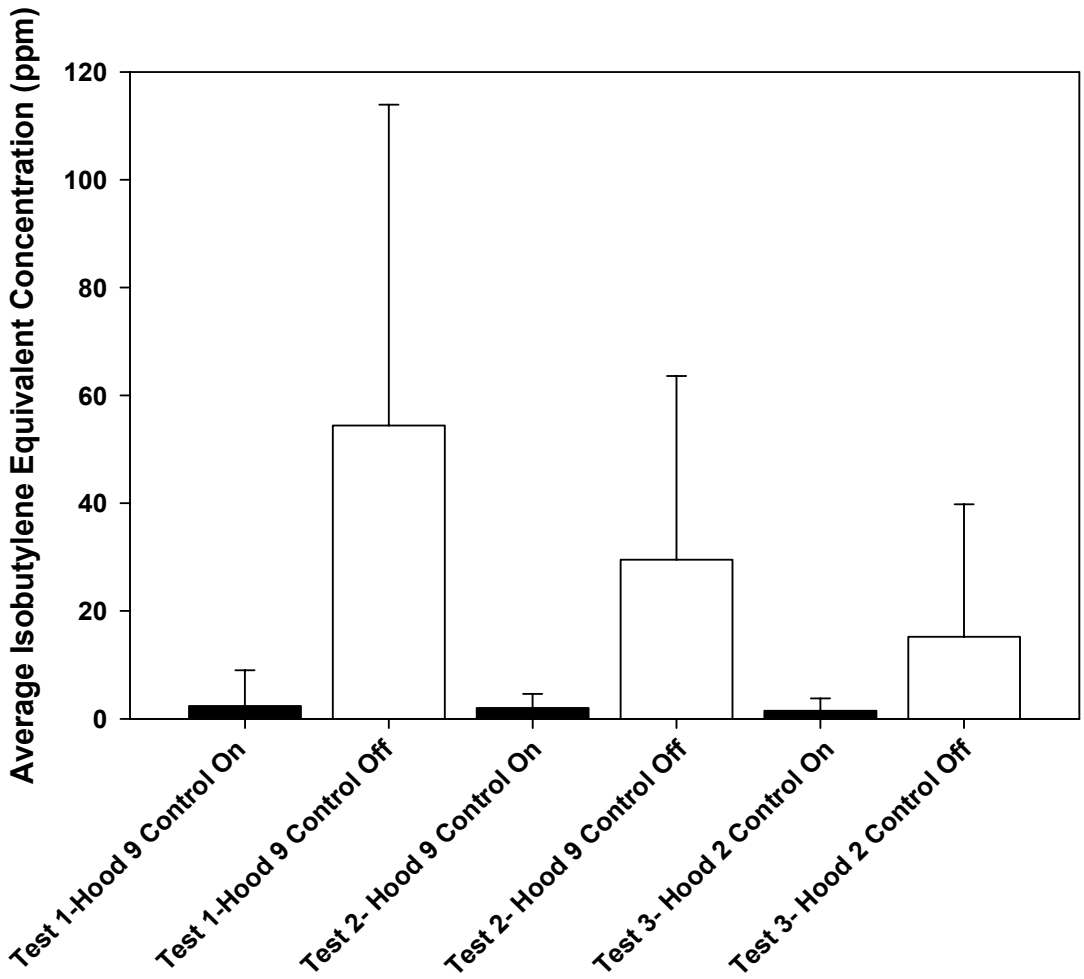

Figure from Appendix II-B.

Figure 14. Rooftop exhaust re-entrainment smoke test, July 2007.

Figure from Appendix II-B.

Figure 15. Employee packaging butter-flavored powder inside booth-type hood in the liquid production room, July 2007.

Figure from Appendix I-C.

Figure16. Hood face velocity measurement grid layout. Dots represent measurement points.

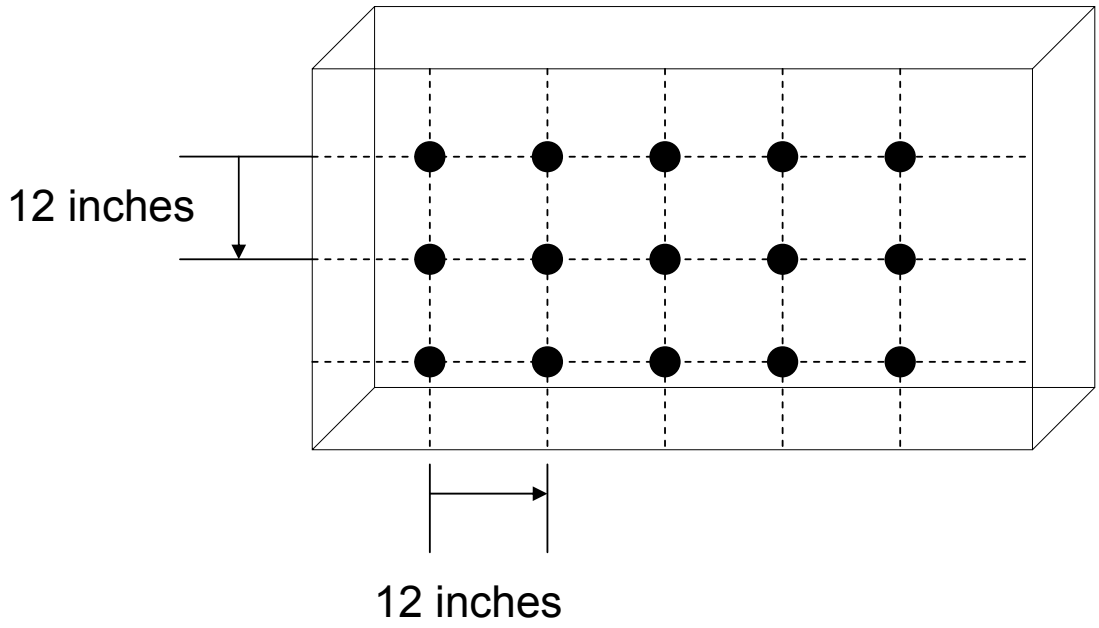

Figure from Appendix II-B

Figure 17. Sulfur hexafluoride (SF_6) source coil for booth-type hood testing.

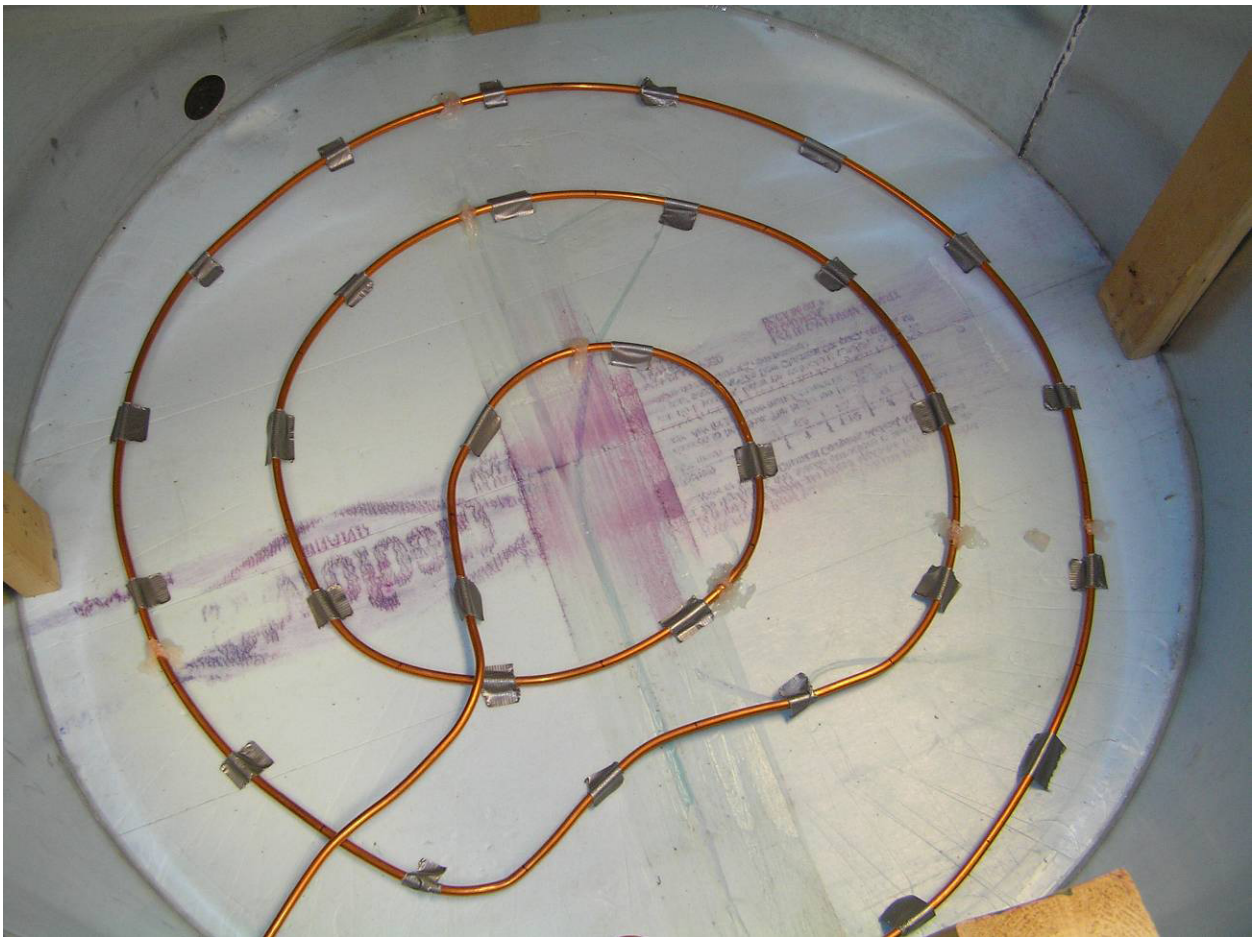

Figure from Appendix II-B.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226-1998

December 19, 2006

Jon Wellwood
Gold Coast Inc.
2429 Yates Avenue
Commerce, California 90040

Dear Mr. Wellwood:

Thank you again for your cooperation during the recent NIOSH visit, November 14-16, 2006. We look forward to working with you during the completion of the exposure assessment report and design, implementation and evaluation of engineering controls. As we discussed, we will be providing additional ventilation/engineering control guidance in subsequent correspondence. And following completion of air sample analysis, additional information regarding sampling results will be provided.

We also appreciate your willingness to allow us to view and photograph the flavor mixing process, work practices, and engineering controls at your facility. Please closely review enclosed CD-rom which contains the photographs and contact us within twenty-one business days if there are any photographs which violate trade secret considerations. NIOSH has a long history of working with companies and handling trade secrets appropriately.

As discussed in our close out meeting, a fully functioning respiratory protection program is necessary at your facility. A formal respiratory protection program that adheres to the requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134) is required; this would include medical testing to assess worker fitness to wear respiratory protection. The program administrator that you select for the program must have adequate training and experience to run it and regularly evaluate its effectiveness. Details on the respiratory protection standard and how a company could set up a respiratory protection program are available on the OSHA website at: http://www.osha/gov/SLTC/etools/respiratory/index.html.

Until the production process in reengineered to control exposure to flavoring chemicals, you should require respirator use by all employees who work to enter the production area. A NIOSH-certified full face respirator with organic vapor, acid gas and particulate filters is the minimum level of respiratory protection recommended by CAL-OSHA for entry into the production areas. A loose-fitting powered air-purifying respirator (PAPR) is another option to consider for increased comfort and, unlike tight-fitting respirators, does not require fit testing.

Even if the appropriate respirators are used and worn correctly, and appropriate cartridge change out schedule must be implemented to continue respirator effectiveness. It is paramount that you follow manufacturer's recommendations for cartridge change out schedules and formally calculate a change-out schedule as required by Cal-OSHA. Providing a respirator storage location outside of the production area should help to minimize cartridge exposure to chemicals off shift and insure that cartridge change out schedules are appropriate.

I-A: Letter from LT McKernan and KH Dunn to J Wellwood (December 19, 2006)

Page 2 - Jon Wellwood

Again, thank you for sharing your valuable time and knowledge with us during recent site visit. If you have questions regarding the information in this letter or have any additional questions, please feel free to contact Lauralynn at 513-841-4571 / LMcKernan@cdc.gov or Kevin at 513-841-4152 / Kdunn@cdc.gov.

Sincerely,

Lauralynn Taylor McKernan, Sc.D. C.I.H
LCDR, Environmental Health Officer
Industrywide Studies Branch
Division of Surveillance, Hazard Evaluation
and Field Studies

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Enclosure

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226-1998

June 4, 2007

Jon Wellwood
Gold Coast, Inc.
2429 Yates Avenue
Commerce, California 90040

Dear Mr. Wellwood:

As you know, a NIOSH field team visited your facility November 14-16, 2006. During this visit, samples were collected to assess ketones, aldehydes, and dust. Upon completion of the exposure assessment analysis, I will provide you with a complete report.

In response to your recent request for specific exposure information in the warehouse area, I have compiled the descriptive statistics in the following table. This data represents samples collected from area baskets hanging in the warehouse area, adjacent to the liquid production room. Samples were collected for approximately eight hours each day, on three subsequent days.

The exposure assessment values are preliminary in nature and represent 8-hr time weighted averages. In compliance with California Occupational Safety and Health Administration (CAL-OSHA) procedures, if multiple sorbent tubes were collected during one work shift and one result was reported below the limit of detection, zero was used for that portion of the exposure calculation.

Diacetyl samples presented were collected and analyzed according to the Occupational Safety and Health Administration (OSHA) analytical method for diacetyl. NIOSH researchers are currently investigating potential relative humidity issues with the analytical methods for diacetyl. One preliminary investigation suggested that high humidity levels may result in an underestimation of true concentrations. A laboratory special measurements project is underway to investigate these factors and determine whether, and at what levels this phenomena may occur. Until this laboratory investigation is complete, diacetyl sample results are considered preliminary.

I-B: Letter from LT McKernan to J Wellwood (June 4, 2007)

Page 2 – Jon Wellwood

Descriptive Statistics for Warehouse Area Location

	Day 1	Day 2	Day 3	Arithmetic Mean
Diacetyl (ppm)	NC	0.35	0.07	0.21
Benzaldehyde (ppm)	0.03	0.04	0.02	0.03
Acetaldehyde (ppm)	0.10	0.06	0.05	0.07
2-Furaldehyde (ppm)	0.005	0.06	0.05	0.07
Isovaleraldehyde (ppm)	ND	ND	ND	ND
Propionaldehyde (ppm)	0.04	0.02	ND	0.02
Total Dust (mg/m^3)	0.10	0.39	0.30	0.26
Respirable Dust (mg/m^3)	0.03	0.20	0.11	0.11

NOTES:
ppm – Parts per Million
NC – Not collected; Pump failed on day 1, no sample collected
ND – Result below limit of detection
mg/m^3 – Milligrams per Cubic Meter

Given the fluctuations in flavor batch processing, it should be recognized that exposure concentrations likely vary widely from day to day in your facility. These values may or may not represent 'typical' exposures depending on how our sampling days compared to normal batch processing.

If you have questions on how these samples were collected or analyzed, I'd be happy you discuss them with you. I can be reached at 513-841-4571 or LMcKernan@cdc.gov. Thank you for your continued cooperation.

Sincerely,

Lauralynn Taylor McKernan, Sc.D CIH
Lieutenant Commander
US Public Health Service
Industrywide Studies Branch
Division of Surveillance, Hazard
Evaluations and Field Studies

cc:
Rachel L. Bailey, NIOSH
Kelly Howard, Cal-OSHA
Dan Leiner, Cal-OSHA

EVALUATING OCCUPATIONAL EXPOSURES

AND WORK PRACTICES

AT

GOLD COAST INGREDIENTS, INC.
COMMERCE, CA

A Technical Assistance Report to the
California/Occupational Safety and Health Administration

REPORT WRITTEN BY:
Lauralynn Taylor McKernan ScD, CIH [1]
Kevin H Dunn MSEE, CIH [2]

REPORT DATE:
January, 2008

REPORT NUMBER:
HETAB20060361-1

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Division of Surveillance, Hazard Evaluation, and Field Studies [1]
Division of Applied Research and Technology [2]
4676 Columbia Parkway, Mail Stop R-14
Cincinnati, Ohio 45226-1998

I-C: Technical Assistance Report—Evaluating Occupational Exposures and Work Practices at Gold Coast Ingredients, Inc. Commerce, CA (January 2008)

SITE SURVEYED:	Gold Coast Ingredients, Inc. Commerce, CA
NAICS CODE:	311
SURVEY DATES:	November 14-16, 2006; July 10-12, 2007
SURVEYS CONDUCTED BY:	November 14-16, 2006: Lauralynn Taylor McKernan, NIOSH Kevin H Dunn, NIOSH Chad H. Dowell, NIOSH Brian Curwin, NIOSH Alberto Garcia, NIOSH July 10-12, 2007: Lauralynn Taylor McKernan, NIOSH Kevin L. Dunn, NIOSH James Couch, NIOSH
EMPLOYER REPRESENTATIVES CONTACTED:	Jon Wellwood

DISCLAIMER

Mention of company names or products does not constitute endorsement by the Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

Table of Contents

FIGURES

Introduction

In response to a technical assistance request from California Division of Occupational Safety and Health (Cal/OSHA) in 2006, researchers from the National Institute for Occupational Safety and Health (NIOSH) conducted site visits of Gold Coast, Inc. at their Commerce, California plant on November 14-16, 2006 and July 11-12, 2007. Gold Coast is participating in the Flavoring Industry Safety and Health Evaluation Program (FISHEP), a voluntary special emphasis program. This program was initiated by the California Department of Health Services (CDHS) and the California Division of Occupational Safety and Health (Cal/OSHA) in 2006 to identify workers with flavoring-related lung disease such as bronchiolitis obliterans (BO) and institute preventive measures in the California flavoring industry. Under FISHEP, companies must report the results of worksite industrial hygiene assessments to CDHS, and implement control measures recommended by Cal/OSHA. This site report was conducted as the result of a formal technical assistance request on occupational exposures to potentially hazardous chemicals in the manufacturing of food flavors.

Due to the high volumes of diacetyl used, this site was selected for inclusion in this investigation at the specific request of Cal/OSHA. The objectives of the industrial hygiene surveys conducted included identifying common work tasks, plant processes, and procedures as well as characterizing potential occupational exposures within the flavoring industry. A secondary goal was to provide preliminary engineering control guidance, which has been addressed in other correspondence[1, 2].

Process Description

The Gold Coast Ingredients, Inc. is a wholesale flavors and color manufacturer. The company produces over 1,500 flavors in liquid, powder, spray dried, natural, natural and artificial, or artificial forms[3]. In October 2006, Gold Coast Ingredients, Inc employed production workers in areas such as the liquid production room, spray drying room, pre-production corridor and powder production room.

Flavors are produced by compounding ingredients identified on recipes on computer batch tickets. These tickets identify the order and quantity of ingredients which need to be added to make a flavor formulation. High

priority chemicals, i.e. substances that may pose a respiratory hazard as designated by the Flavoring Extract and Manufacturing Association[4], are identified and appropriate respiratory protection is also highlighted on the batch ticket. Some chemicals, such as diacetyl, are cold-stored to reduce volatility during use.

Exposures vary dramatically depending upon the flavor formulations completed on a particular day. An employee can make numerous flavor formulations daily depending upon the size and complexity of a batch order. It was not unusual to observe at least 7 different batches being compounded concurrently by different employees in the production areas. The majority of flavors manufactured are on an as ordered basis, with little advance notice.

Liquid Flavor Production

The liquid production area typically consists of a total of 17 stationary or mobile open tanks for mixing liquid flavoring ingredients (Figure 1). There were 4 tanks greater than 4 feet in diameter and 13 tanks smaller than this size. There were several small and medium mobile tanks which were moved throughout the facility according to need of the batch or formulation. Employees typically pour and mix small quantities of flavoring ingredients on top of a bench top. Employees complete large pours, near the large open tanks often pouring directly into the tank. The liquid room is served by a combination of general exhaust and supply ventilation registers located on the ceiling of the room. There are six air registers located in the room overall. Measurements of the flow from each register showed that two were exhausting air at a combined flow rate of 980 cubic feet per minute (cfm), one was supplying air at a rate of 1300 cfm, and three were not moving air at all. In addition to general ventilation, there was a fume canopy exhaust hood over two mixing tanks which exhaust air when the fan was activated. These tanks are heated and used to produce flavored fruit fillings.

Following the initial survey in November 2006, recommendations on the design and implementation of engineering controls were provided to the company in a letter, dated February 7, 2007. A new local exhaust ventilation system was developed and installed in the liquid production room by Gold Coast in conjunction with a contractor. These controls were installed during the May-June 2007 timeframe and consist of two main types of local exhaust ventilation hoods. The first type is a ventilated bench-top, back draft slotted hood used to control

worker exposure to chemicals during small batch mixing, weighing and pouring activities which comprise a majority of the workday. Overall, five bench-top ventilated workstations were installed in the liquid compounding room. The second hood type is a small booth hood which allows for the rolling in of large kettles. The primary function of this hood is to collect chemical vapors when the worker is pouring flavoring ingredients into the large mixers and to contain evaporative losses when a flavor is being mixed. However, this hood was also observed being used during the packaging of powder flavorings. A total of three of these hoods were installed in the liquid compounding room.

Powder Flavor Production

Powders or pastes were typically mixed within ribbon industrial blenders in the powder production room. In these mixers, a starch or carbohydrate was combined with a liquid or paste flavoring agent. The mixing process was a source of potential exposures with visible airborne dust depending upon the work practices employed during pouring, mixing and packaging. The powder production room and the two spray-drying areas were substantially smaller than the liquid production room. The powder compounding area consisted of 2 blenders, both outfitted with local exhaust ventilation. Both blenders were located on platforms with fixed ladders used for access. The smaller blender was 5 feet 6 inches (length) x 2 feet 8 inches (wide) and was outfitted with a canopy-type exhaust hood. The larger blender was 8 feet (length) x 3 feet 6 inches (wide) and outfitted with a slotted exhaust hood located about 8 feet above the platform and behind the work platform. There was no supply air directly provided to the powder compounding room. Airflow into the room comes solely from infiltration from the warehouse area through the 10 feet x 10 feet door opening and a 15 inch x 15 inch vent opening located about 11 feet above the floor. The vent is open to the warehouse area.

Spray Drying Production

Adjacent to the powder blending room, the spray dryer production room contained three spray dryers (one large and one medium stationary spray dryer, and one mobile spray dryer). Inside a spray dryer, a slurry compound is infused with a flavor, which is converted to encapsulated particles. Many volatile compounds are encapsulated in an amorphous carbohydrate, producing more stable products with more manageable properties. Release of the

flavor from the encapsulated particle is generally fast and complete upon contact with moisture.[5]
Weighing and measuring of flavoring ingredients can occur at various locations throughout the production room, usually near the mixing tank or blender that will be used to produce the final product. It was noted that, for the most part, workers were assigned to either liquid, powder, or spray drying flavoring processes.

Materials and Methods

Information on processes and procedures was obtained through discussions with management and by observation of the processes. Prior to the site visit, the management provided production quantities for chemicals identified as 'high priority' by FEMA. This information was used to refine the sampling scheme used by investigators. Use of personal protective equipment, and work practices were also observed during site visits.

The primary objective of the November survey was to comprehensively characterize worker exposures in the production areas. The objective of the July survey was to again document occupational exposures, but with alternate sampling methods for diacetyl. Characterization of the workplace environment was accomplished through the use of personal, area, and task based air sampling methods (see figures 1 and 2 for facility layout and sample locations). In November, personal and area air samples were collected for various processes at a number of locations throughout the facility including: liquids, powders, pre-production corridor, quality assurance, office administration and research and development locations. Air samples were collected for diacetyl, acetoin, total and respirable particulates, acids (phosphoric, butyric, acetic and propionic) and five specific aldehydes (2-furaldehyde, acetaldehyde, benzaldehyde, isovaleraldehyde, and propionaldehyde). In July, area air measurements were collected in liquids, powders, pre-production corridor, distribution warehouse and spray drying locations for diacetyl, acetoin and five specific aldehydes (2-furaldehyde, acetaldehyde, benzaldehyde, isovaleraldehyde, and propionaldehyde). Relative humidity and temperature measurements were collected using HOBO Pro Model H08-032-08 temperature and humidity dataloggers (Onset Computer Corp., Bourne, MA) in all area locations. Table 1 lists the sample type, flow rate, and standard methods utilized during the November and July site visits. Figure 1 and Figure 2 display sample locations for the November and July site visits, respectively. All sampling pumps were calibrated in accordance with the sampling methods utilized. Pump calibration was conducted using a Bios Drycal DC-LITE , Model DCL-M primary flow standard (BIOS, Butler, NJ). Additional air monitoring equipment used during the survey was within their calibration periods, and checked for accuracy

for the contaminant of interest before being used to collect field measurements.

Personal Air Sampling

November Site Visit

During the November site visit, eight-hour time weighted average (TWA) personal air samples were collected over three consecutive days on almost all of the employees (9 of 13) assigned to work in the liquid and powder production areas. Personal samples were collected for ketones, acids, and aldehydes using calibrated battery-powered personal sampling pumps (SKC Inc., Model 210-1002, Eighty Four, PA) with appropriate sampling media for the contaminant of interest (Table 1, Figure 3). Diacetyl and acetoin samples were collected using carbon molecular sieve media at a flowrate of approximately 0.1 liters per minute and were analyzed according to NIOSH method 2557. Acid samples were collected with silica gel media (200mg/400mg) at a flowrate of approximately 0.2 liters per minutes and were analyzed according to draft NIOSH method 5048 (acetic, butyric and propionic) or NIOSH method 7903 (phosphoric acid). Aldehyde samples were collected using dinitrophenylhydrazine (DNPH) treated silica gel media at a flowrate of approximately 0.1 Liters per minute and were analyzed according to EPA TO-11 method. Employees working in the powder production room were also sampled for an Eight-hour TWA for respirable dust using the model GK 2.69, personal cyclone sampler (BGI , Waltham, MA.) mated with an Airchek 2000 personal sampling pump at a flowrate of approximately 4.2 Liters per minute (SKC Inc., Eighty Four, PA). Respirable dust samples were analyzed according to NIOSH method 0600.

July Site Visit

Personal 8-hour TWA sampling was not conducted during the July site visits.

During both the July and November site visits, short duration task-based air sampling was also conducted for ketones, aldehydes or acids using appropriate sampling media and calibrated pumps to obtain measurements of exposure during selected short-term procedures. Task-based samples were collected during particular tasks (i.e pouring or mixing) or during batch formulations which contained higher quantities of ketones, acids or aldehydes. Samples were collected for the duration of a pouring task (diacetyl, ketones or acids), or the entire duration of a mixing batch formulation depending on the overall length of the process. Video exposure monitoring was conducted for select tasks or work practices that were anticipated to produce elevated airborne concentrations

(i.e., increased potential for inhalation exposures) during both November and July site visits. Video monitoring consisted of filming the task or work process of interest, while simultaneously measuring the workers inhalation exposure to volatile organic compounds (VOCs) in real time using a MiniRAE 2000 or ToxiRAE photoionization detector (PID) (Rae Systems, Inc., Sunnyvale, CA).

Area Air Sampling

November Site Visit

In November, area samples were also collected in various locations in the plant, including the administration office, pre-production corridor, quality-control area, and research and development laboratory (Figure 1) to map contaminant concentrations. Eight-hour time weighted average (TWA) area air samples were collected over three consecutive days for ketones (diacetyl and acetoin), aldehydes (acetaldehyde, benzaldehyde, isovaldehyde, 2-furaldehyde, propionaldehyde) and acids (acetic, butyric, proprionic and phosphoric). Area samples for diacetyl were collected according to the NIOSH method 2557 and a modified U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Method PV2118. This modified OSHA method used larger collection tubes (400/200 milligram silica gel tubes) which have greater collection capacity and minimize breakthrough of contaminant to the backup tube.

All area sample collection devices were housed inside a metal basket, which was located near employee work stations (Figure 4). Respirable dust and total dust samples were also collected in the powder production areas. Respirable dust samples were collected using a BGI cyclone at a flowrate of 4.2 liters per minute (lpm). Real-time VOC concentrations were measured in selected area baskets using MiniRAE 2000 and ToxiRAE photoionization detectors (PID) (Rae Systems, Inc., Sunnyvale, CA). PIDs were programmed to log volatile organic compound (VOC) concentrations every minute. The PIDs were calibrated for isobutylene and could detect isobutylene equivalent VOC concentrations from 1 ppm to 2000 ppm.

Thermal desorption samples were collected at all area locations for approximately two hours each day. The stainless steel thermal desorption tubes contained three beds of sorbent material: the first section contains Carbopack Y (90 mg), the second section contains Carbopack B (115 mg) and the last section contains Carboxen

1003 (150 mg). The thermal tube sorbents were run for approximately 2 hours at a flowrate of 0.1 liters per minute and were analyzed according to NIOSH method 2549. These samples provided both a qualitative and a semi-quantitative analysis of volatile organic compounds in the work environment.

Area real-time dust concentrations were monitored in the powder production room on one day using the Model PDR-1000An/1200 Personal DataRams® (PDR) (Thermo Electron Corporation, Franklin, MA). These monitors were calibrated at the factory using SAE Fine (ISO fine) powder with a mass median aerodynamic particle diameter of 2-3 um and a bulk density of 2.6-2.65 g/cm^3. Each monitor was set to log dust concentrations every minute throughout the sampling period.

July Site Visit

In July, area samples were collected in various sampling locations in the plant, including the powder production area, liquid production area, pre-production corridor, spray dry room and distribution warehouse (Figure 2). Two-hour TWA area air samples were collected over two consecutive days for ketones (diacetyl and acetoin) and aldehydes (acetaldehyde, benzaldehyde, isovaldehyde, 2-furaldehyde, propionaldehyde). All ketone (diacetyl/acetoin) samples were collected over approximately two hours at a flow rate of 0.05 LPM using a modified OSHA Method PV2118. (Since select OSHA results from the November site visits exhibited breakthrough of the front tube due to extended sampling volumes, the volumes were reduced in July.) Aldehyde samples were also run for two hours at a flowrate of 0.2 liter per minute and were analyzed according to EPA TO-11. Additional details on the industrial hygiene sampling methods used during this survey are provided in Table 1.

After the November site visit was complete, a laboratory investigation indicated that the NIOSH method for diacetyl was affected by relative humidity, resulting in an underestimation of true concentrations. A NIOSH project is currently underway and chamber studies of generated atmospheres are planned to investigate the extent of this phenomenon and determine at what relative humidity levels it occurs.

Statistical Analyses

Laboratory reports provided sample results in micrograms (µg) of analyte per sample. Analytical results were converted to an airborne concentration by dividing by the air volume associated with the sample (mg/m^3), then

converting to parts per million (ppm) by volume standard temperature and pressure using the gram molecular weight of the analyte at standard temperature and pressure. All calculations to determine airborne concentrations, and provide descriptive statistics were conducted using SAS (SAS 9.1.3, SAS Institute, Cary, NC). Sampling results that were below the limit of detection for the sampling methods used were assigned a value of one-half of the airborne concentration limit of detection (LOD) for statistical analyses [6].

Applicable Occupational Exposure Limits (OELs)

In evaluating the hazards posed by workplace exposures, NIOSH investigators use both mandatory (legally enforceable) and recommended occupational exposure limits (OELs) for chemical, physical, and biological agents as a guide for making recommendations. OELs have been developed by Federal agencies and safety and health organizations to prevent the occurrence of adverse health effects from workplace exposures. Generally, OELs suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. However, not all workers will be protected from adverse health effects even if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the exposure limit. Also, some substances can be absorbed by direct contact with the skin and mucous membranes in addition to being inhaled, thus contributing to the overall exposure.

Most OELs are expressed as a time-weighted average (TWA) exposure. A TWA refers to the average exposure during a normal 8- to 10-hour workday. Some chemical substances and physical agents have recommended short-term exposure limits (STEL) or ceiling values where there are health effects from higher exposures over the short-term. Unless otherwise noted, the STEL is a 15-minute TWA exposure that should not be exceeded at any time during a workday, and the ceiling limit is an exposure that should not be exceeded at any time.

In the U.S., OELs have been established by Federal agencies, professional organizations, state and local

governments, and other entities. Some OELs are legally enforceable limits; others are recommendations. The U.S. Department of Labor OSHA PELs [29 CFR 1910 (general industry); 29 CFR 1926 (construction industry); and 29 CFR 1917 (maritime industry)] are legal limits that are enforceable in workplaces covered under the Occupational Safety and Health Act. NIOSH recommended exposure limits (RELs) are recommendations that are made based on a critical review of the scientific and technical information available on the given hazard and the adequacy of methods to identify and control the hazards. NIOSH RELs can be found in the *NIOSH Pocket Guide to Chemical Hazards[7]*. NIOSH also recommends preventive measures (e.g., engineering controls, safe work practices, personal protective equipment, and environmental and medical monitoring) to minimize the risk of exposure and adverse health effects from these hazards. Other OELs that are commonly used and cited in the U.S. include the threshold limit values (TLVs)® recommended by the American Conference of Governmental Industrial Hygienists (ACGIH)®, a professional organization[8] and the workplace environmental exposure levels (WEELs) recommended by the American Industrial Hygiene Association, another professional organization. ACGIH TLVs are considered voluntary guidelines for use by industrial hygienists and others trained in this discipline "to assist in the control of health hazards." WEELs have been established for some chemicals "when no other legal or authoritative limits exist"[9].

Employers should understand that not all hazardous chemicals have specific OSHA PELs and for some agents the legally enforceable and recommended limits may not reflect current health-based information. However, an employer is still required by OSHA to protect their employees from hazards even in the absence of a specific OSHA PEL. OSHA requires an employer to furnish employees a place of employment that is free from recognized hazards that are causing or are likely to cause death or serious physical harm [Occupational Safety and Health Act of 1970, Public Law 91–596, sec. 5(a)(1)]. Thus, NIOSH investigators encourage employers to make use of other OELs when making risk assessment and risk management decisions to best protect the health of their employees. NIOSH investigators also encourage the use of the traditional hierarchy of controls approach to eliminating or minimizing identified workplace hazards. This includes, in preferential order, the use of: (1) substitution or elimination of the hazardous agent, (2) engineering controls (e.g., local exhaust ventilation, process enclosure, dilution ventilation) (3) administrative controls (e.g., limiting time of exposure, employee training, work practice changes, medical surveillance), and (4) personal protective equipment (e.g., respiratory protection, gloves, eye protection, hearing protection). Table 2 contains a listing of all substances sampled during the July

and November site visits, and provides applicable OELs, where available.

Results

Descriptive statistics for the 8-hr time weighted average samples, by work area, and task based samples from the November site visits are presented in Table 3, Table 4 and Table 5, respectively. Overall two hour samples, by work area from the July site visits are presented in Tables 6 and 7. Task based samples from the July site visit are presented in Table 8.

Outdoor air temperatures ranged from 56°F to 87°F during the November site visit (no indoor air temperatures were collected). Indoor air temperatures in the facility ranged from 71 °F to 90 °F during the July site visit. Relative humidity in the powder production, liquid production, pre-production corridor, distribution warehouse and spray drying area during the July survey ranged from 28% to 78%, 33% to 63%, 35% to 55%, 28% to 53%, 23% to 65%, respectively during the two days of sampling.

Ketones (Diacetyl and Acetoin)

A total of 39 personal and area diacetyl/acetoin 8-hr time weighted samples were collected using NIOSH method 2557/2558 and fourteen area 8-hr time weighted average samples were collected using modified OSHA method PV2118 during the November site visit (Tables 3 and Table 4). The distributions of diacetyl concentrations were skewed to the right; therefore, the natural logarithm of the sample concentration was used in all statistical analyses. Diacetyl area samples and personal samples collected on the same day in the same production area were not significantly different than one another (p-value = 0.384). Accordingly both personal and area samples are presented together in Table 3 and Table 4. A total of 30 2-hr TWA samples and 10 task-based samples were collected for diacetyl during the July site visit, all using the modified OSHA method (Tables 6-8).

As stated earlier, a recent laboratory investigation revealed that the NIOSH method #2557 for diacetyl is influenced by relative humidity concentrations. Although diacetyl samples analyzed using the NIOSH method have been presented, it should be noted that these measurements are likely underestimates of true concentrations. Therefore, we have presented these results solely for comparison to previous investigations.

During both the November and July site visits, area diacetyl samples were collected using a modified OSHA method for diacetyl (200 mg/400 mg silica gel media). Select OSHA modified method results from the November site visits exhibited breakthrough of the front tube due to extended sampling volumes. Sample volumes were significantly reduced for the July site visits. Based on the initial laboratory study, it is believed that samples analyzed with the modified OSHA analytical method provide more accurate results than samples analyzed with the NIOSH method.

In an analysis limited to samples analyzed according to the modified OSHA method, average area diacetyl concentrations were highest in the liquid production room (Arithmetic Mean(AM): 0.46 ppm, n= 3) followed by the powder production room (AM: 0.34 ppm, n=3) and the pre-production corridor (AM:0.21ppm, n=2) during the November site visit.

During the July site visit (Tables 6 and 7), two-hour time weighted average diacetyl concentrations were again higher in the liquid production room (AM: 0.529ppm) compared to the powder production room (AM: 0.483 ppm). The highest diacetyl two-hour time weighted average (6.33 ppm) measured in the facility was in the spray drying room when spray drying was in operation in the early morning hours of July 11, 2007. The diacetyl concentration in the preproduction corridor was also highest during the early morning hours when spray drying was in operation. Measurable diacetyl concentrations in the distribution warehouse also occurred during the late morning and early afternoon hours of July 12, 2007.

Task Based Samples

All task-based sample results are shown in Tables 5 and 8. Diacetyl exposures varied considerably during the site visits depending upon production area, batch formula, worker task and work practices. During the November site visit, a worker was observed pouring diacetyl from a 55 gallon drum into multiple 5 gallon containers in the pre-production corridor. During the operation, the worker wore a full-face respirator and a task-based concentration of 11 ppm was observed. Eight-hour TWA area concentrations in the pre-production corridor were also notably higher on this day.

During the July site visit, several task based samples were collected on a variety of flavor formulations (Table 8). Sifting and packaging powder formulations resulted in the highest diacetyl concentrations observed. The highest task-based diacetyl sample (17.4 ppm) was observed over an eight minute time period while a worker scooped butter flavored powder from a large metal container and packaged it into smaller containers. Diacetyl comprised less than 2% of the total butter flavored powder formulation. The worker was wearing a respirator during this process. This task was performed inside one of the newly installed booth-type kettle ventilation hoods in the liquid compounding room. A 10 minute task-based concentration of 10 ppm diacetyl was measured while an employee re-packaged butter flavored powder from larger storage bin into smaller containers. The employee wore a respirator while he completed this procedure inside a ventilated booth-type hood. A task-based sample concentration of 9.32 ppm was also measured over approximately 1 hour when an employee (wearing respiratory protection) scooped butter flavored powder into a manual sifter. The worker reached deeply into the metal grinder vat to successfully remove all butter flavored powder placing his breathing zone into the contaminated area. Also, when an employee (wearing respiratory protection) packaged dairy flavored powder into smaller containers, a task-based sample concentration of 4.75 ppm was observed over a thirty-three minute sample period. Diacetyl comprised less than 1% of the total dairy flavored powder formulation.

Acetoin

In November, acetoin concentrations were highest in the liquid production room (AM = 0.15 ppm, n=17). In July, the average acetoin concentrations were highest in the spray dryer operation room, with all measurements lower than 1 ppm. Acetoin was always observed in lower concentrations than diacetyl during the task-based samples. The highest task-based acetoin sample concentration in the liquid compounding room was measured during the mixing of a butter flavor during the November site visit (1.05 ppm). The highest task-based acetoin sample concentration in the powder compounding room was measured during the packaging of a butter flavor during the July site visit (2.78 ppm).

Thermal Desorption Samples

One hundred and ninety-one contaminants were identified on the thermal desorption tubes collected at this facility. To interpret the response from the thermal tube sample analysis, these responses were categorized (using

height of peak and area under peak) in each sample as 1) non-detected, 2) trace quantity present, 3) minor component of mixture, 4) significant quantity present, and 5) major component of mixture. The top 100 contaminants identified during each site visit are presented in Table 9, in order of decreasing magnitude.

The compounds observed in the liquid, powder and other areas did not appear appreciably different during each site visit and were found in relatively high abundance. Overall, the thermal desorption results from the July visit suggest better environmental controls in the workplace, because concentrations were lower even though the magnitude of contaminants was similar.

Acids

During the November site visit, 8-hr TWA acetic, butyric and propionic acid samples were collected on employees working in production areas and within area baskets samples throughout the facility. All samples were below occupational exposure limits for these compounds (Table 2). Eight-hour TWA personal samples collected in the powder production area were the highest acid samples observed in the facility (Table 4). Acid concentrations were observed while a worker poured and mixed ingredients for a butter flavor batch during task-based sampling (Table 5, acetic acid: 1.93 ppm, butyric acid: 1.20 ppm, propionic acid: 1.43 ppm).

Phosphoric Acid

A total of 14 8-hr TWA phosphoric acid samples were collected in all area baskets during the November site visits. All samples were below the analytical limit of detection and all occupational exposure limits for phosphoric acid(Table 2).

Dust Concentrations

Respirable and total dust concentrations were measured on employees working in the powder production room, but were at concentrations below established occupational exposure limits (Table 2). Real-time dust concentrations were continuously logged for one-minute periods during powdered flavor production over one day during the November site visit. The dust concentrations were highly variable as exhibited on the right axis illustrated in Figure 5. One-minute average dust concentrations peaked as high as 1.6 mg/m^3. The dust

concentrations are shown along with the VOC concentrations in Figure 5. During some time-periods, increasing dust concentrations corresponded with rising VOC concentrations. This suggests that some dust formulations also contained high quantities of VOC content. There were also examples where VOC concentrations rose, but dust concentrations did not increase. This scenario could be reflective of a liquid pour preceding the initiation of blending.

Real-time VOC samples

Real-time PIDs measured room area VOC concentrations during the November site visit (see Figures 5-8). These detectors respond to a broad range of volatile compounds and do not provide concentrations specific to any particular compound. However, they do provide insight into the variation of VOCs throughout the workday. Figures 5-8 illustrate the instantaneous concentrations of VOCs by production area presented as ppm isobutylene equivalent. Concentrations were highly variable in all work areas and likely reflect the diversity of batches and their ingredients. The most variable and highest peak concentrations throughout the three sampled days were measured in the liquid production room. The pre-production corridor also showed increasing VOC concentrations throughout the workday. Although real-time concentrations in all production areas were reviewed, no apparent trends were observed. It did not appear that sudden peaks in the liquid or powder rooms resulted in corresponding increases in VOC levels in the pre-production corridor (reflecting migration) during these sampling periods.

Respiratory Protection Program

A respiratory protection program was operational in the facility. The program's quality evolved throughout the several visits at the facility. During the November site visits, production employees generally wore respirators at all times in the liquid and powder production area. In November, respirator use included both half-face cartridge respirators and full-face cartridge respirators with organic and P100 cartridges and employees had been qualitatively fit tested. During conversations with employees, they seemed uncertain how often to change respirator cartridges. Respirators were stored in the production areas. NIOSH provided specific guidance to both management and employees on respirator use, and storage. Cal/OSHA representatives were also in communication with the company regarding respiratory protection following the November site visit.

During the July site visit, the respiratory protection program was notably improved. Respirators had a specific storage location outside the powder production area. Management indicated that cartridges were changed after approximately eight hours and had stored used cartridges to confirm this schedule. New cartridges were visibly available and employee use seemed more consistent. Management reported that production workers had been quantitatively fit-tested and trained. Observations suggested respirators were worn more frequently and appropriately by production workers. There were still some individuals (quality control officials, management officials, etc) who entered the production areas without respiratory protection periodically.

Discussion

The July task-based diacetyl samples clearly demonstrate that packaging product, whether liquid or powder, was an activity associated with the highest exposures. Tasks such as scooping powders and manually sifting them into packages as well as the filling of liquid containers were identified as high exposure procedures. These activities should always be conducted with respiratory protection and engineering controls.

The November task-based samples revealed the highest exposure when an employee redistributed pure diacetyl from a 55 gallon drum into 5 gallon containers in the pre-production corridor. When performing this task, employees should continue to wear appropriate respiratory protection and storing diacetyl in cold storage prior to use. (Cold storage can reduce volatility.) Redistributing diacetyl should be completed in the liquid production area within a ventilated booth to reduce worker exposure and migration of diacetyl to other areas of the facility.

During both the November and July site visits, diacetyl concentrations were higher in the liquid production room compared to the powder production room. Although engineering controls were installed in the liquid production room prior to the July visit, diacetyl concentrations in the liquid production room were higher during this survey than during the November visit. This may be due to the fact that batch ingredients vary dramatically, and that the formulations completed in July simply contained more diacetyl than those completed in November. Additionally, samples collected in November were collected over an eight-hour average versus a two hour averages in July. Short duration samples will more accurately reflect peak exposures compared to samples integrated over a longer time period.

However, there may have been another reason for the higher levels of diacetyl measured in the liquid compounding room. During the collection of short term diacetyl samples, a worker was packaging butter flavored powder inside one of the ventilated booths located in the liquid production room. A personal sample collected on the worker and area samples throughout the liquid production room showed high concentrations of diacetyl during this procedure. After reviewing the data and pictures taken with the facility, an alternate hypothesis was developed as described below.

NIOSH investigators found the engineering controls installed in the liquid production room exhibited good capture when testing the emission of contaminants from a mixing tank within the ventilated booths. However, it is possible that the exhaust fan was not operating during the powder packaging. The exhaust fans on these booths are activated when an object (such as a tank) comes within an inch or so of a proximity switch mounted on the back of the booth. This feature decreases electricity usage by shutting down the fans while the booths are not in use. If the powder packaging apparatus did not effectively engage this switch, the fan would not have come on and the contaminant would not have been captured (see Figure 9). Therefore, it is possible that the dust and vapors emitted during this process were not adequately captured and contributed to the personal and area diacetyl concentrations measured during this operation. Unfortunately, the fan operation cannot be verified by sound due to the high background noise levels from the adjacent fan/hood systems. A visual indicator such as a fan operational light should be connected to the fan circuit and mounted on the booth to indicate to the employee that the fan is operational. Secondly, boxes with packaged material were moved outside the booth after packaging. This would allow compounds to be emitted in the liquid production room before being closed entirely.

The implementation of ventilated booths in the liquid production room provides a good engineering control which can be used for a variety of tasks including large tank ventilation. Other operations such as powder packaging and pouring/redistribution of diacetyl and other high priority chemicals can be more safely completed in these booths once the workers have been properly trained on use and new operation safeguards such as the one mentioned above are implemented. Important topics for training include verifying fan operation status, making sure that the worker knows to always position the contaminant source between him and the exhaust hood, and closing packaged boxes completely before removing them from the ventilated booths.

The thermal desorption results provide evidence that the benchtop ventilation stations were working as designed. Although similar compounds were observed and diacetyl was higher in the rank order, the relative abundance was lower for most contaminants overall.

Recommendations

1. Engineering Controls:

1) Re-design the proximity switch to insure ventilation systems are on when employees operate the engineering controls in liquid production room. Add a fan operational status light to each hood to provide an indication to the worker that the booth is functional.

2) Install appropriate engineering controls in the powder production and spray dryer rooms. These controls should address the potential sources of exposure documented in the letter from NIOSH, dated February 7, 2007.

3) Train employees on how to use the engineering control hoods properly; provide guidance on proper usage and good work practices such as avoiding filling up the bench-top hoods with non-essential items.

4) Engineering controls should be evaluated periodically to insure proper operation in accordance with engineering control guidance[2]. System performance checks should be added to a preventative maintenance routine.

2. Work Practices:

1) Avoid pouring, measuring, or open transfer of flavoring chemicals or ingredients in the pre-production corridor. These operations should be completed in a ventilated booth using appropriate work practices.

2) Continue to improve work practices for any flavoring containing diacetyl or other priority chemicals to fully utilize the engineering controls employed in the liquid production room.

3) Avoid removing containers packaged with flavoring containing diacetyl or other priority chemicals product from the ventilated booth until they are closed entirely.

4) Keep containers of flavoring chemicals and/or ingredients sealed when not in use.

5) Utilize cold water washes and cold storage of chemicals when feasible.

6) Clean spills promptly to minimize emissions of chemical vapors.

7) Add diacetyl and other high priority chemicals into a batch last, when possible, to minimize volatilization and exposure potential/duration.

8) Wear personal protection equipment including respirators and skin protection when cleaning up spills or washing empty containers of flavoring chemicals or ingredients.

3. Respiratory Protection:

1) Continue to require mandatory respirator use for all production workers, distribution warehouse workers, and other workers who enter the production area.

2) Re-locate the respirator storage and cartridge re-load area from outside the powder production room/ pre-production corridor to an alternate area with lower concentrations of flavoring chemicals.

3) Restrict access to the pre-production corridor, liquid production room, powder production room, spray-drying areas, and distribution warehouse to only employees that need to be there, have been properly quantitatively fit-tested, and are wearing appropriate respiratory protection.

4) In accordance with Cal/OSHA direction, "full-facepiece respirators fit-tested with an approved quantitative method are needed as minimal protection for employees exposed to flavoring ingredients in

this industry. All employees entering flavor formulation areas or unprotected areas (e.g., packaging areas) must wear respirators" (FISHEP correspondence from K. Howard dated Oct. 13, 2006). Specifically, a NIOSH-certified full-face respirator with organic vapor/acid gas cartridges and particulate filters is the minimum level of respiratory protection recommended in conjunction with a fully operational respiratory protection program. Information about respirators is available at the NIOSH website (http://www.cdc.gov/niosh/npptl/topics/respirators/ and http://www.cdc.gov/niosh/docs/2005-100/default.html). Details on the OSHA Respiratory Protection Standard are available on the OSHA website (http://www.osha.gov/).

4. Eye Protection:

1) Enforce use of eye protection in the laboratory and quality controls areas. Full face respirators provide eye protection in the production areas.

5. Skin Protection:

1) Wear long sleeve shirts, pants, and chemical-resistant gloves in the production areas.

6. Medical Surveillance:

1) Follow medical surveillance guidance and recommendations as specified in communication related to health hazard request 2007-033 [10, 11]

7. Hazard Communication:

1) Ensure workers understand the hazards associated with flavoring chemicals and how to protect themselves. OSHA's Hazard Communication Standard, also known as the "Right to Know Law" (29 CFR 1910.1200) requires that employees are informed and trained of potential work hazards and associated safe practices, procedures, and protective measures.

The California Code of Regulations, Title 8, Section 5194, Hazard Communication, is available at http://www.dir.ca.gov/title8/5194b.html.

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I-C: Technical Assistance Report—Evaluating Occupational Exposures and Work Practices at Gold Coast Ingredients, Inc. Commerce, CA (January 2008)

Table 1. Sampling and Analysis Table

Type	Analysis Method	Media	Analytes	Objective	Flowrate	Sample Duration
November Site Visit						
Aldehydes	EPA TO-11	Dinitrophenylhydrazine (DNPH) treated silica (150/300 mg)	2-Furaldehyde Acetaldehyde, Benzaldehyde, Isovaleraldehyde Propionaldehyde	8-hr TWA	100cc/min	300 minutes
Aldehydes	EPA TO-11	Dinitrophenylhydrazine (DNPH) treated silica	2-Furaldehyde Acetaldehyde, Benzaldehyde, Isovaleraldehyde Propionaldehyde	Task Based Sample	200cc/min	15 minutes -1 hour
Acids	Draft NMAM 5048	Silica Gel (200mg/400mg)	Acetic Acid Butyric Acid Propionic Acid	8-hr TWA	200cc/min	480 minutes
Acids	NMAM 7903	Silica Gel (200mg/400mg)	Phosphoric Acid	8-hr TWA	200cc/min	480 minutes
Acids	Draft NMAM 5048	Silica Gel (200mg/400mg)	Acetic Acid Butyric Acid Propionic Acid	Task Based Sample	200cc/min	15 minutes -1 hour
Ketones	OSHA PV2118 (modified method)	Silica Gel (200mg/400mg)	Diacetyl	8-hr TWA	100cc/min	480 minutes
Ketones	NIOSH 2557/2558	CMS (75mg/150mg)	Diacetyl/Acetoin	8-hr TWA	100cc/min	480 minutes
Ketones	NMAM 2557/2558	CMS (75mg/150mg)	Diacetyl/Acetoin	Task Based Sample	200cc/min	15 minutes -1 hour

Table 1 cont.

Type	Analysis Method	Media	Analytes	Objective	Flowrate	Sample Duration
November Site Visit (continued from previous page)						
VOCs	NMAM 2549	Thermal Desorption Tubes	Varied based on Thermal tubes	2-hr TWA	100cc/min	60 minutes
Respirable dust	NMAM 0600	37 mm PVC filter, BGI cyclone	Respirable dust	8-hr TWA	4.2L/min	240 minutes
Total Dust	NMAM 0500	37 mm PVC filter	Total dust	8-hr TWA	1.5L/min	240 minutes
July Site Visit						
Aldehydes	EPA TO-11	Dinitrophenylhydrazine (DNPH) treated silica	2-Furaldehyde Acetaldehyde, Benzaldehyde, Isovaleraldehyde Propionaldehyde	2-hr TWA	200cc/min	120 minutes
Aldehydes	EPA TO-11	Dinitrophenylhydrazine (DNPH) treated silica	2-Furaldehyde Acetaldehyde, Benzaldehyde, Isovaleraldehyde Propionaldehyde	Task Based Sample	200cc/min	15 minutes -1 hour
Ketones	OSHA PV2118 (modified method)	Silica Gel (200mg/400mg)	Diacetyl/Acetoin	2-hr TWA	50cc/min	120 minutes
Ketones	OSHA PV2118 (modified method)	Silica Gel (200mg/400mg)	Diacetyl/Acetoin	Task Based Sample	50cc/min	15 minutes -1 hour

NOTES:
NMAM: NIOSH Manual of Analytical Methods

Table 2. Relevant Occupational Exposure Limits

	Occupational Exposure Limits								
	NIOSH REL			OSHA PEL			ACGIH TLV		
Chemical Name	TWA	STEL	Ceiling	TWA	STEL	Ceiling	TWA	STEL	Ceiling
2-Furaldehyde	NE	NE	NE	5 ppm [A]	NE	NE	2 ppm [A,B]	NE	NE
Acetaldehyde	NE [C]	NE [C]	NE [C]	200 ppm	NE	NE	NE	NE	25 ppm [B]
Acetic acid	10ppm	15ppm	NE	10ppm	NE	NE	10ppm	15ppm	NE
Acetoin	NE	NE	NE	NE	NE	NE	NE	NE	NE
Benzaldehyde	NE	NE	NE	NE	NE	NE	NE	NE	NE
Butyric acid	NE	NE	NE	NE	NE	NE	NE	NE	NE
Diacetyl	NE	NE	NE	NE	NE	NE	NE	NE	NE
Isovaleraldehyde	NE	NE	NE	NE	NE	NE	NE	NE	NE
Phosphoric acid	1 mg/m^3	3 mg/m^3	NE	1 mg/m^3	NE	NE	1 mg/m^3	3 mg/m^3	NE
Propionaldehyde [D]	NE	NE	NE	NE	NE	NE	20 ppm	NE	NE
Propionic acid	10 ppm	15 ppm	NE	NE	NE	NE	10 ppm	NE	NE
Respirable particulate	NE	NE	NE	5 mg/m^3	NE	NE	3 mg/m^3	NE	NE
Total particulate	NE	NE	NE	15 mg/m^3	NE	NE	10 mg/m^3 [E]	NE	NE
Total volatile organic compounds	NE	NE	NE	NE	NE	NE	NE	NE	NE

NOTES:

[A] - Skin notation
[B] - ACGIH confirmed animal carcinogen with unknown relevance to humans [8]
[C] - NIOSH potential occupational carcinogen - (See Appendix A and C in the NIOSH Pocket Guide to Chemical Hazards [7]
[D] - Testing has not been completed to determine the carcinogenicity of acrolein, butyraldehyde (CAS#: 123-72-8), crotonaldehyde, glutaraldehyde, glyoxal (CAS#: 107-22-2), paraformaldehyde (CAS#: 30525-89-4), propiolaldehyde (CAS#: 624-67-9), propionaldehyde (CAS#: 123-38-6), and n-valeraldehyde, nine related low-molecular-weight-aldehydes. However, the limited studies to date indicate that these substances have chemical reactivity and mutagenicity similar to acetaldehyde and malonaldehyde. Therefore, NIOSH recommends that careful consideration should be given to reducing exposures to these nine related aldehydes. [12]
[E] - Inhalable fraction [8]
NE - Not established

Table 3 November Site Visit Eight-hour Time Weighted Average Descriptive Statistics

Analyte	units	n	AM	SD	GM	GSD	Min	Max
2-Furaldehyde	ppm	39	0.01	0.01	0.01	3.00	0.0002	0.06
Acetaldehyde	ppm	39	0.09	0.11	0.06	2.49	0.001	0.68
Acetic Acid	ppm	38	0.44	0.98	0.13	4.47	0.018	4.80
Acetoin	ppm	39	0.12	0.10	0.08	2.84	0.005	0.47
Benzaldehyde	ppm	39	0.05	0.03	0.04	2.43	0.001	0.11
Butyric Acid	ppm	38	0.07	0.07	0.03	3.59	0.007	0.30
Diacetyl (MOSHA)[1]	ppm	14	0.23	0.29	0.10	4.21	0.019	1.00
Diacetyl (NIOSH)[2]	ppm	39	0.19	0.35	0.04	6.64	0.001	1.71
Isovaleraldehyde	ppm	39	0.03	0.05	0.01	4.32	0.001	0.30
Respirable Particulate	mg/m^3	24	0.17	0.18	0.11	2.55	0.032	0.73
Propionaldehyde	ppm	39	0.03	0.02	0.02	2.32	0.002	0.08
Propionic Acid	ppm	38	0.08	0.09	0.03	5.95	0.003	0.35
Total Particulate	mg/m^3	15	0.47	0.49	0.25	3.42	0.034	1.47

NOTES:

n: Number of samples

AM: Arithmetic Mean

SD: Standard Deviation

GM: Geometric Mean

GSD: Geometric Standard Deviation

Max: Maximum

Min: Minimum

[1] **Collected/analyzed using modified OSHA method PV2118 for diacetyl**
[2] **Collected/analyzed using NIOSH method 2557 for diacetyl, which likely underestimates true exposure.**

Table 4. November Site Visit Descriptive Statistics
Eight-hour Time Weighted Averages, Area and Personal Samples by Work Area

Analyte	units	n	AM	SD	GM	GSD	Min	Max
Powder Production								
2-Furaldehyde	ppm	12	0.01	0.01	0.004	4.04	0.0002	0.04
Acetaldehyde	ppm	12	0.14	0.19	0.08	2.64	0.026	0.68
Acetic Acid	ppm	11	0.75	1.45	0.20	5.08	0.018	4.80
Acetoin	ppm	12	0.09	0.58	0.08	1.79	0.035	0.19
Benzaldehyde	ppm	12	0.03	0.01	0.03	1.50	0.012	0.07
Butyric Acid	ppm	11	0.10	0.09	0.05	3.88	0.007	0.30
Diacetyl (MOSHA)[1]	ppm	3	0.34	0.28	0.17	6.38	0.020	0.52
Diacetyl (NIOSH)[2]	ppm	12	0.35	0.51	0.09	8.29	0.005	1.71
Isovaleraldehyde	ppm	12	0.01	0.01	0.01	2.40	0.003	0.04
Respirable Particulate	mg/m^3	12	0.26	0.22	0.19	2.40	0.038	0.73
Propionaldehyde	ppm	12	0.03	0.02	0.02	2.63	0.003	0.06
Propionic Acid	ppm	11	0.12	0.12	0.05	6.37	0.003	0.35
Total Particulate	mg/m^3	3	1.28	0.21	1.26	1.18	1.058	1.47
Liquid Production Area								
2-Furaldehyde	ppm	17	0.01	0.01	0.01	1.89	0.002	0.03
Acetaldehyde	ppm	17	0.07	0.03	0.06	2.71	0.001	0.14
Acetic Acid	ppm	17	0.44	0.86	0.15	4.45	0.018	3.60
Acetoin	ppm	17	0.15	0.13	0.09	3.54	0.005	0.47
Benzaldehyde	ppm	17	0.07	0.02	0.07	1.46	0.035	0.11
Butyric Acid	ppm	17	0.08	0.06	0.05	2.84	0.008	0.21
Diacetyl (MOSHA)[1]	ppm	3	0.46	0.05	0.20	7.41	0.021	1.00
Diacetyl (NIOSH)[2]	ppm	17	0.14	0.27	0.03	6.64	0.001	1.05
Isovaleraldehyde	ppm	17	0.05	0.07	0.02	3.74	0.003	0.30
Respirable Particulate	mg/m^3	3	0.14	0.84	0.11	2.32	0.043	0.18

Table 4. November Site Visit Descriptive Statistics (cont.)
Eight-hour Time Weighted Averages, Area and Personal Samples by Work Area- *Continued*

Analyte	units	n	AM	SD	GM	GSD	Min	Max
Liquid Production Area (continued from previous page)								
Propionaldehyde	ppm	17	0.02	0.01	0.02	2.16	0.002	0.77
Propionic Acid	ppm	17	0.09	0.08	0.05	4.08	0.003	0.26
Total Particulate	mg/m^3	3	0.61	0.35	0.52	2.11	0.224	0.91
Quality Assurance/ Quality Control								
2-Furaldehyde	ppm	3	0.01	0.01	0.01	2.35	0.003	0.02
Acetaldehyde	ppm	3	0.06	0.04	0.05	2.08	0.024	0.10
Acetic Acid	ppm	3	0.09	0.08	0.07	2.94	0.020	0.17
Acetoin	ppm	3	0.07	0.05	0.05	2.98	0.015	0.12
Benzaldehyde	ppm	3	0.06	0.03	0.05	1.68	0.031	0.09
Butyric Acid	ppm	3	0.008	0.0003	0.008	1.04	0.008	0.008
Diacetyl (MOSHA)[1]	ppm	3	0.07	0.06	0.05	2.29	0.028	0.13
Diacetyl (NIOSH)[2]	ppm	3	0.02	0.01	0.02	1.81	0.012	0.04
Isovaleraldehyde	ppm	3	0.003	0.002	0.002	2.05	0.001	0.005
Respirable Particulate	mg/m^3	3	0.05	0.10	0.05	1.11	0.043	0.05
Propionaldehyde	ppm	3	0.05	0.01	0.04	1.45	0.028	0.05
Propionic Acid	ppm	3	0.003	0.0001	0.003	1.04	0.003	0.003
Total Particulate	mg/m^3	3	0.08	0.06	0.07	2.08	0.034	0.14
Pre-Production Corridor								
2-Furaldehyde	ppm	3	0.02	0.03	0.01	3.87	0.005	0.05
Acetaldehyde	ppm	3	0.07	0.03	0.07	1.49	0.047	0.10
Acetic Acid	ppm	3	0.08	0.06	0.06	2.67	0.02	0.14
Acetoin	ppm	3	0.07	0.06	0.04	5.22	0.006	0.11
Benzaldehyde	ppm	3	0.03	0.01	0.03	1.26	0.023	0.04
Butyric Acid	ppm	3	0.008	0.0004	0.008	1.05	0.007	0.008

Table 4. November Site Visit Descriptive Statistics (cont.)
Eight-hour Time Weighted Averages, Area and Personal Samples by Work Area- *Continued*

Analyte	units	n	AM	SD	GM	GSD	Min	Max
Pre-Production Corridor								
Diacetyl (MOSHA)[1]	ppm	2	0.21	0.20	0.16	3.20	0.068	0.35
Diacetyl (NIOSH)[2]	ppm	3	0.07	0.09	0.04	3.74	0.013	0.17
Isovaleraldehyde	ppm	3	0.002	0.001	0.001	2.25	0.001	0.003
Respirable Particulate	mg/m^3	3	0.11	0.08	0.09	2.46	0.034	0.20
Propionaldehyde	ppm	3	0.02	0.02	0.02	2.44	0.007	0.04
Propionic Acid	ppm	3	0.003	0.0002	0.003	1.05	0.003	0.003
Total Particulate	mg/m^3	3	0.26	0.15	0.22	2.13	0.095	0.39
Office Administration								
2-Furaldehyde	ppm	1	0.02					
Acetaldehyde	ppm	1	0.04					
Acetic Acid	ppm	1	0.02					
Acetoin	ppm	1	0.04					
Benzaldehyde	ppm	1	0.01					
Butyric Acid	ppm	1	0.007					
Diacetyl (MOSHA)[1]	ppm	1	0.02					
Diacetyl (NIOSH)[2]	ppm	1	0.003					
Isovaleraldehyde	ppm	1	0.01					
Respirable Particulate	mg/m^3	1	0.05					
Propionaldehyde	ppm	1	0.05					
Propionic Acid	ppm	1	0.003					

NOTES:
n: Number of samples; AM: Arithmetic Mean; SD: Standard Deviation; GM: Geometric Mean; GSD: Geometric Standard Deviation; Max: Maximum; Min: Minimum
[1] Collected/analyzed using modified OSHA method PV2118 for diacetyl
[2] Collected/analyzed using NIOSH method 2557 for diacetyl, which likely underestimates true exposure.
Other: Per analyte, the total number of samples (n) in Table 4 may not equal the total number of samples (n) presented in Table 3. Some employees worked in multiple production areas within a day and could not be listed within one particular production area.

Table 5. November Site Visit Task Based Personal Sampling

Production Area	Task completed	Duration (mins)	Analyte	(ppm)	Flavor
Liquid	Pouring and Mixing Ingredients	53	2-Furaldehyde	0.01	Fruit Flavor
Liquid	Pouring and Mixing Ingredients	53	Acetaldehyde	0.19	Fruit Flavor
Liquid	Pouring and Mixing Ingredients	45	Acetoin	0.16	Butter Flavor
Liquid	Pouring and Mixing Ingredients	61	Acetoin	1.05	Butter Flavor
Liquid	Pouring and Mixing Ingredients	15	Acetoin	0.09	Butter Flavor
Liquid	Pouring and Mixing Ingredients	59	Acetoin	0.18	Carmel Flavor
Liquid	Pouring and Mixing Ingredients	55	Acetoin	0.50	Fruit Flavor
Powder	Small Pouring and Mixing Ingredients	15	Acetoin	0.18	Carmel Flavor
Powder	Pouring and Mixing Ingredients	26	Acetoin	0.05	Powder Mix
Pre-production Corridor	Pouring Diacetyl from 55 gallon drum to 5 gal drum	10	Acetoin	0.14	Diacetyl Transfer
Liquid	Pouring and Mixing Ingredients	45	Diacetyl(NIOSH)[1]	0.04	Butter Flavor
Liquid	Pouring and Mixing Ingredients	61	Diacetyl(NIOSH)[1]	0.08	Butter Flavor
Liquid	Pouring and Mixing Ingredients	15	Diacetyl(NIOSH)[1]	0.09	Butter Flavor
Liquid	Pouring and Mixing Ingredients	59	Diacetyl(NIOSH)[1]	0.02	Carmel Flavor
Liquid	Pouring and Mixing Ingredients	55	Diacetyl(NIOSH)[1]	0.03	Fruit Flavor

Table 5 cont.

Production Area	Task completed	Duration (mins)	Analyte	(ppm)	Flavor
Powder	Small Pouring and Mixing Ingredients	15	Diacetyl(NIOSH)[1]	1.58	Carmel Flavor
Powder	Pouring and Mixing Ingredients	26	Diacetyl(NIOSH)[1]	0.05	Powder Mix
Pre-production Corridor	Pouring Diacetyl from 55 gallon drum to 5 gal drum	10	Diacetyl(NIOSH)[1]	11.04	Diacetyl Transfer
Liquid	Pouring and Mixing Ingredients	53	Isovaleraldehyde	0.04	Fruit Flavor
Liquid	Pouring and Mixing Ingredients	53	Propionaldehyde	0.05	Fruit Flavor
Liquid	Pouring and Mixing Ingredients	61	Acetic Acid	1.93	Butter Flavor
Liquid	Pouring and Mixing Ingredients	61	Butryic Acid	1.20	Butter Flavor
Liquid	Pouring and Mixing Ingredients	61	Propionic Acid	1.43	Butter Flavor

NOTES:
[1] **Collected/analyzed using NIOSH method 2557 for diacetyl, which likely underestimates true exposure.**
ppm: parts per million

Table 6. July Site Visit Two-hour Time Weighted Average Descriptive Statistics, Area Samples

Analyte (ppm)	n	AM	SD	GM	GSD	min	max
2-Furaldehyde	30	0.009	0.009	0.005	3.59	0.001	0.04
Acetaldehyde	30	0.22	0.513	0.045	5.19	0.006	2.57
Acetoin [1]	30	0.115	0.083	0.096	1.77	0.048	0.37
Benzaldehyde	30	0.076	0.238	0.013	5.46	0.001	1.29
Diacetyl [1]	30	0.445	1.168	0.085	6.53	0.008	6.33
Isovaleraldehyde	30	0.076	0.149	0.011	7.49	0.001	0.43
Propionaldehyde	30	0.032	0.039	0.011	6.2	0.001	0.17

NOTES:

n: Number of samples

AM: Arithmetic Mean

SD: Standard Deviation

GM: Geometric Mean

GSD: Geometric Standard Deviation

Max: Maximum

Min: Minimum

[1] **Collected/analyzed using modified OSHA method PV2118 for diacetyl**

Table 7 July Site Visit Descriptive Statistics,
Two-hour Time Weighted Averages, Areas Samples by Work Area

Analyte (ppm)	n	AM	SD	GM	GSD	Min	Max
Distribution Warehouse							
Acetoin [1]	6	0.067	0.01	0.066	1.18	0.048	0.08
Diacetyl [1]	6	0.041	0.053	0.023	3.12	0.008	0.14
2-Furaldehyde	6	0.007	0.010	0.002	5.75	0.001	0.02
Acetaldehyde	6	0.014	0.007	0.013	1.56	0.008	0.03
Benzaldehyde	6	0.004	0.003	0.003	2.53	0.001	0.01
Isovaleraldehyde	6	0.002	0.002	0.001	2.48	0.001	0.01
Propionaldehyde	6	0.016	0.017	0.007	5.66	0.001	0.04
Liquid Production Area							
Acetoin [1]	6	0.07	0.009	0.07	1.137	0.058	0.09
Diacetyl [1]	6	0.529	0.297	0.467	1.712	0.26	1.04
2-Furaldehyde	6	0.007	0.004	0.006	1.67	0.004	0.01
Acetaldehyde	6	0.273	0.245	0.17	3.32	0.031	0.69
Benzaldehyde	6	0.295	0.498	0.09	5.49	0.016	1.29
Isovaleraldehyde	6	0.011	0.005	0.01	1.71	0.004	0.02
Propionaldehyde	6	0.031	0.027	0.02	5.65	0.001	0.06
Powder Production Area							
Acetoin [1]	6	0.163	0.082	0.144	1.78	0.07	0.26
Diacetyl [1]	6	0.483	0.572	0.288	2.97	0.10	1.58
2-Furaldehyde	6	0.008	0.007	0.004	3.76	0.001	0.02
Acetaldehyde	6	0.343	0.45	0.112	5.95	0.015	1.02
Benzaldehyde	6	0.034	0.055	0.017	2.98	0.007	0.15
Isovaleraldehyde	6	0.013	0.055	0.012	1.52	0.006	0.02
Propionaldehyde	6	0.080	0.056	0.061	2.48	0.012	0.17

Table 7 July Site Visit Descriptive Statistics, (cont.)
Two-hour Time Weighted Averages, Areas Samples by Work Area – continued

Analyte (ppm)	n	AM	SD	GM	GSD	Min	Max
Pre-Production Corridor							
Acetoin [1]	6	0.077	0.027	0.074	1.35	0.053	0.13
Diacetyl [1]	6	0.098	0.151	0.031	5.13	0.009	0.38
2-Furaldehyde	6	0.012	0.015	0.005	4.99	0.001	0.04
Acetaldehyde	6	0.029	0.018	0.024	2.16	0.006	0.05
Benzaldehyde	6	0.012	0.005	0.012	1.51	0.007	0.02
Isovaleraldehyde	6	0.006	0.004	0.004	3.36	0.001	0.01
Propionaldehyde	6	0.011	0.016	0.003	6.60	0.001	0.04
Spray Dryer Production							
Acetoin [1]	6	0.20	0.118	0.165	1.99	0.063	0.37
Diacetyl [1]	6	1.07	2.578	0.048	11.5	0.011	6.33
2-Furaldehyde	6	0.01	0.01	0.007	2.40	0.003	0.03
Acetaldehyde	6	0.44	1.042	0.032	8.74	0.008	2.57
Benzaldehyde	6	0.03	0.07	0.005	7.21	0.001	0.18
Isovaleraldehyde	6	0.35	0.131	0.309	1.88	0.086	0.43
Propionaldehyde	6	0.02	0.023	0.010	5.03	0.001	0.05

NOTES:

n: Number of samples

AM: Arithmetic Mean

SD: Standard Deviation

GM: Geometric Mean

GSD: Geometric Standard Deviation

Max: Maximum

Min: Minimum

[1] **Collected/analyzed using modified OSHA method PV2118 for diacetyl**

Table 8. July Site Visit Personal Task-Based Sampling Results

Area	Task Description	Duration (mins)	Analyte	Result (ppm)	Batch Flavor
Liquid	Benchtop Liquid Pouring	12	2-Furaldehyde	0.004	Nut Emulsion
Powder	Packaging powder product into boxes	33	2-Furaldehyde	0.04	Dairy flavored Powder
Liquid	Mixing into stand alone vessel	33	2-Furaldehyde	0.001	Tropical Fruit Flavor
Liquid	Liquid Pouring	12	Acetaldehyde	0.01	Nut Emulsion
Powder	Packaging powder product into boxes	33	Acetaldehyde	4.02	Dairy flavored Powder
Liquid	Mixing	33	Acetaldehyde	0.08	Tropical Fruit Flavor
Liquid	Benchtop Pouring	12	Acetoin	0.17	Nut Emulsion
Liquid	Scooping butter from metal bin into boxes; Worker leaned into bin remove all powder	8	Acetoin	0.59	Butter flavor.
Liquid	Benchtop mixing	35	Acetoin	0.24	Wine Flavor
Liquid	Worker prepares for task (setting up boxes, moving equip., etc). Worker scoops powder (one scoop at a time) over head into a mechanical sifter.	61	Acetoin	0.88	Butter flavored powder
Liquid	Cleaning grinder/sifter (used for butter powder) with hose	21	Acetoin	0.10	Butter flavored powder
Liquid	Pouring butter emulsion into 1-gallon bottles; cleans pan of butter blend to catch butter drippings.	33	Acetoin	0.06	Butter Emulsion
Powder	Packaging powder product into boxes	33	Acetoin	2.78	Dairy flavored powder
Liquid	Worker used exhaust hood to scoop out butter flavor powder into smaller packages.	10	Acetoin	0.72	Butter flavored powder

Table 8. July Site Visit Personal Task-Based Sampling Results- continued

Area	Task Description	Duration (mins)	Analyte	Result (ppm)	Batch Flavor
Powder	Benchtop liquid pour, Dumping substrate into mixer, Mixing, Packaging, pulling QC sample	17	Acetoin	0.12	Confectionary flavor
Small Spray Dryer	Operating small spray dryer	99	Acetoin	0.14	Dried fruit flavor
Liquid	Benchtop Liquid Pouring	12	Benzaldehyde	0.13	Nut emulsion
Powder	Packaging powder product into boxes	33	Benzaldehyde	0.06	Dairy flavored powder
Liquid	Mixing into stand alone vessel	33	Benzaldehyde	0.05	Tropical fruit flavor
Liquid	Benchtop Pouring	12	Diacetyl	0.27	Nut emulsion
Liquid	Scooping butter from metal bin into boxes; Worker leaned into bin remove all powder	8	Diacetyl	17.38	Butter flavor
Liquid	Benchtop mixing	35	Diacetyl	0.65	Wine flavor
Liquid	Worker prepares for task (setting up boxes, moving equip., etc). Worker scoops powder (one scoop at a time) over head into a mechanical sifter.	61	Diacetyl	9.32	Butter flavored powder
Liquid	Cleaning grinder/sifter (used for butter powder) with hose	21	Diacetyl	0.53	Butter flavored powder
Liquid	Pouring butter emulsion into 1-gallon bottles; cleans pan of butter blend to catch butter drippings.	33	Diacetyl	1.03	Butter emulsion
Powder	Packaging powder product into boxes	33	Diacetyl	4.75	Dairy flavored powder
Liquid	Worker used exhaust hood to scoop out butter flavor powder into smaller packages.	10	Diacetyl	10.05	Butter flavored powder.
Powder	Benchtop liquid pouring, Dumping substrate into mixer, Mixing, Packaging, pulling QC sample	17	Diacetyl	4.84	Confectionary flavor
Small Spray Dryer	Operating small spray dryer	99	Diacetyl	0.11	Dried fruit
Liquid	Benchtop Liquid Pouring	12	Isovaleraldehyde	0.01	Nut emulsion

Table 8. July Site Visit Personal Task-Based Sampling Results- continued

Area	Task Description	Duration (mins)	Analyte	Result (ppm)	Batch Flavor
Powder	Packaging powder product into boxes	33	Isovaleraldehyde	0.01	Dairy flavored powder
Liquid	Benchtop Liquid Pouring	12	Propionaldehyde	0.004	Nut emulsion
Powder	Packaging powder product into boxes	33	Propionaldehyde	0.002	Dairy flavored Powder
Liquid	Mixing into stand alone vessel	33	Propionaldehyde	0.02	Tropical fruit

NOTES:
ppm: parts per million

Table 9. The 100 Most Abundant Compounds Observed in Thermal Desorption Sample Results in Rank Order

November Visit	July Visit
Limonene	Limonene
Ethyl butyrate	Ethyl butyrate
Benzaldehyde	Benzaldehyde
C10H16 terpene, alpha-pinene	Ethyl acetate
Ethyl acetate	Isoamyl acetate (3-methyl-butyl acetate)
Isoamyl acetate (3-methyl-butyl acetate)	Propylene glycol
Butyl butyryl lactate	Diacetyl
Decamethylcyclopentasiloxane	Isovaleraldehyde (3-methylbutanal)
Ethyl propionate	Vanillin
p-Cymene	Ethyl isovalerate (ethyl 3-methyl butyrate)
C10H16 terpene, beta-pinene	C3H4O2 isomer, methyl glyoxal
C10H16 terpene, myrcene	Ethyl propionate
Propylene glycol	Methyl amyl ketone
Methyl amyl ketone	Isovaleraldehyde propylene glycol acetal
Ethyl isovalerate (ethyl 3-methyl butyrate)	Trimethyl pyrazine
Ethyl caproate (hexanoate)	Amyl alcohol
Cinnamaldehyde	Ethyl 2-methyl butyrate
Gamma-Terpinene	C10H16 terpenes (such as thujene,sabinene,fenchene,phellandrene,etc.)
Diacetyl	p-Cymene
Toluene	Gamma-Terpinene
Diethylphthalate	C10H16 terpene, alpha-pinene
2-Methylbutyl acetate	Ethanol
Ethanol	Linalool
Isovaleraldehyde (3-methylbutanal)	Butyl butyryl lactate
Ethyl 2-methyl butyrate	p-Dichlorobenzene
C10H16 terpenes (such as thujene, sabinene, fenchene, phellandrene,etc.)	Ethyl phenyl acetate

Table 9. The 100 Most Abundant Compounds Observed in Thermal Desorption Sample Results in Rank Order - continued

November Visit	July Visit
Hexyl acetate	5-Methylfurfural
Isopropyl myristate	SO2
Pentane	Pentane
Acetic acid	Acetic acid
Methyl salicylate	Benzene/butanol
Trans-anethole	Toluene
Isobutyl acetate	Hexanal
C3H4O2 isomer, methyl glyoxal	Ethyl caproate (hexanoate)
Isoamyl butyrate	C10H16 terpene, beta-pinene
Isopentane	C10H16 terpene, myrcene
Butyric acid	Decane
Dodecane	Menthol
C6 aliphatic hydrocarbons	Allyl caproate
cis 3-Hexen-1-ol	Valeraldehyde propylene glycol acetal
Ethyl benzene/xylene	Ethyl vanillin
Butyl acetate	Isopentane
Decane	Furfural
Isoamyl caprylate (octanoate)	Hexyl acetate
Vanillin	Methyl salicylate/naphthalene/
Benzene/butanol	Isoamyl caprylate (octanoate)
Trichloroethylene	gamma-Nonalactone
Isooctane	C7 aliphatic hydrocarbons
Hexanal	Isoamyl phenyl acetate
Benzyl acetate	Methyl vanillin
SO2	Methylcyclopentane
Methylcyclopentane	Propionic acid
Octane	Isooctane
Furfural	Isobutyl acetate

Table 9. The 100 Most Abundant Compounds Observed in Thermal Desorption Sample Results in Rank Order - continued

November Visit	July Visit
Benzyl alcohol	Octane
C10H14O isomer, carvone	Ethyl valerate
gamma-Nonalactone	Isoamyl butyrate
Methyl cinnamate	Benzyl acetate
Amyl alcohol	Ethyl caprylate (octanoate)
2-Hexenal	Cinnamaldehyde
Ethyl vanillin	Trans-anethole
Styrene	Menthyl acetate
C15H24 isomer, beta-caryophyllene	delta-Decalactone
Ethyl valerate	Butyric acid
Acetoin	Butyl acetate
Propionic acid	Isovaleric acid
Dimethyl styrene isomer	2-Methylbutyl acetate
Ethyl caprate (decanoate)	6-methyl-5-hepten-2-one
Isoamyl alcohol (3-methyl-1-butanol)	Menthone
2-Methylbutanol	Isomenthone
Ethyl lactate	Dodecane
C10H16 terpene, camphene	Isopropyl myristate
C15H24 isomer, alpha-copaene	Methyl ethyl ketone
Ethyl benzoate	Cyclohexane
C10H16O isomers (such as neral, geranial, citral)	Heptane
Hexanoic acid	Isoamyl isovalerate (apple oil)
Isovaleric acid	Methyl caprylate (octanoate)
Linalool	2-Butoxyethanol
delta-Decalactone	nonanal
gamma-Undecalactone	Formaldehyde
Menthol	C6 aliphatic hydrocarbons
Melitol	Acetol

Table 9. The 100 Most Abundant Compounds Observed in Thermal Desorption Sample Results in Rank Order - continued

November Visit	July Visit
Formaldehyde	Cyclohexanone
Ethyl caprylate (octanoate)	Hexanoic acid
Ethyl pelargonate (nonanoate)	Benzyl alcohol
delta-dodecalactone	Tolualdehyde
Ethyl ether	Dimethyl styrene isomer
Hexanol	Maltol
alpha-Terpineol	C10H16O isomers (such as neral, geranial, citral)
Glyoxal	Menthene
Acetol	Neral/geranial acetates
6-methyl-5-hepten-2-one	Dimethyl anthranilate
Menthone	gamma-Decalactone
Carane	
2-Methylfuran	
Hexane	

NOTES:
This list is not comprehensive and only lists the top 100 compounds.

Figure 1. Facility Layout and November Site Visit Sampling Locations

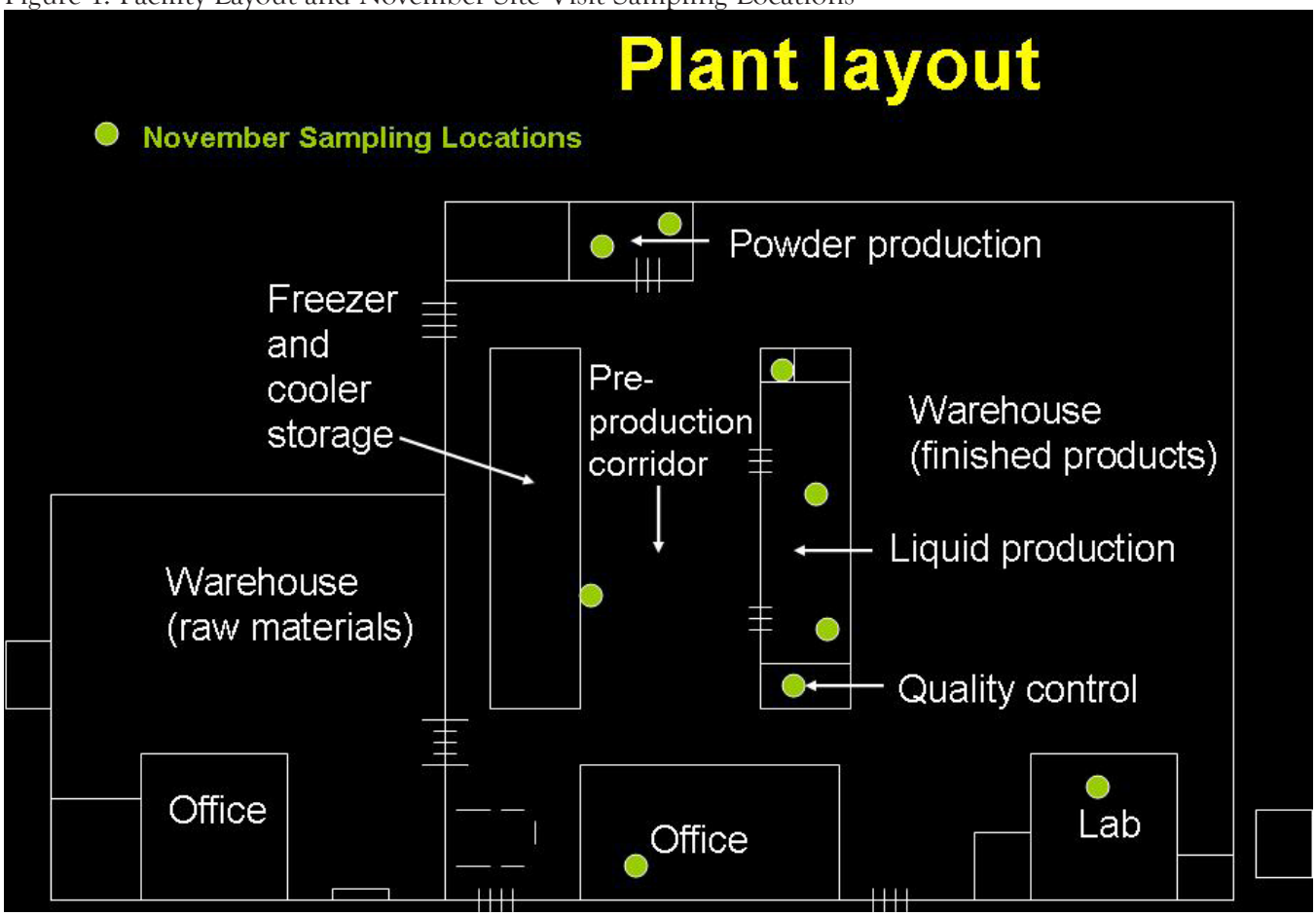


Figure 2. July Site Visit Sampling Locations

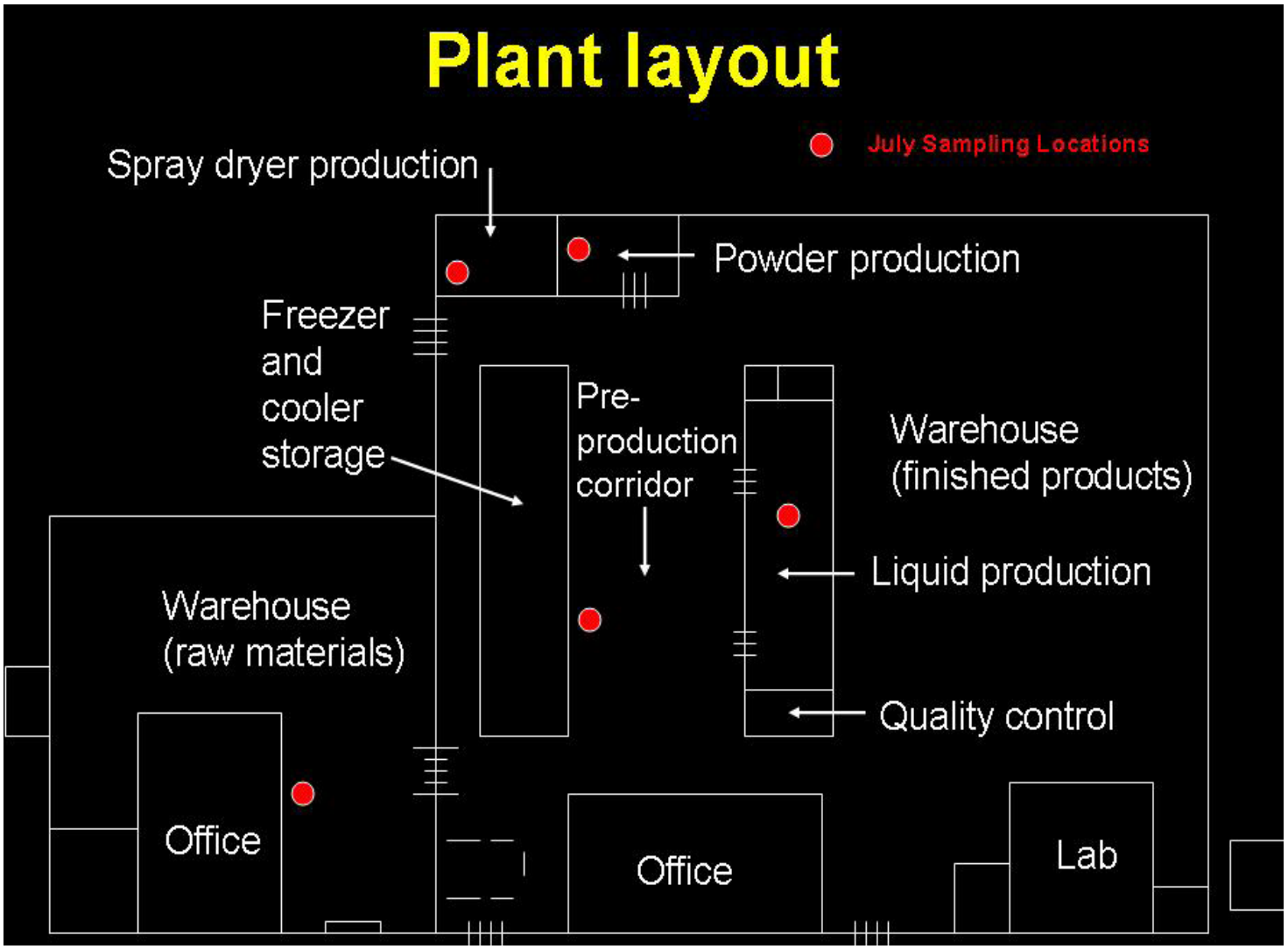


Figure 3. Personal Sampling

Figure 4. Area Sampling

Figure 5. Total Dust and VOC Concentrations in Powder Production Area

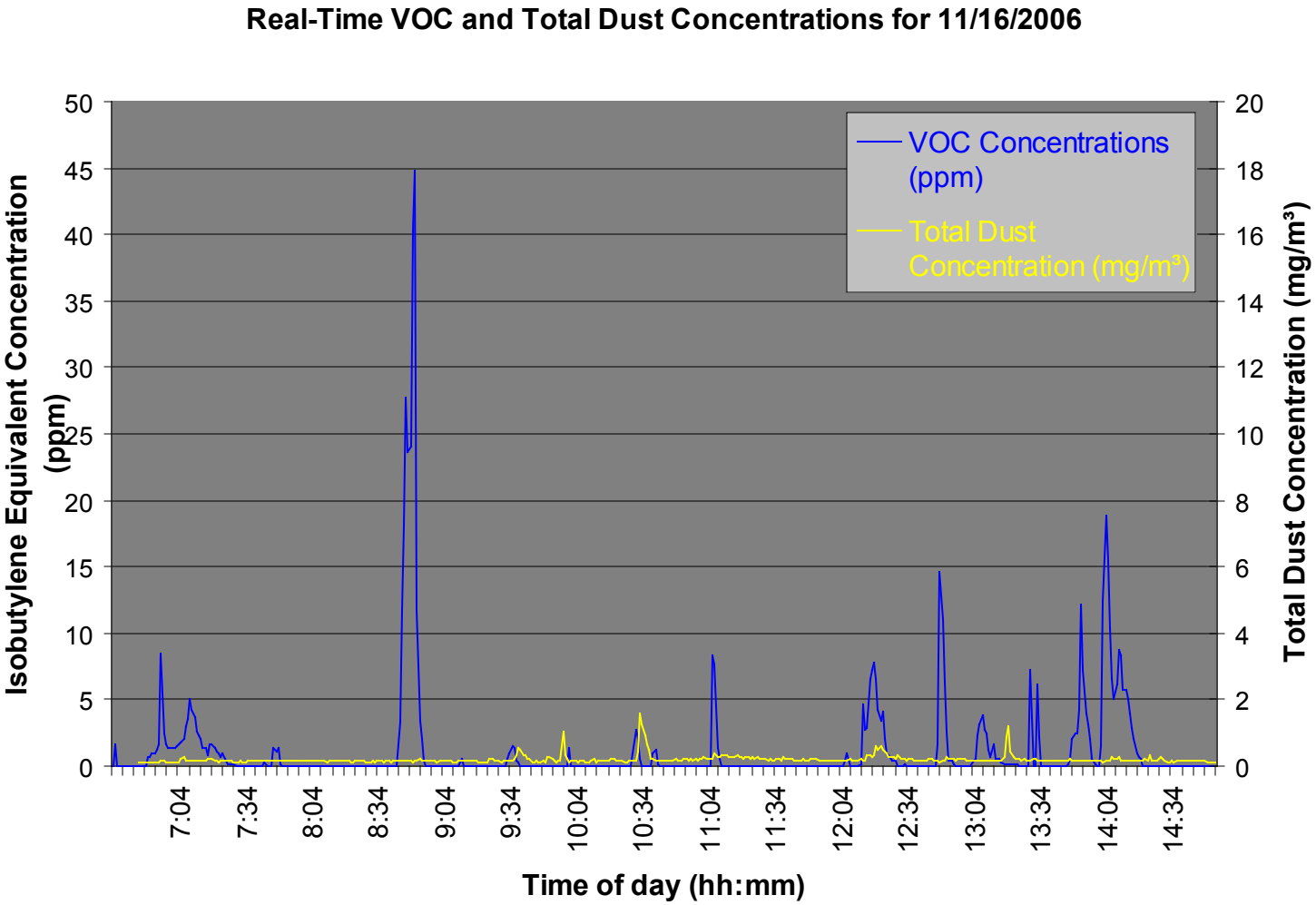


Figure 6.

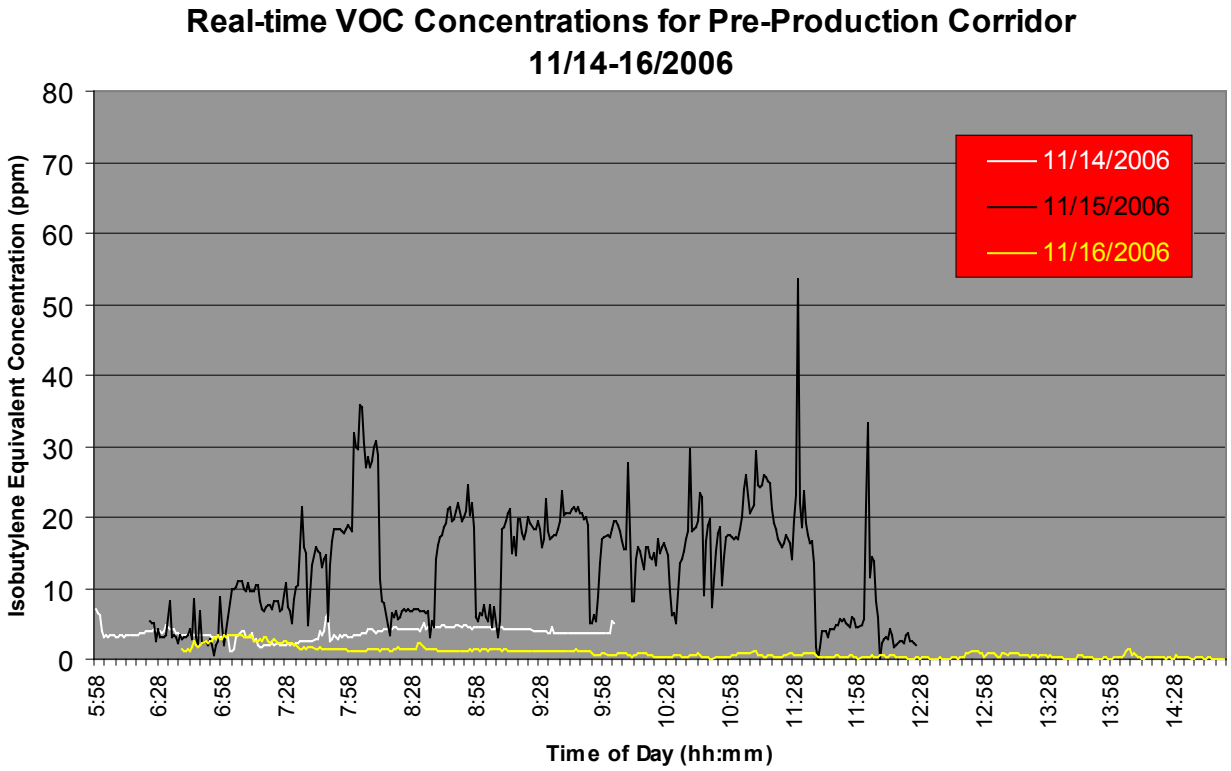

Real-time VOC Concentrations for Pre-Production Corridor
11/14-16/2006
Isobutylene Equivalent Concentration (ppm)
0
10
20
30
40
50
60
70
80
5:58
6:28
6:58
7:28
7:58
8:28
8:58
9:28
9:58
10:28
10:58
11:28
11:58
12:28
12:58
13:28
13:58
14:28
Time of Day (hh:mm)
11/14/2006
11/15/2006
11/16/2006

Figure 7. VOC Concentrations in the Liquid Production Area

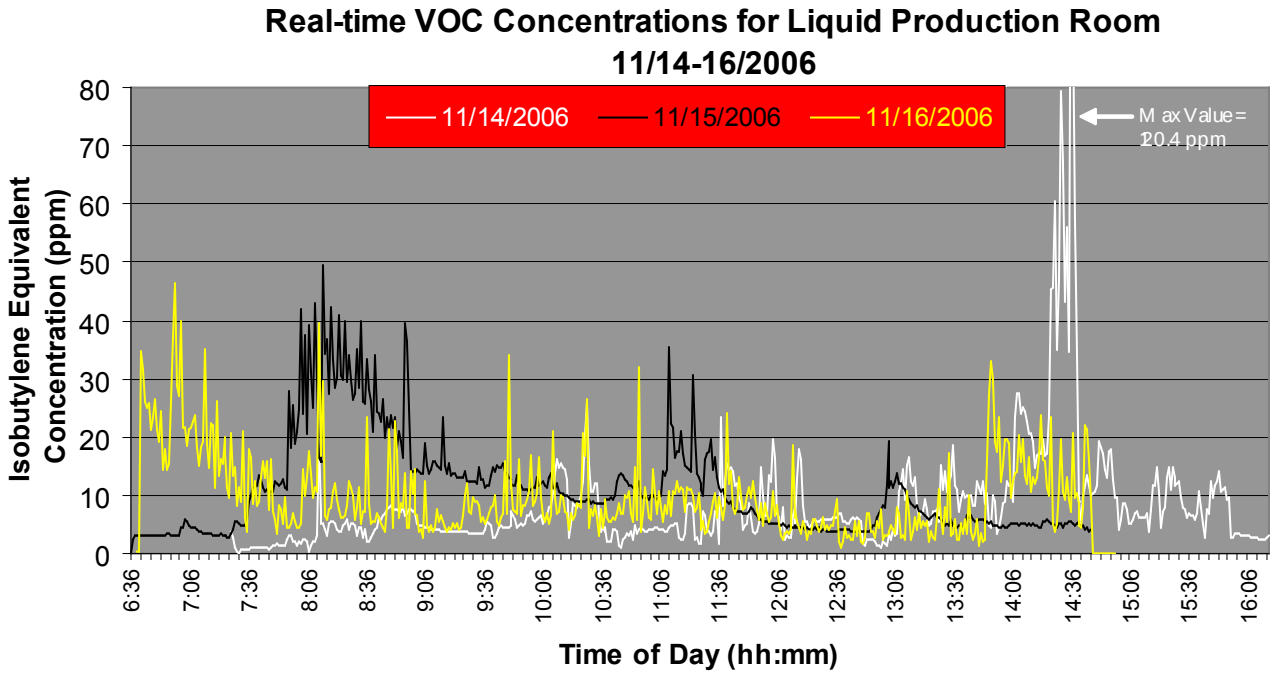


Figure 8. VOC Concentrations in the Powder Production Area

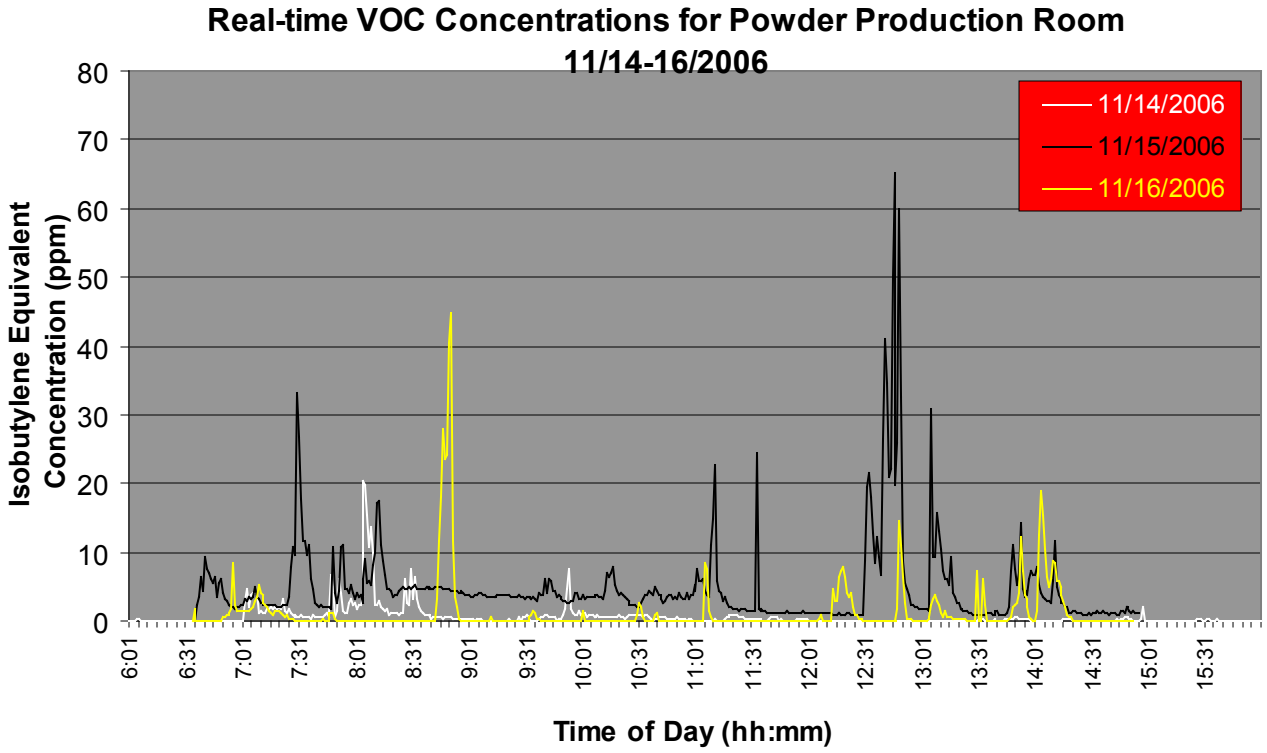
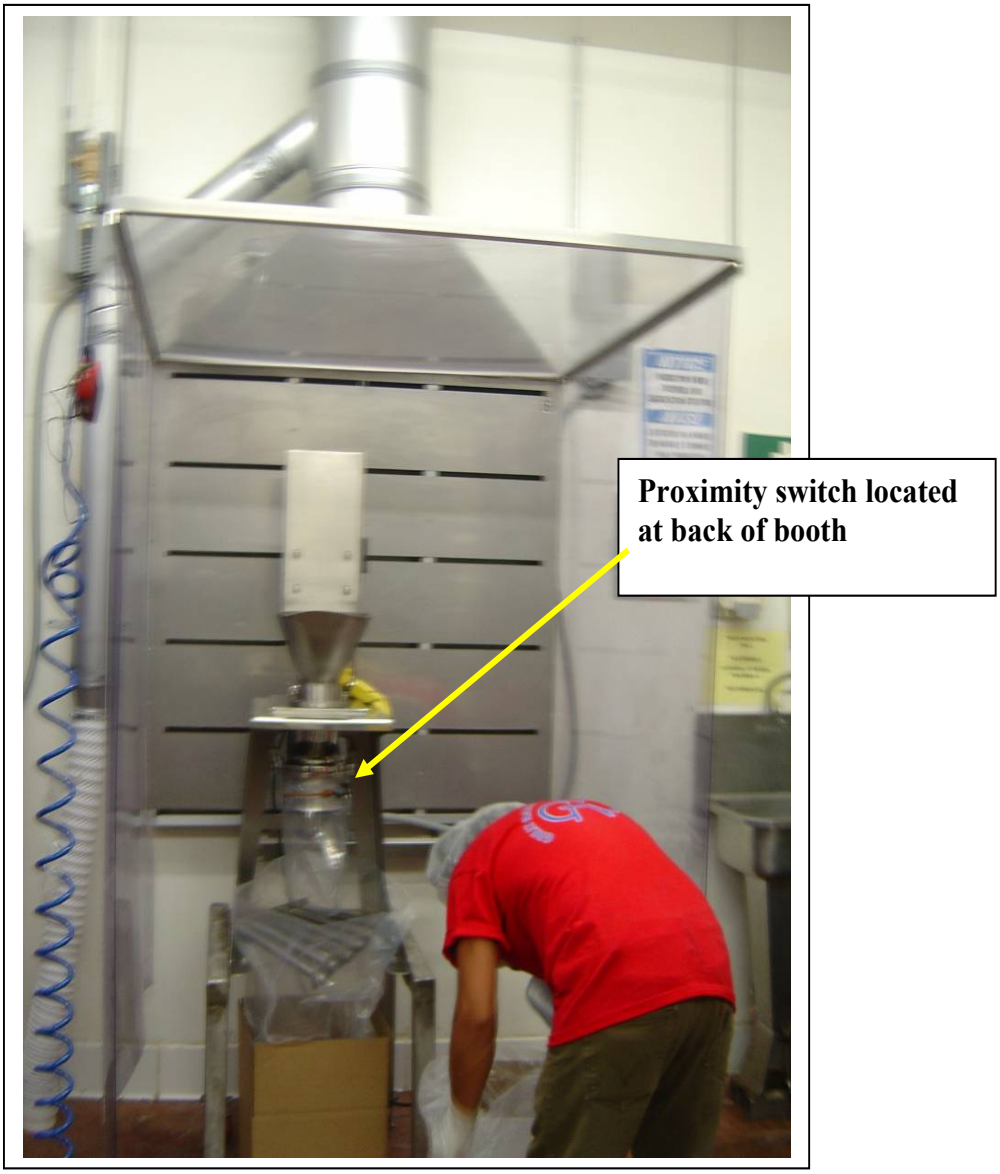


Figure 9. Packaging of butter flavored powder in the ventilated mixing tank booth



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226-1998

February 7, 2007

Mr. Jon Wellwood
Gold Coast, Incorporated
2429 Yates Avenue
Commerce, California 90040

Dear Mr. Wellwood:

I appreciate your cooperation during the NIOSH visit on November 14-16, 2006. As we discussed in our closing meeting, I am writing to provide some background information on reducing worker exposure to process chemicals through the complementary approaches of work practices, engineering controls, and respiratory protection.

Background

Occupational exposures in the flavoring industry have been associated with respiratory disease, including bronchiolitis obliterans, an uncommon lung disease characterized by fixed airways obstruction. Previous NIOSH health hazard evaluations have documented this rare respiratory disease among workers in the popcorn industry, and similar respiratory diseases have been observed among bakers (NIOSH 1986, Kreiss et al. 2002, Akpinar-Elci et al. 2004, Kanwal et al. 2006). In California, workers from at least two companies involved in the production of flavorings were recently diagnosed with bronchiolitis obliterans (Cal DHS 2006).

Employees within the flavoring production industry have complex exposures in terms of the physical form of the agents (solid, liquid, and gas) and the number of different chemicals used. Although there are thousands of flavoring compounds in use, only a minority have occupational exposure limits. Little is currently known about which chemicals used in flavorings have the potential to cause lung disease and other adverse health effects, and what workplace exposure concentrations are safe. Due to the complex mixed exposures within the industry and lack of a known disease causing agent, engineering controls are being recommended as a primary means of providing exposure control.

Currently, there is no model or standard guidance for engineering controls for flavoring processes and, as a result, a wide range of systems have been observed, many with marginal effectiveness. Cal/OSHA has requested that NIOSH assist in the development of exposure control guidance for the flavoring industry. The goals of this technical assistance include: 1) to identify and evaluate engineering controls utilized within the industry, 2) to develop and evaluate the efficacy of new engineering controls to reduce occupational exposures and, 3) to disseminate study results to workers, trade associations, public health officials and stakeholders. As a part of this assistance, NIOSH is providing some assistance to flavoring companies in their goal to develop engineering

controls.

Exposure Controls

Where possible, it is always best to use engineering controls to reduce exposure followed by administrative controls such as implementing new work practices. Finally, the use of respirators is the least attractive option given the burdens placed on the worker to properly use the equipment and upon the employer to administer a respiratory protection program properly. However, given the recent identification of severe obstructive lung disease in workers in the flavoring industry, an approach which seeks to reduce worker exposure immediately is necessary. This approach must include a respiratory protection program for all employees who work or enter the production area.

The approaches discussed below are somewhat general in nature as they need to be adapted to your processes. You need to use your detailed understanding of your processes to implement the exposure controls. In general, worker exposure to air contaminants can be reduced by a combination of efforts to minimize air contaminant emissions and to control the emissions at their source. The ventilation options were obtained from the American Conference of Governmental Industrial Hygienists (ACGIH) Industrial Ventilation Manual (ACGIH 2004) and an industrial ventilation consultant. Where references have been made, I have enclosed copies of the appropriate pages from the manual. Employers should always contact their local air pollution control agency to ensure compliance with emissions requirements for new or revised engineering controls.

Work Practices and Process Emission Minimization

The emission of the volatile components in each flavoring mixture can be minimized by preventing spillage and using lids on mixing and holding tanks while not in immediate use. To the extent possible, open containers used to mix and store flavoring chemicals should be covered when not in use. This practice would minimize the evaporation of chemical into the workplace air. Until lids for mixing vessels become available, the continued use of plastic wrap with sealing tape seems appropriate for this purpose. Manual handling of chemicals also provides a potentially significant source of worker exposures and emissions. Use of closed transfer processes, where feasible, would significantly reduce exposure. Also slow, careful pouring/handling of chemicals can reduce splashing, spillage and exposure during this activity (Boylstein et al. 2006). Reduction in spills and eliminating leakage from vessels will aid in reducing the overall emission of chemicals into the workplace and lower worker exposure.

Another source of evaporation of chemicals may come from the cleaning of mixing tanks using hot water. A suggested change in process which includes an initial wash down with cold water followed by a rinse with warm water may reduce the emission of chemical vapors during this process. Another potential method for reducing emissions is to provide cold storage of chemicals on the Flavor and Extract Manufacturer's Association (FEMA) priority list prior to use. The pouring and mixing of these chemicals at a lower temperature should reduce the amount of evaporative emissions arising from their use.

Respiratory Protection

In the liquid and powder production rooms, workers routinely wore respirators during pouring, weighing and mixing. However, respirator type differed from person to person and included both half and full-face piece. In accordance with Cal/OSHA direction, "full-facepiece respirators fit-tested with an approved quantitative method are needed as minimal protection for employees exposed to flavoring ingredients in this industry. All employees

entering flavor formulation areas or unprotected areas (e.g., packaging areas) must wear respirators" (FISHEP correspondence from K. Howard dated Oct. 13, 2006). A full-facepiece respirator will also protect the eyes from airborne dust and chemical splashes that might occur during pouring, mixing, or cleaning.
NIOSH recommendations, OSHA regulations, and good safety and health practice dictate that respirators should only be used: (1) when effective engineering controls are not feasible for preventing airborne contamination of the workplace, (2) while they are being put into place, and (3) during emergencies. In addition, the use of respirators in the workplace imposes several requirements upon the employer. These requirements include, but are not limited to the following items:

- selection of a NIOSH-certified respirator appropriate to the hazard,
- medical evaluation of the workers who will be required to use the respirator,
- fit-testing of respirators that rely upon a tight-fitting face-to-facepiece seal in order to be effective,
- regularly cleaning, disinfecting, and maintaining (e.g., inspecting and repairing) the respirators,
- safe storage,
- employee training,
- providing a respirator cartridge change schedule,
- establishing and maintaining an effective respiratory protection program, including written procedures and policies.

Guidance for appropriate use of respirators in the workplace can be found on-line at http://www.osha.gov/SLTC/etools/respiratory/index.html and http://www.cdc.gov/niosh/npptl/topics/respirators/.

The effectiveness of the respirator depends upon its proper use, such as maintaining the face-to-facepiece seal when a tight-fitting respirator is used. Barriers to an effective seal include the presence of facial hair and repeatedly lifting the respirator to communicate. OSHA prohibits the use of tight-fitting respirators when employees have facial hair that comes between the sealing surface of the facepiece and the face or that interferes with valve function (29 CFR 1910.134 (g)(1)(i)(A)). The use of respirators with speaking diaphragms or other devices, such as voice amplifiers to enhance communication will improve the employees' ability to communicate while wearing a respirator without disturbing the face-to-facepiece seal.

Cal/OSHA identified the potential use of supplied-air, pressure-demand respirators where feasible. The use of supplied-air respirators imposes additional requirements to ensure their safe use by employees. For example, compressed breathing air, regardless of whether it comes from a compressor, tank, or portable cylinder, must at least meet the requirements for Grade D breathing air described in ANSI/Compressed Gas Association Commodity Specification for Air, G-7.1-1989. In addition, there are requirements that impact the choice and location of compressors used to supply air to the respirator. Among these are requirements to ensure safe levels of carbon monoxide within the supply air, to locate compressors used to supply breathing air in order to prevent entry of contaminated air into the air-supply system, and to provide air supply lines with suitable in-line air-purifying sorbent beds and filters to further ensure breathing air quality. The remaining requirements can be found in the OSHA respiratory protection standard, 29CFR1910.134, §(i).

Ventilation Controls

The options presented below are a result of our observations of the work processes and measurements collected while at the plant. A general approach that addresses each potential emission point is detailed along with some engineering control alternatives. There are several different approaches that could be used to control worker exposure to dust and vapors in your plant. The approaches outlined below are provided for your information and have not been fully evaluated. The assistance of a qualified ventilation engineer is still necessary for the design and implementation of any additions or modifications to your facility.

Where applicable, I have enclosed a list of suppliers for various engineering control devices in Appendix A. ***I am providing them as examples of approaches to reduce occupational exposures. Mention of company names or products does not constitute endorsement by NIOSH.*** Also, when referenced in the recommendations below, applicable figures from the ACGIH ventilation manual have been included in Appendix B.

1. **General Ventilation -** a properly designed supply air ventilation system can provide plant ventilation, building pressurization, and exhaust air replacement. As new local exhaust hoods are installed in the production area, it is important to consider the need for replacement air. In general, it is necessary to balance the amount of exhausted air with a nearly equal amount of supply air. Without this replacement air, uncontrolled drafts will exist at doors, windows and other openings; doors will become difficult to open due to the high pressure difference, and exhaust fan performance may degrade. Good supply air design will consist of ducted supply with air discharge registers about 10 feet above floor level.

   The liquid room is served by a combination of exhaust and supply ventilation registers located on the ceiling of the room (see Figure 1). An Accubalance air capture hood (TSI Inc., Shoreview, MN) was used to measure the flow at each register in the liquid compounding room. Measurements of the flow from six air registers showed that 2 (EF-1 and EF-2) were exhausting air at a combined flow rate of 980 cubic feet per minute (cfm) and one register (SF-1) was supplying air at a rate of 1300 cfm. Three air registers (EF-3, EF-4 and EF-5) were not moving air at all; an investigation into one of these registers showed that it was disconnected at the duct above the ceiling. The fume canopy exhaust hood over mixing tanks 3 and 4 were also exhausting air when the fan was activated. Measurements of the exhaust register (EF-6) over mixing tank 3 indicated a flow rate of 950 cfm. We were not able to measure the exhaust flow rate of the register (EF-7) located over mixing tank 4 because the tank was in the way.

   A hotplate/stove was observed being used during the survey (see Figure 2). This unit was previously located under a canopy-type fume hood but had recently been relocated nearer to the mixing work bench area. As the introduction of heat increases evaporation of chemicals, the stove should be relocated under the hood to reduce emission of chemicals into the mixing room.

   There was no supply air directly provided to the powder compounding room. Airflow into the room comes solely from infiltration from the warehouse area through the 10 feet x 10 feet door opening and a 15 inch x 15 inch vent opening located about 11 feet above the floor which is open to the warehouse area.

   In the dry and liquid compounding areas, a slight negative pressure with respect to the rest of the building is recommended. Air pressure differentials were checked between the liquid and powder rooms and all neighboring areas using a smoke tracer. This simple test indicates whether air is flowing into the room or out of the room into nearby adjacent areas. These tests showed that the liquid room was generally under negative pressure with respect to the warehouse. This, however, is dependent on the operation of the canopy hood over mixing tanks 3 and 4. When this exhaust fan was on, the overall exhaust flow rate was higher than the measured supply air flow rate. However, when this fan was off, the measured supply flow rate was higher than the exhaust creating a positive pressure with respect to the warehouse. Similar measurements conducted in the powder room showed that air flowed into the powder room from the warehouse. In order to maintain a slight negative pressure from the production area to adjacent areas, the supply air volume should be slightly less than the exhaust air. A general rule of thumb is to set a 5%-10% flow difference between supply and exhaust flow rates but no less than 50 cfm.

2. **Mixing tank/kettle ventilation -** he control of exposure to chemicals from mixing tanks and kettles during pouring and mixing operations is critical. A primary source of exposure in the liquid compounding

room is the evaporation of chemicals from the mixing tanks. The use of local exhaust ventilation at the source is a fundamental method that should be used to minimize emissions into the production room and reduce worker exposure.

To control evaporation of chemicals from tanks during mixing operations

a. To contain evaporation during mixing, one approach which has been adopted by another flavoring company is to keep the tanks under slight negative pressure at all times. Their approach was to use hinged tank lids which remained closed during mixing but were modified with a ventilation takeoff which was exhausted at a low flow rate.

b. Another approach would be to move the tanks into a ventilated enclosure while they are mixing. The use of a ventilated booth with flexible strip curtains would allow for the movement of mixing tanks into and out of the ventilated enclosure (see Figure 3). A low flow rate should be sufficient to maintain a negative pressure in the enclosure.

To control worker exposure during pouring operations for tanks smaller than 2 feet in diameter

During pouring and other activities which require operator involvement, additional localized exhaust is required to capture the vapors due to the increased surface area open to the atmosphere and the proximity of the worker to the chemicals.

a. One method for reducing the emission from the surface is to minimize the amount of open area. The possibility of moving to lids with smaller openings for pouring through funnels was discussed during our meeting at your facility. This would appear to be a good approach for minimizing loss of chemicals to the atmosphere and reducing the amount of exhaust air that would need to be collected and treated.

b. An annular exhaust which provides a semi-circular ventilation ring around the edge of the tank has been used for tank ventilation in other industries. Figure VS-15-01 from the book, *Industrial Ventilation-A Manual of Recommended Practice* contains recommendations for a barrel filling operation (see design at top left of figure). This approach was originally used for 55 gallon drums and might not be effective for open surface tanks with a diameter greater than about 2 feet.

To control worker exposure during pouring operations for tanks larger than 2 feet in diameter

For larger mixing tanks approaches which include limiting the open area and providing continuous ventilation may be required. The use of backdraft slotted exhaust hoods *is not recommended* for tanks much larger than 2 feet due to the amount of exhaust required for adequate control. For example, a flanged backdraft exhaust hood such as the one shown in Figure VS-55-10 would require an exhaust flow rate of approximately 12,000 cfm to provide a capture velocity of 100 feet per minute (fpm) at the lip of a 4 foot diameter tank furthest from the hood (based on 4 foot x 6 inch hood face area). By reducing open area through the use of lids and small openings for pouring, this exhaust volume could be substantially reduced.

a. The limiting of tank open area through the use of hinged lids would allow the ventilation of only ½ of the tank surface area substantially reducing exhaust air requirements. The airflow required is directly proportional to the square of the distance from the hood to the furthest control

point. By closing half of the tank and moving the hood within 2 feet of the furthest edge, the requirement for the flanged backdraft hood discussed above could be reduced to approximately 3000 cfm.

b. Another method for reducing the emission from the surface is to use lids with smaller openings and pouring through funnels. This would minimize the loss of chemicals to the atmosphere and reduce the amount of exhaust air that would need to be collected and treated.

3. **Workstation ventilation -** the use of local exhaust ventilation is recommended for the pouring, weighing, and mixing of chemicals. Since most weighing and pouring is performed by workers along a bench-top station, the addition of slotted backdraft ventilation for both the bench and the weighing area is recommended. There are commercially available sources for backdraft workstations or they can be fabricated using appropriate design guidance (see Appendix A).

   Figure VS-90-01 from the book, *Industrial Ventilation-A Manual of Recommended Practice, 25th edition* contains recommendations for a welding ventilation bench hood. This type of design would be appropriate for the work bench areas. The key design parameters are the overall flow rate of 350 cfm/ft of bench length, a slot velocity of 2000 fpm and a maximum plenum velocity of ½ of the slot velocity. These design characteristics should provide adequate airflow to capture chemical evaporation for a work bench no greater than 2 feet in width. Baffles should also be placed along the length of the bench at appropriate work intervals to enhance hood performance. The addition of horizontal baffles attached at the top of the non-tapered portion of the hood and extending 6 inches or more will further enhance the slot hood performance.

   Alternatively, a simple bench-top mixing hood designed for 100-150 cfm per square foot of open access area could enclose the pouring operation and sufficiently contain any generated contaminant at a lower air and energy expense (see Figure 4).

4. **Bag dump ventilation for blenders -** significant dust exposures were observed during bag dumping. The powder compounding area consisted of 2 blenders, both outfitted with local exhaust ventilation. Both blenders were located on platforms with fixed ladders used for access. The smaller blender was 5 feet 6 inches x 2 feet 8 inches and was outfitted with a canopy-type hood (see Figure 5). The larger blender was 3 feet 6 inches x 8 feet and outfitted with a slotted hood located about 8 feet above the platform and behind the worker (see Figure 6).

   The ventilation systems on both blenders were not designed appropriately to capture the dust. Specifically, the design of each hood allowed the potential for the pulling of dust laden air through the breathing zone of the worker (see Figures 5 and 6). The canopy hood over the smaller blender allows a worker to put their head in between the dust emission source and the hood allowing the transport of dust directly through their breathing zone. The slot over the larger blender is located above and behind the head of the worker. The slot is so far away from the emission source that it is unlikely to have an impact on exposure reduction. Also, the location of the slot is such that it would also pull dust towards the operator and directly through his/her breathing zone.

   Figure VS-50-10 contains recommendations for a bag dump station. The primary design considerations are to enclose the face of the blender as much as possible and to maintain a face velocity of approximately 150 feet per minute. For large blenders, the use of slots would help distribute the exhaust flow more evenly across the face of the hood.

A secondary source of exposure is the handling of the bags following dumping. This process has been shown in other industries to be a major source of uncontrolled exposure. An integral pass through to a bag disposal chute/compactor may help reduce dust exposure resulting from bag handling. Other approaches may also be beneficial; one study reported that a company sprayed the inside of bags with water before compacting to reduce dust generations. There are several commercial vendors of bag dumping and handling stations (see Appendix A).

5. **Blender product collection -** another source of dust exposure is in the collection of powder product from the ribbon blenders. There are several ways to reduce the escape of dust from this process. The use of a bungee-type cord to secure the top of the product bag to the outlet of the blender while product is being unloaded would provide a simple method to reduce dust escape during this process. A solution being used in other industries is the continuous liner which provides a continuous pull-down bag which can be crimped at each end to contain any dust generated during product collection (see Appendix A).

   Also, the use a local exhaust ventilation hood around the outlet could provide containment of the potential dust emissions. A hood such as the one shown in Figure VS-15-02 provides a ventilated collar around the discharge point.

Summary

In summary, a comprehensive respiratory protection program must be implemented at your facility. A formal respiratory protection program that adheres to the requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134) is required; this would include medical testing to assess worker fitness to wear respiratory protection. A NIOSH-certified full face respirator with organic vapor, acid gas and particulate filters is the minimum level of respiratory protection recommended for entry into the production areas.

Control strategies can be implemented in phases from simple approaches to more complicated solutions. Process changes such as using cold water washes and cold storage of priority chemicals may be implemented immediately without much cost and effort. The reduction in spills and leaks throughout the facility will help in minimizing the uncontrolled emission of chemical vapors. In general, it is important that you work with qualified industrial ventilation engineers with experience in controlling emissions from flavoring or similar processes. They should be very familiar with the design principles contained in the ACGIH manual. You should also contact your local air pollution control agency to ensure compliance with emissions requirements for new or revised engineering controls. As you move forward with the design and implementation of ventilation controls, we would like to continue to be involved in the evaluation of your efforts to control exposure of your workers to these chemicals. It is important to verify that any new ventilation systems are working properly and controlling worker exposures. In addition, you should make sure that periodic performance checks and maintenance are included in your plants PM schedule.

If you have any questions about the information in this letter, please do not hesitate to contact me by e-mail at KDunn@cdc.gov or by phone at (513) 841-4152.

II-A: Letter from KH Dunn to J Wellwood (February 7, 2007)

Sincerely yours,

Kevin H. Dunn MS, CIH
Research Mechanical Engineer
Engineering and Physical Hazards Branch
Division of Applied Research and Technology

cc:
Mr. Kelly Howard, Cal/OSHA Consultation Services

References

ACGIH (American Conference of Governmental Industrial Hygienists) [2004]. Industrial Ventilation: A Manual of Recommended Practice, 25th edition: Cincinnati, OH.

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Kanwal R, Kullman G, Piatitelli C, Boylstein R, Sahakian N, Martin S, Fedan K, Kreiss K [2006]. Evaluation of flavorings-related lung disease risk at six microwave popcorn plants. J. Occup. Environ. Med. *48*:149-157.

Kreiss K, Gomaa A, Kullman G, Fedan K, Simoes E, Enright P. [2002]. Clinical bronchiolitis in workers at a microwave-popcorn plant. N. Engl. J. Med. *347*:3301-338.

NIOSH [1986]. Hazard Evaluation and technical assistance report: International Bakers Services, Inc. South Bend, IN. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, NIOSH HETA Report No. 85-171-1710.

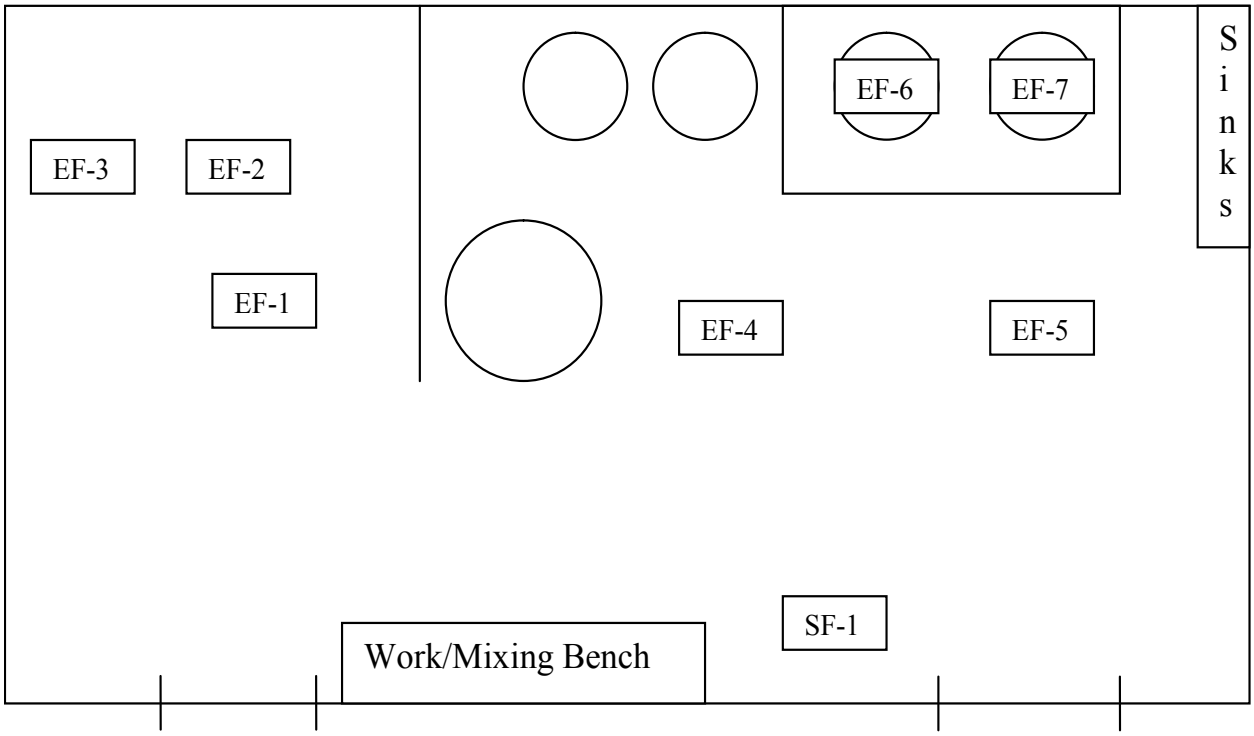
OSHA. 29 CFR 1910.134, Occupational Safety and Health Administration. Code of Federal Regulations, Respiratory Protection Standard. Washington, D.C: U.S. Government Printing Office, Office of the Federal Register.

II-A: Letter from KH Dunn to J Wellwood (February 7, 2007)

DISCLAIMER

Mention of company names or products does not constitute endorsement by the Centers for Disease Control and Prevention.

Figure 1. Liquid compounding room layout.



Note: EF refers to an air exhaust fan. SF refers to an air supply fan.

Figure 2. Hotplate used for heating mixtures.

Figure 3. Ventilated Mixing Station Enclosure. Drawing modified and used with permission from K&B Technic Inc., Cincinnati, Ohio.

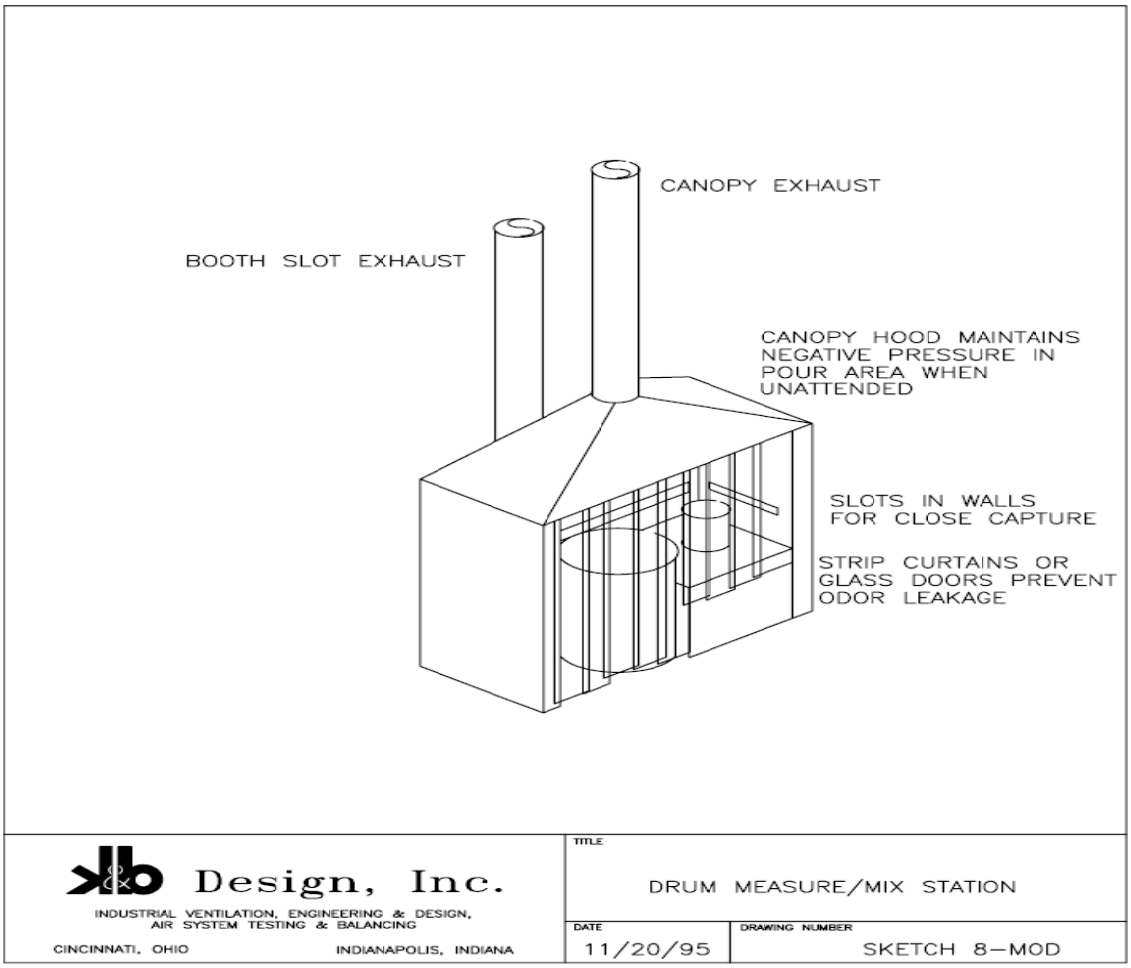


Figure 4. Ventilated small batch mixing workstation. Drawing used with permission from K&B Technic Inc., Cincinnati, Ohio.

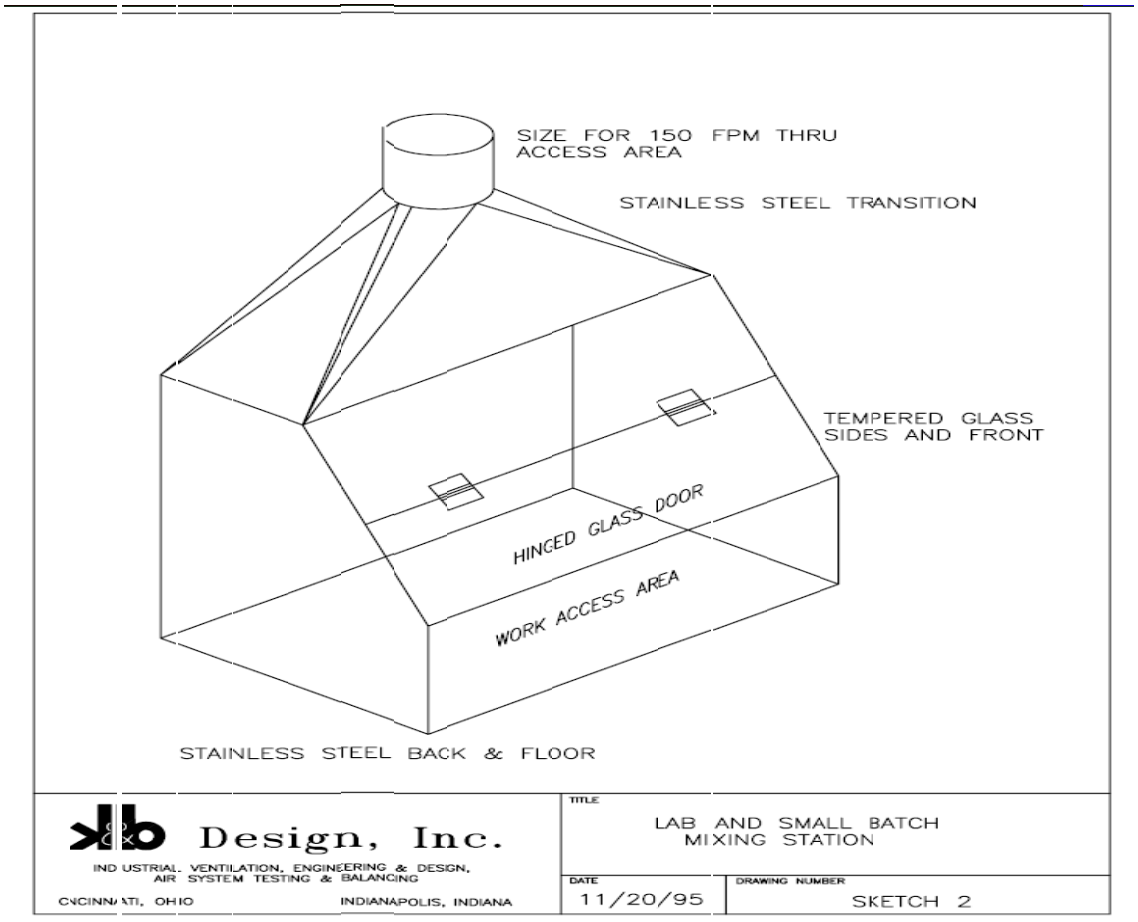
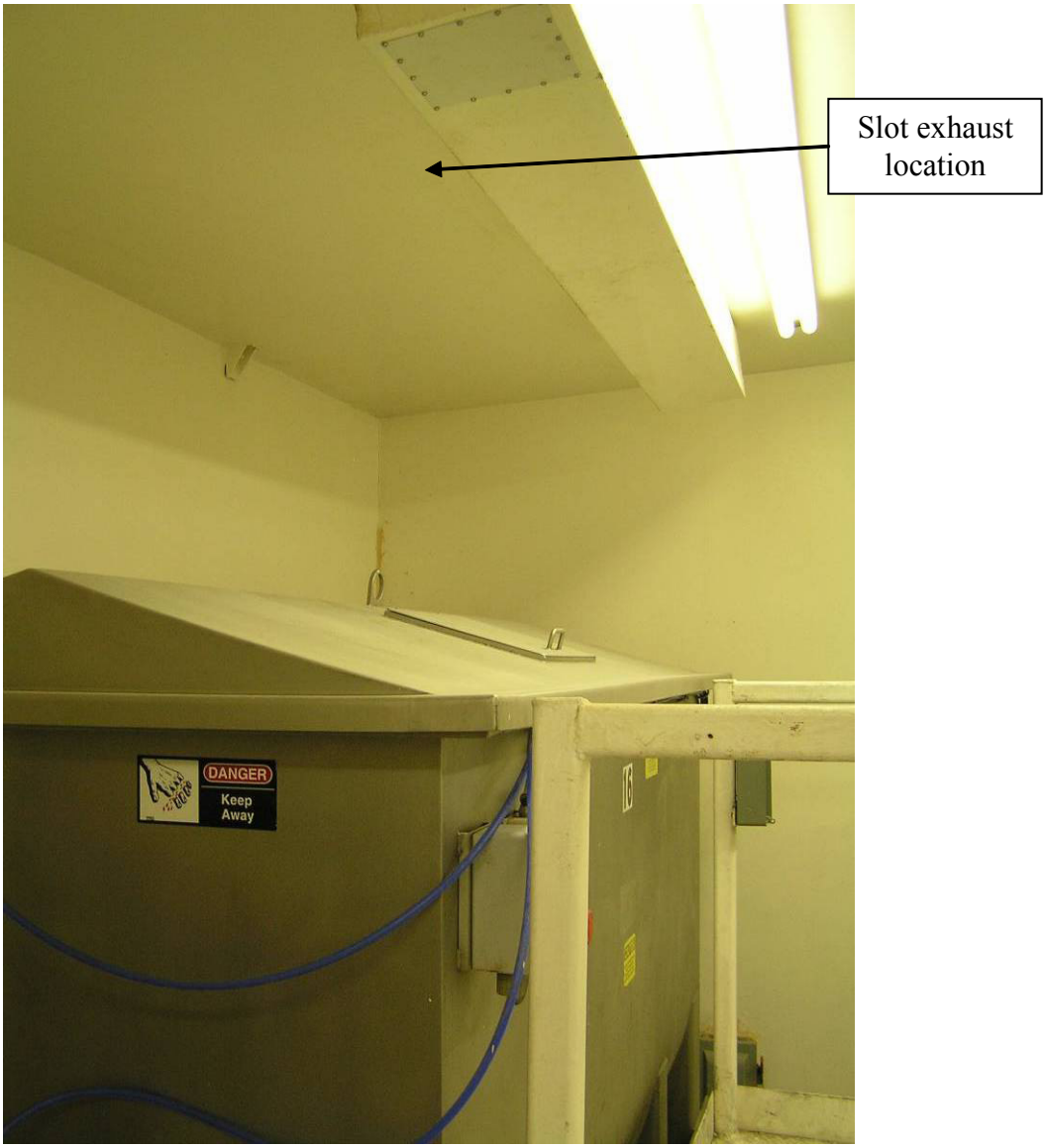


Figure 5. Canopy hood over smaller blender.

Figure 6. Slot hood over larger blender.



Appendix A - List of ventilation products manufacturers

DISCLAIMER Mention of company names or products does not constitute endorsement by NIOSH.

Backdraft Ventilation Work Bench Suppliers

TBJ Incorporated
1671 Orchard Drive
Chambersburg, Pennsylvania 17201
Phone: (717) 261-9700
Web address: www.tbjinc.com

Mopec,
21750 Coolidge Highway
Oak Park, Michigan 48237
Phone: (800) 362.8491
Web Address: http://www.mopec.com/index.html (see grossing stations/backdraft)

Labconco Incorporated
8811 Prospect Avenue
Kansas City, Missouri 64132-2696
Phone: (800) 821-5525
Web address: http://www.labconco.com/_Scripts/editc25.asp?catid=325
(see lab fume hoods for examples of backdraft type benches)

Bag Opening, Emptying and Disposal Product Suppliers

Whirl-Air Flow
20055 177th Street
Big Lake, Minnesota 55309
Phone: (800) 373-3461
Web address: http://www.whirlair.com/index.htm

Hapman
2002 East Kilgore Road
Kalamazoo, Michigan 49048
Phone: (800) 427-6260
Web address: http://www.hapman.com/

Young IndustriesO Box 30
Muncy, Pennsylania 17756-0030
Phone: (570) 54-3165
Web address: http://www.younginds.com/

Dust Collection/Containment Systems

Ventilation Sleeves for Dust Containment

EHS Solutions
3309 Woodhams Avenue
Portage, Michigan 49002
Phone: (800) 463-7817
Web address: http://www.ehsnow.com/products_ventilation-sleeve.html

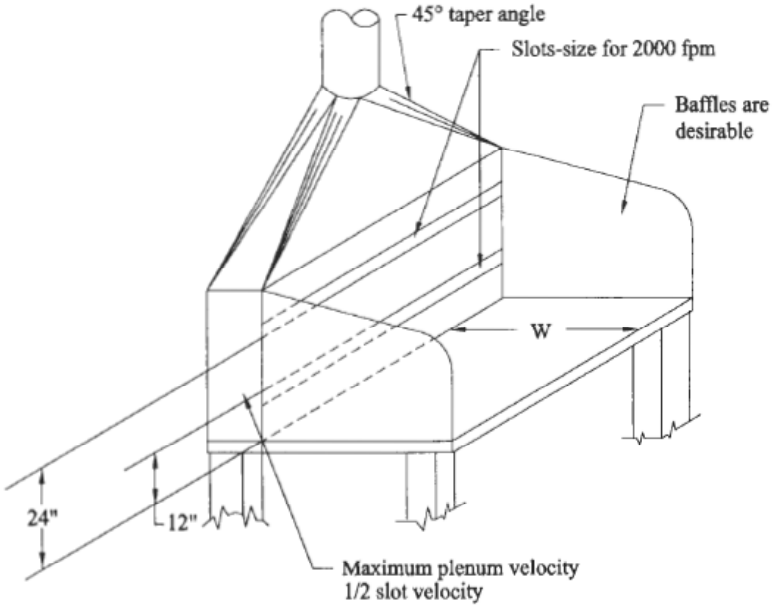
Continuous Liner suppliers

ILC Dover
One Moonwalker Road
Frederica, Delware, 19946-2080
Phone: (302) 335-3911
Web address: http://www.ilcdover.com/products/pharm_biopharm/operations/continuousliner.htm

Fab Ohio
52 East 7th Street
Uhrichsville, Ohio 44683
Phone: (740) 922-4233
Web Address: http://www.fabohio.com/

Appendix B—Figures from ACGIH Ventilation Manual

10-154 Industrial Ventilation



Q = 350 cfm/ft of hood length
Hood length = required working space
W = 24" maximum, if W greater than 24" see Chapter 3
Minimum duct velocity = 2000 fpm
$h_e = 1.78\ VP_s + 0.25\ VP_d$

General ventilation, where local exhaust cannot be used:

Rod, dia.	cfm/welder
5/32	1000
3/16	1500
1/4	3500
3/8	4500

or

A. For open areas, where welding fume can rise away from the breathing zone:
cfm required = 800 × lb/hour rod used

B. For enclosed areas or positions where fume does not readily escape breathing zone:
cfm required = 1600 × lb/hour rod used

For toxic materials higher airflows are necessary and operator may require respiratory protection equipment.

Other types of hoods
Local exhaust: See VS-90-02
Booth: For design see VS-90-30
Q = 100 cfm/ft^2 of face opening
MIG welding may require precise air flow control.

ACGIH WORLDWIDE

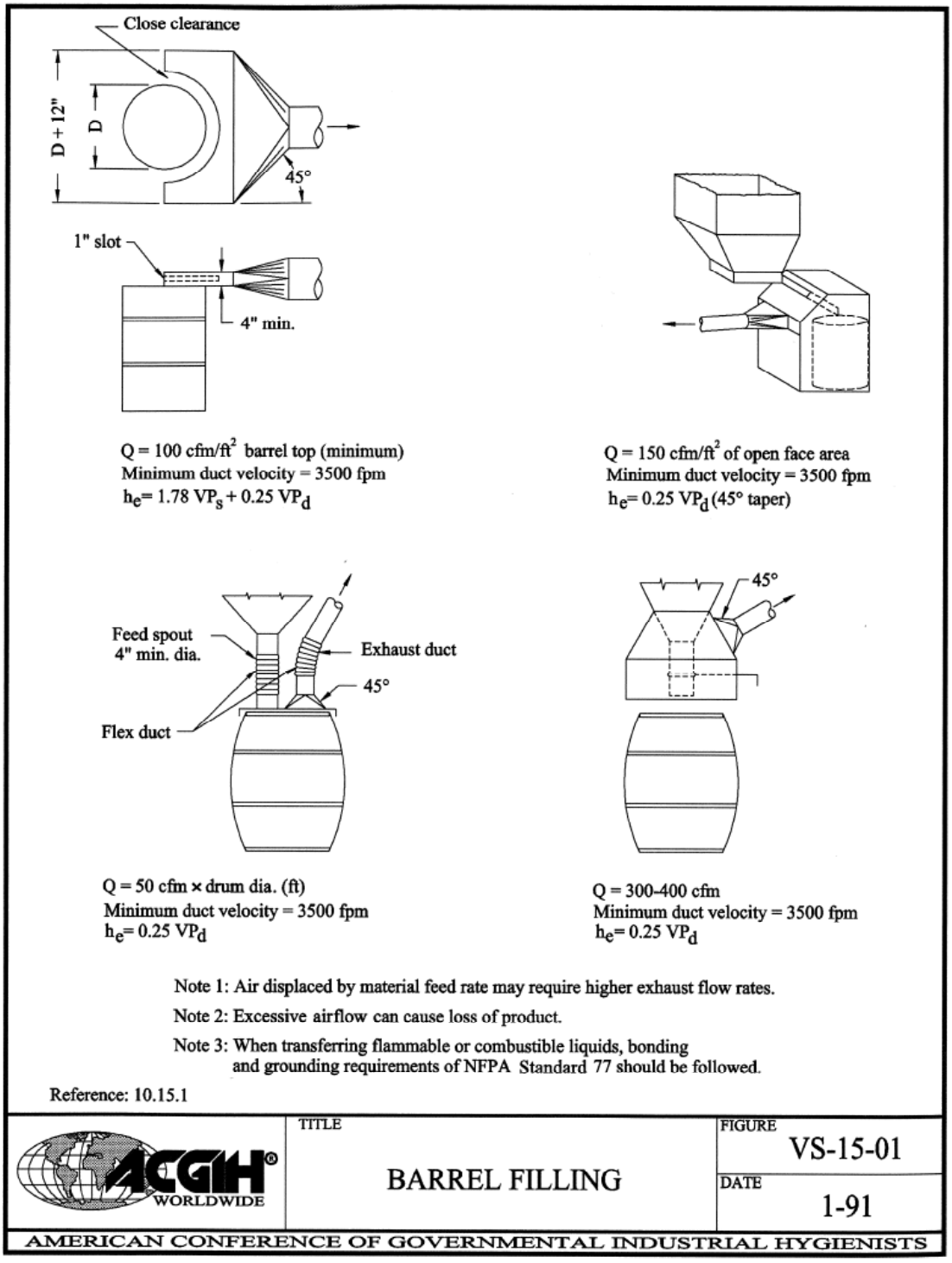
TITLE
WELDING VENTILATION
BENCH HOOD

FIGURE
VS-90-01

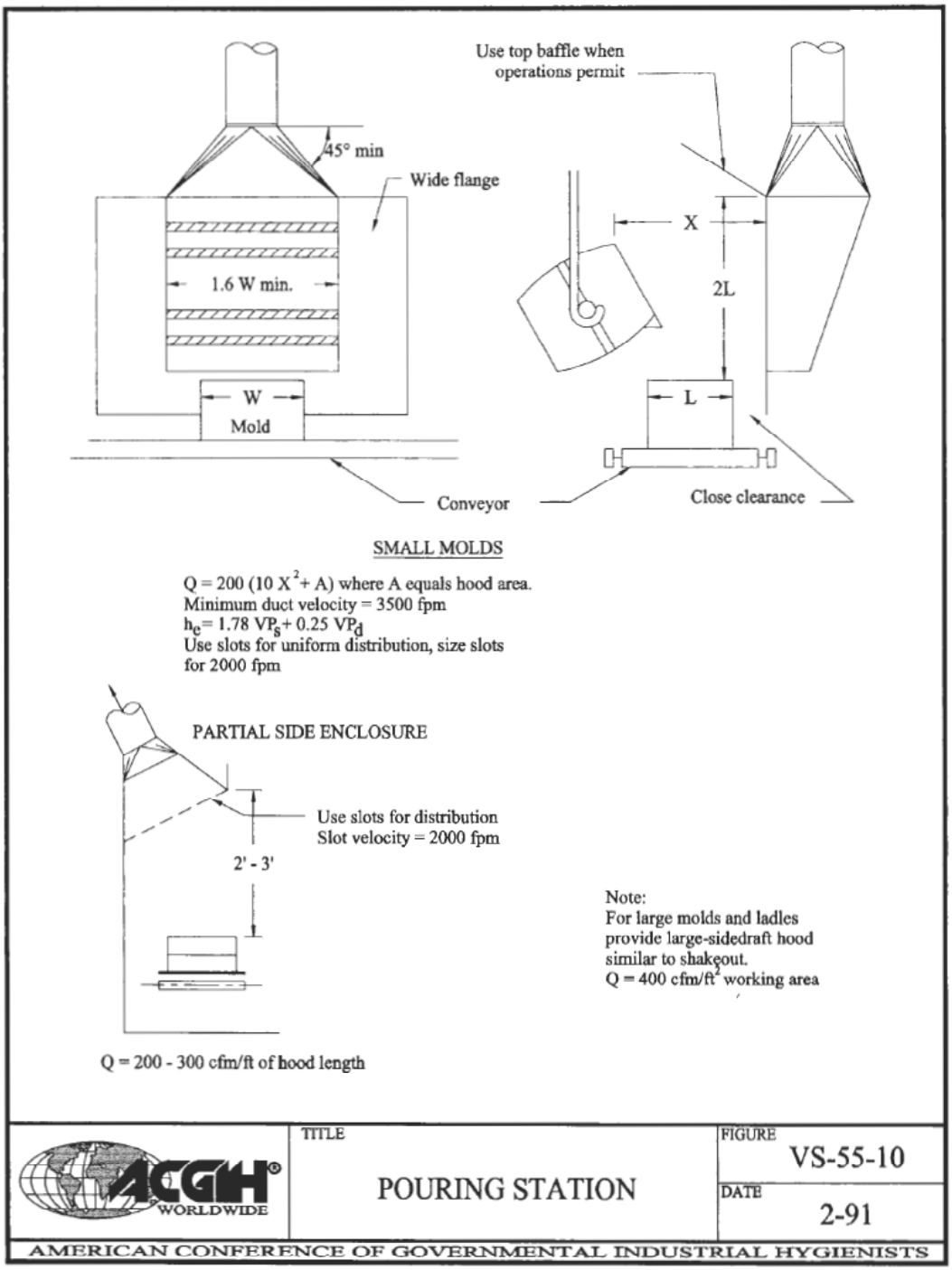
DATE
1-91

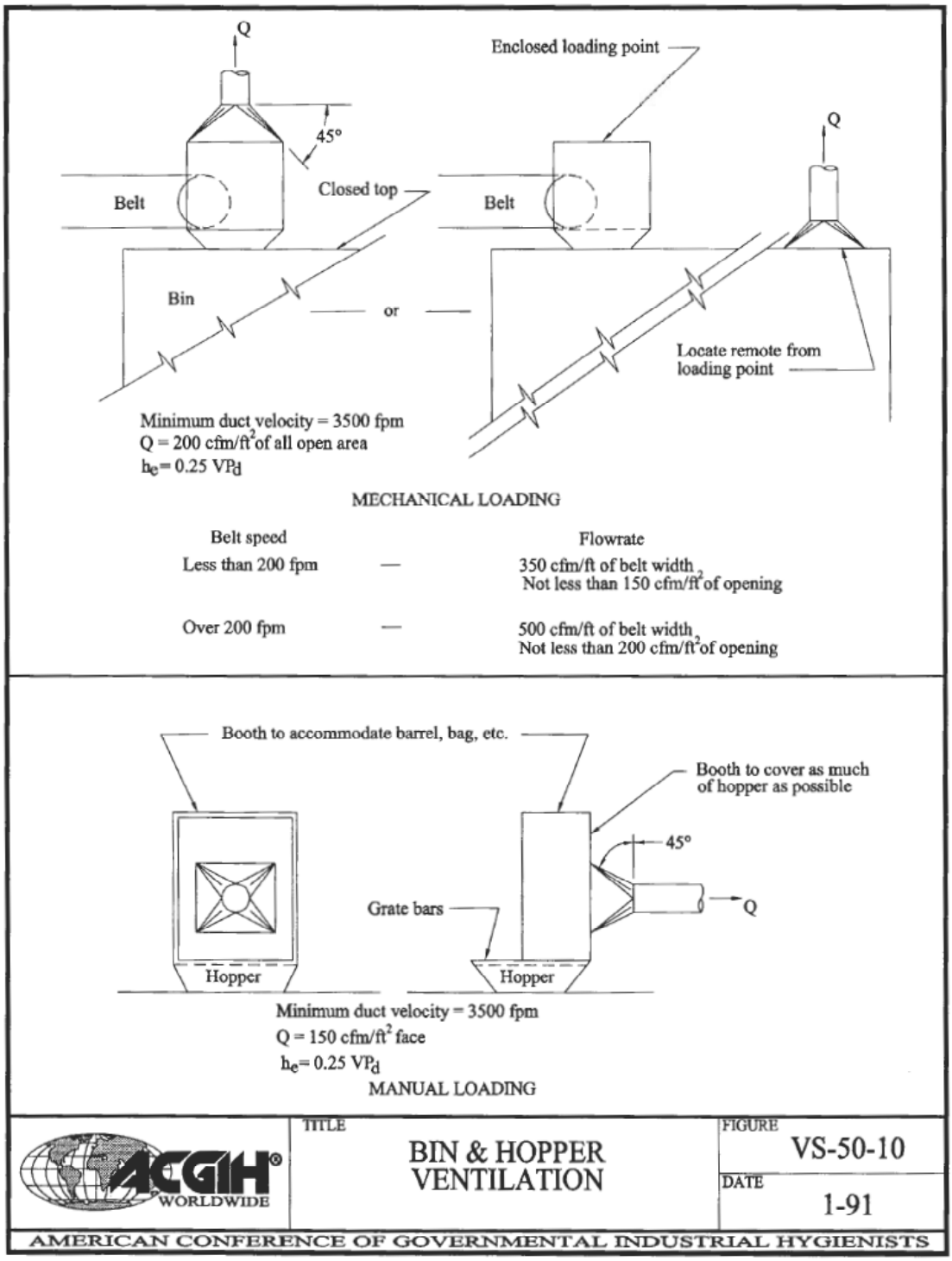
AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS

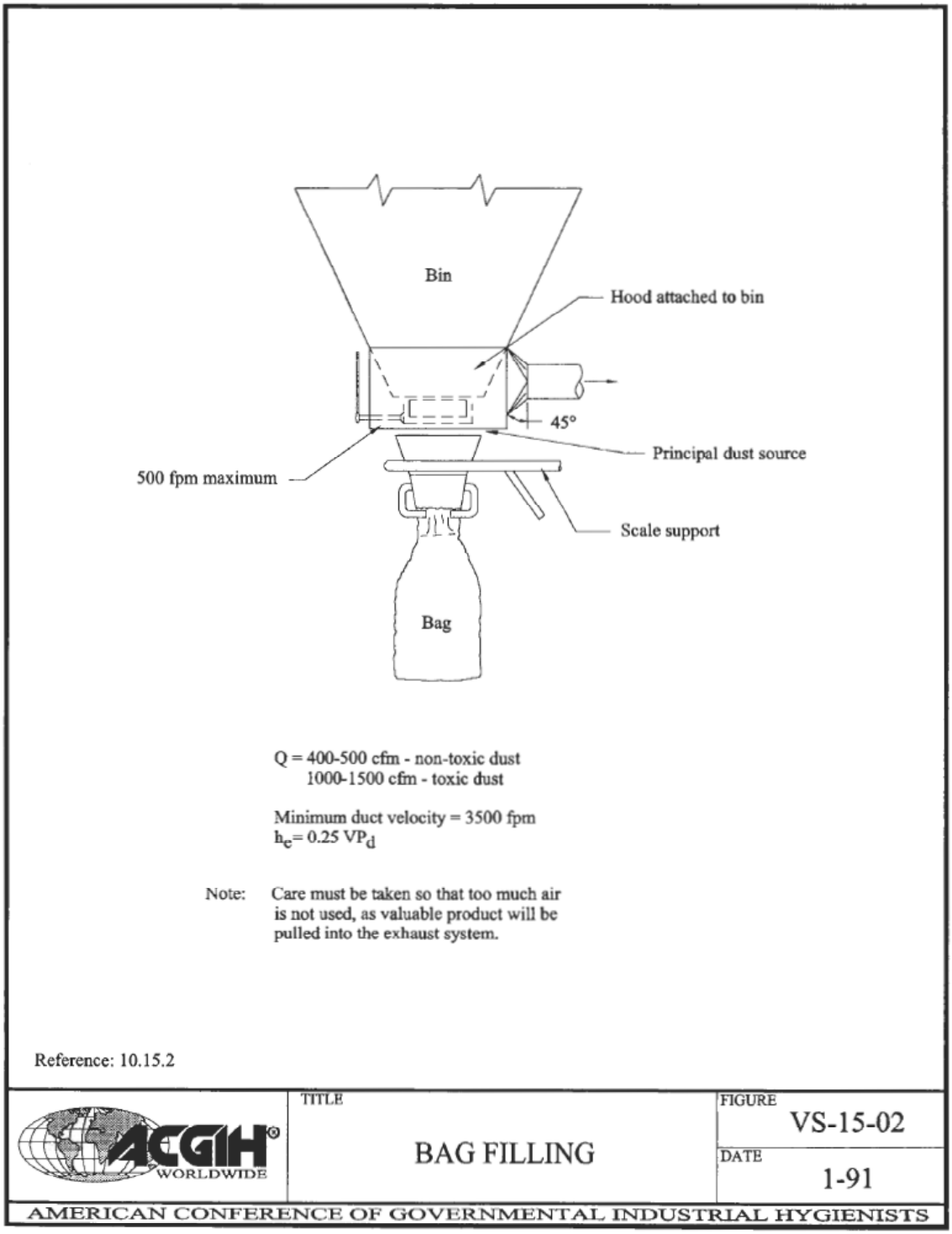
10-14 Industrial Ventilation



II-A: Letter from KH Dunn to J Wellwood (February 7, 2007)




Q
45°
Belt
Closed top
Bin
or
Enclosed loading point
Q
Belt
Locate remote from loading point
Minimum duct velocity = 3500 fpm
Q = 200 cfm/ft² of all open area
he = 0.25 VPd
MECHANICAL LOADING
Belt speed
Flowrate
Less than 200 fpm — 350 cfm/ft of belt width, Not less than 150 cfm/ft² of opening
Over 200 fpm — 500 cfm/ft of belt width, Not less than 200 cfm/ft² of opening
Booth to accommodate barrel, bag, etc.
Booth to cover as much of hopper as possible
45°
Grate bars
Q
Hopper
Hopper
Minimum duct velocity = 3500 fpm
Q = 150 cfm/ft² face
he = 0.25 VPd
MANUAL LOADING
ACGIH WORLDWIDE
TITLE
BIN & HOPPER VENTILATION
FIGURE
VS-50-10
DATE
1-91
AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS


Bin
Hood attached to bin
45°
Principal dust source
500 fpm maximum
Scale support
Bag
Q = 400-500 cfm - non-toxic dust
1000-1500 cfm - toxic dust
Minimum duct velocity = 3500 fpm
$h_e = 0.25\ VP_d$
Note: Care must be taken so that too much air is not used, as valuable product will be pulled into the exhaust system.
Reference: 10.15.2
ACGIH WORLDWIDE
TITLE
BAG FILLING
FIGURE
VS-15-02
DATE
1-91
AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS

bcc:

IN-DEPTH SURVEY REPORT: EVALUATION OF ENGINEERING CONTROLS FOR THE MIXING OF FLAVORING CHEMICALS

at

Gold Coast Ingredients, Inc.
Commerce, CA

REPORT WRITTEN BY:
Kevin H. Dunn, MS, CIH
Alan Echt, MPH, CIH
Alberto Garcia, MS

REPORT DATE:
January 2008

REPORT NO:
EPHB 322-11a

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Division of Applied Research and Technology
Engineering and Physical Hazards Branch
4676 Columbia Parkway, Mail Stop R-5
Cincinnati, Ohio 45226-1998

II-B: Technical Assistance Report—In-depth Survey Report: Evaluation of Engineering Controls for the Mixing of Flavoring Chemicals at Gold Coast Ingredients, Inc., Commerce, CA (January 2008)

SITE SURVEYED:	Gold Coast Ingredients, Inc. Commerce, CA
NAICS CODE:	311
SURVEY DATES:	July 9-12, 2007
SURVEYS CONDUCTED BY:	Kevin H. Dunn, NIOSH Alan Echt, NIOSH Alberto Garcia, NIOSH
EMPLOYER REPRESENTATIVES CONTACTED:	Jon Wellwood

DISCLAIMER

Mention of company names or products does not constitute endorsement by the Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

Table of Contents

II-B: Technical Assistance Report—In-depth Survey Report: Evaluation of Engineering Controls for the Mixing of Flavoring Chemicals at Gold Coast Ingredients, Inc., Commerce, CA (January 2008)

EXECUTIVE SUMMARY

Researchers from the National Institute for Occupational Safety and Health (NIOSH) conducted an evaluation of a local exhaust ventilation system installed in the liquid compounding room at Gold Coast Ingredients, Inc. The ventilation control system was developed and installed by Gold Coast in conjunction with a contractor to reduce the potential for employee exposure to harmful flavoring chemicals. The ventilation system for the compounding room was developed following an initial visit by NIOSH in November 2006. Following that survey, recommendations on the design and implementation of engineering controls were provided to the company in a letter dated February 7, 2007. This survey was conducted to evaluate the installation of new ventilation controls for the weighing and pouring of chemicals on the bench top and the mixing of large scale batches of flavorings in mixing tanks.

Evaluations were based on a variety of tests including tracer gas experiments, air velocity measurements, and smoke release observations. The experiments showed that generally there is good capture by the all LEV hoods under the tested conditions. Tracer gas tests were performed under a variety of conditions including the movement of the emission source to areas across the bench top surface to evaluate the spatial capture efficiency. Also, experiments were conducted using a mannequin to evaluate the effect of the disturbance of the body on the performance of the hoods. Capture efficiencies were calculated based on measurements of the concentration of tracer gas in the exhaust duct under test conditions versus the concentration when tracer was released directly into the duct (100% capture condition). The measured capture efficiencies exceeded 95% for all hoods installed. Air visualization tests and velocity measurements indicated good capture characteristics and were consistent with the results of tracer gas testing. Despite the test results indicating excellent hood performance, air samples collected during the survey indicated that flavored powder packaging done in one of the ventilated booths yielded high worker exposures and a corresponding increase in concentrations of diacetyl in the general flavoring production area. This is likely to be due to issues associated with the operation/location of the proximity switches in those booths.

Based on the results in this report, the following recommendations are made to further improve the local exhaust ventilation in the liquid compounding room:

- Evaluate the design and operation of the proximity switches in the booth-type hoods for all processes including powder packaging and any other auxiliary procedures. Check all operations being conducted in these booths to evaluate whether the worker is being adequately protected during all tasks.
- Install hood static pressure gauges on each hood to provide important information on hood performance. Include the recording of hood static pressure and performance of hood airflow checks into the preventative maintenance schedule.
- Extend the bench-top hood side baffles to the edge of the bench. The extension of the side baffles on the bench-top hoods will further enclose the operation and improve performance by minimizing the effect of cross drafts on hood capture.
- Discontinue the use of floor fans and wall-mounted fans as they interrupt the capture of the hood and reduce hood performance by creating drafts within the room. Consider using ceiling-mounted supply registers to provide lower velocity and more uniform cooling/air movement in the compounding room.
- Consider upgrading hood and duct materials to higher gauge galvanized steel when appropriate. Upgrading to a higher gauge (thicker) galvanized sheet metal will improve the system's ability to withstand the wear and tear of ordinary use.
- Consider installing an indication of exhaust fan operating status (on/off) such as a light for each hood

so that workers know when the system is operating and they are being protected when working with the hoods.

- Provide worker training on proper techniques for using hoods such as clearing the bench of unnecessary chemicals/materials and as much as possible to reduce the obstruction of airflow into the slot exhaust
- Consider using the booth for packaging of liquid flavorings and pouring of high priority chemicals until other controls are in place for these tasks. Ensure that the workers use proper techniques and that the control system allows for activation of the exhaust fan when performing these tasks.
- Consider reworking the roof-top exhaust stack design to ensure that hood exhaust is effectively discharged.

II. INTRODUCTION

As part of a technical assistance request from the California Division of Occupational Safety and Health (Cal/OSHA) in 2006, researchers from the National Institute for Occupational Safety and Health (NIOSH) conducted an engineering control evaluation of Gold Coast, Inc. at their Commerce, California plant on July 9 -12, 2007. Gold Coast is participating in the Flavoring Industry Safety and Health Evaluation Program (FISHEP), a voluntary special emphasis program. This program was initiated by the California Department of Health Services (CDHS) and the California Division of Occupational Safety and Health (Cal/OSHA) in 2006 to identify workers with flavoring-related lung disease such as bronchiolitis obliterans (BO) and institute preventive measures in the California flavoring industry. Under FISHEP, companies must report the results of worksite industrial hygiene assessments to CDHS, and implement control measures recommended by Cal/OSHA.

This site was selected for inclusion in this investigation at the specific request of Cal/OSHA. The primary objective of the engineering control survey was to evaluate a new local exhaust ventilation system implemented for the liquid flavoring compounding process. A secondary goal was to evaluate and document the performance of control techniques in reducing potential health hazards to common processes within the flavoring production industry.

The Engineering and Physical Hazards Branch (EPHB) of the Division of Applied Research and Technology (DART) has been given the lead within NIOSH to study and develop engineering controls and assess their impact on reducing occupational illness. Since 1976, EPHB (and its forerunner, the Engineering Control and Technology Branch) has conducted a large number of studies to evaluate engineering control technology based upon industry, process, or control technique.

Background

Occupational exposures in the flavoring industry have been associated with respiratory disease, including bronchiolitis obliterans, an uncommon lung disease characterized by fixed airways obstruction. Previous NIOSH health hazard evaluations have documented cases of this illness among workers in the popcorn industry, and similar respiratory disorders have been observed among flavoring mixers (NIOSH 1986, Kreiss et al. 2002, Akpinar-Elci et al. 2004, Kanwal et al. 2006). In California, at least seven workers involved in the production of flavorings have been diagnosed with obstructive lung disease since 2004 (CDC 2007).

Employees within the flavoring production industry have complex exposures in terms of the physical form of the agents (solid, liquid, and gas) and the number of different chemicals used. Although there are thousands of flavoring compounds in use, few have occupational exposure limits. Due to the complex mixed exposures within the industry and the absence of inhalation toxicology data for most chemicals, engineering controls are being recommended as a primary means of providing exposure control.

Currently, there is no model or standard guidance for engineering controls for flavoring processes and, as a result, a wide range of systems have been observed, many with marginal effectiveness. Cal/OSHA has requested that NIOSH assist in the development of exposure control guidance for the flavoring industry. The goals of this technical assistance include: 1) to identify and evaluate engineering controls utilized within the industry; 2) to develop and evaluate the efficacy of new engineering controls to reduce occupational exposures, and; 3) to

disseminate study results to workers, trade associations, public health officials and stakeholders. As a part of this request, NIOSH is providing some assistance to flavoring companies to reach their goal of developing engineering controls.

Where possible, it is always best to use engineering controls to reduce exposure followed by administrative controls such as implementing new work practices. The use of respirators is the least attractive option given the burdens placed on the worker to properly use the equipment and upon the employer to administer a respiratory protection program properly. However, given the recent identification of severe obstructive lung disease in workers in the flavoring industry, an approach which seeks to reduce worker exposure immediately is necessary. This approach must include a respiratory protection program for all employees who work or enter the production area.

Facility Description

Gold Coast manufactures and distributes liquid and powdered flavors to other companies for use in a variety of food products. The facility has been producing flavorings and extracts since the 1990s. Approximately 800 different flavors are produced at this facility, requiring ~ 1,000 chemicals or natural ingredients. The facility consists of a liquid production room, powder production room, color room, walk-in cooler and freezer, two spray-drying areas, raw materials warehouse, finished products warehouse, laboratory, quality control, and offices.

The production workers measure and pour flavoring ingredients which are then transferred to open tanks for liquid flavoring compounding or to ribbon blenders for powdered flavoring production. Computerized batch tickets are used to pull ingredients for the various flavors from the warehouse. Exposures vary dramatically depending upon the flavor formulations being completed on a particular day. An employee can work with numerous flavoring chemicals daily depending upon the size and complexity of a batch order. It was not unusual to observe at least 7 different batches being compounded concurrently by different employees in the production areas. The majority of flavors manufactured are on an as ordered basis, with little advance notice.

Description of Processes and Controls

This survey is focused on the liquid production area since controls were installed in this room and were not yet implemented in the powder production or spray dryer areas. The liquid production room contains both stationary and mobile open tanks for mixing liquid flavoring ingredients. There are several small and medium mobile tanks which can be moved throughout the facility according to need of the batch or formulation. Employees typically prepare small quantities of flavoring ingredients on top of a bench top. Workers then complete mixes by pouring the bench-top key ingredients and other chemicals into large mixing tanks, typically manually transferring the ingredients directly into the tank.

Following the initial walkthrough in November 2006, recommendations on the design and implementation of engineering controls were provided to the company in a letter, dated February 7, 2007. A new local exhaust ventilation system was developed and installed in the liquid production room by Gold Coast in conjunction with a contractor from May through June 2007. Two main types of local exhaust ventilation hoods were designed and installed within the liquid compounding room at the facility. A layout of the liquid production room is shown in Figure 1. The first type is a ventilated bench-top, back-draft slotted hood used to control worker exposure to

chemicals during small batch mixing, weighing, and pouring activities which comprise a majority of the workday (see Figure 2). Overall, five bench-top ventilated workstations were installed in the liquid compounding room. The second hood type is a small booth hood which allows for the rolling in of large mixing tanks (see Figure 3). The primary function of this hood is to collect chemical vapors when the worker is pouring flavoring ingredients into the large mixers and to contain evaporative losses when a flavor is being mixed. A total of three of these hoods were installed in the liquid compounding room. A third type of hood designed to control vapors from the largest mixer was partially installed but was not operational and thus not evaluated during the survey (Hood #4, see Figure 1).

Each hood is connected to a unique dedicated duct and exhaust fan system resulting in nine fans located on the rooftop with discharge stacks connected to each fan/hood combination. Bench top hood numbers 1, 2, 3, 5, and 9 are each serviced individually by a Dayton Model 4C661B 18 inch belt-drive, tubeaxial fan with a one horsepower motor. Ventilated booth-type hood numbers 6, 7, and 8 are individually connected to a Dayton Model 3C411B 24 inch belt-drive tubeaxial fan. Hood dimensions and details are given in Table 1. Each fan is controlled by a proximity switch which activates the fan when they make contact with or come within a certain distance of an object. When someone is mixing/weighing chemicals, the fan is activated and shuts down following the cessation of activities or when the bench top is cleared. The booth-type hoods are activated when a mixing tank is placed in the booth far enough back to trigger the proximity switch. No indication of fan operational status (on/off) is in place for any of the exhaust hoods.

III. METHODS

Local Exhaust Ventilation Characterization

A variety of methods were used to evaluate the local exhaust ventilation system (see Table 2). Initial characterization included measuring exhaust flowrates, face (capture) velocity and slot velocity for each hood. In addition to the face and slot velocity measurements, a smoke tracer is used to confirm that the direction of the airflow is correct and to assess the effect of secondary airflows on hood performance. Tracer gas tests and real-time exposure monitoring methods were also performed to evaluate quantitative capture efficiency for each hood.

Hood Velocity Measurements

Equipment

A Velocicalc Plus Model 8388 thermal anemometer (TSI Incorporated, St. Paul, MN) was used to measure air speeds at the face of each hood. This instrument was also used to measure velocity pressures in the ducts to evaluate exhaust flow rate.

Procedure

The face velocity tests were performed by dividing the opening of the hood into equal area grids of approximately 1 square foot and measuring the velocity at the center of each grid (see Figure 4). Hood face velocities were taken at each grid point averaged over a period of 5 seconds. To measure the velocities achieved by the control at each grid point, the anemometer was held perpendicular to the air flow direction at those points. In addition, the air velocities were measured across all slots for each hood to evaluate distribution of exhaust. Slot velocities were logged approximately every 12 inches across the length of the slot.

Hood exhaust flow rates were calculated based on pitot tube measurements of duct velocities. Readings were

taken at the center of annular rings of equal area in the duct cross section. The velocity pressures were measured at each point, converted into duct velocities, and averaged across the cross section. The average duct velocity was

multiplied by the duct cross-sectional area to yield the average exhaust flow rate.

Airflow Visualization Test

Equipment
A Rosco fog machine model 1500 (Rosco Laboratories, Inc., Stamford, CT) was used to visualize air movement inside and around the periphery of the hood.

Procedure
Smoke was released around the edge of and inside the hood to qualitatively visualize the airflow patterns in and around the hood and to determine whether it was being effectively captured and removed by the ventilation system. If the smoke was captured quickly and directly by the hood, it was a good indication of acceptable control design and performance. If the smoke escaped from the hood and went into the room or if the amount of time required to clear the smoke from the hood was excessive (greater than 15-30 seconds), the hood design was considered marginal. Also, the adverse effect of cross drafts on the hood was evaluated by releasing smoke near the edge of the hood face to look for areas where the smoke was not effectively captured. Finally, smoke was injected into the base of a 5 gallon bucket to allow for the observation of contaminant capture during simulation of bench top pouring activities.

Tracer Gas Capture Test

Equipment
The tracer gas, sulfur hexafluoride (SF_6), was supplied through a model FMA 5518 mass flow controller (Omega Inc., Stamford, CT) set to produce about 2-3 parts per million (ppm) in the exhaust outlet of the system. The release mechanism used to test the bench top hoods was a tracer gas ejector developed according to ASHRAE Standard 110-1995 for evaluation of fume hoods (see Figure 5). For the ventilated booth hoods, evaporation of chemicals was simulated using an area source consisting of a copper tubing coil perforated with uniformly spaced 1/16 inch diameter holes (see Figure 6). This coil delivered low momentum tracer gas distributed across the surface of the mixing tank cross section. The concentration of the SF_6 was measured in the exhaust duct at a location above the hood and below the roof. Each hood in the liquid compounding room was evaluated with the exception of hood #4 which was not installed at the time of testing.

In order to sample this air stream uniformly, the hood exhaust air was drawn through a 1/4 in. diameter sample probe constructed from copper tubing having 3/64 in. diameter holes spread evenly across the duct diameter. These probes were mounted inside each hood exhaust duct perpendicular to the air flow. Air was drawn from these probes through tygon tubing using an AirCon 2 high volume air sampler (Gilian Instrument Corporation, West Caldwell, New Jersey) at approximately 15 liters per minute (lpm) and routed to the analyzer. Prior to being drawn into the analyzer, the air was filtered using a Carbon-Cap 150 activated carbon/HEPA filter (Whatman Inc., Florham Park, NJ) to remove dust and volatile compounds. The SF6 concentration was measured using a MIRAN 205B Sapphire portable ambient air analyzer (Thermo Environmental Instruments, Franklin, MA). The exhaust from the analyzer was routed to an adjacent hood exhaust to minimize the possibility of contaminating the compounding room with SF6 (and affecting test results). Real-time SF6 concentration was collected from the MIRAN through a USB 12-bit analog and digital I/O module (Measurement Computing Corp, Norton, MA) and logged on a laptop computer.

Procedure
Hood capture efficiency is defined as the ratio of the captured contaminant to the total amount of contaminant

released by the process. The tracer gas test helps quantify the capture effectiveness of the hood. Since the real contaminant cannot be used in many cases, a surrogate is used for evaluation. When using a surrogate contaminant (tracer gas), it is important to simulate the contaminant generation mechanism as closely as possible. The tracer gas mixture, 10% sulfur hexafluoride (SF_6) in air, was released at a constant rate at various points to determine the capture efficiency of each hood at these release points. Release points included areas where workers typically process flavorings on the work benches and inside the mixing tanks where flavoring ingredients can evaporate.

Exhaust duct tracer gas concentration was logged every second for a period of 2 to 4 minutes. The C100 concentration corresponding to 100% capture was measured by releasing the SF_6 directly into a duct supplying the exhaust intake in that part of the system. This measurement was made immediately before each hood capture test to detect and correct for drift at the100% level. Following the completion of the C100 test, a second test was performed with the tracer gas being emitted from a device used to simulate the actual release of the chemicals being used. When testing the bench-top hoods, a tracer gas ejector which emitted a low flow gas in all directions was used to simulate the evaporation of chemicals from a container. When testing the booth hoods, an area source which consisted of a perforated copper tubing coil was used. The relative concentration in the exhaust as a result of tracer dosing when simulating the pollutant is then measured in the exhaust duct. The ratio of the simulation concentration to the C100 concentration yields the hood capture efficiency for the test conditions (see Figure 7).

Control On/Off Test

Equipment
A MiniRAE 2000 (RAE Systems Inc., San Jose, CA) photoionization detector (PID) was used to measure volatile organic compound concentrations during control on/off tests.

Procedure
The PID was placed on a NIOSH researcher to evaluate engineering control effectiveness during weighing, pouring and whisking of alcohol. These tests were conducted on hoods 9 and 2 within the Gold Coast liquid production room. Alcohol was used due to its low toxicity and good detection using the personal PID. The researcher performed the different tasks for a period of approximately 3 minutes and 30 seconds. During this test procedure, alcohol was poured from a 5 gallon bucket into a stainless steel canister and then vigorously whisked. This sequence of tasks was repeated with the ventilation system turned on and again when the system was turned off. The evaluation of these simulated tasks was performed to provide a more realistic evaluation of control effectiveness during common worker activities. Overall, there were three trials with the control on and three with the control off.

Exhaust Re-entrainment Evaluation

Equipment
A Rosco fog machine model 1500 (Rosco Laboratories, Inc., Stamford, CT) was used to visualize air movement on the roof at the exhaust fan/duct outlet. Also, a Velocicalc Plus Model 8388 thermal anemometer (TSI Incorporated, St. Paul, MN) was used to measure air speeds at the exhaust duct outlet.

Procedure
Smoke was released within each hood in the production room while a researcher on the roof, accompanied by a Gold Coast employee, observed the movement of the smoke following the emission of the air through the exhaust stack (see Figure 8). The test helped evaluate the potential for re-entrainment of exhaust into any air intakes or

roof openings. There were no air supply intakes on the roof of the facility. However, a few roof vents located on the roof deck provide a potential opening for hood exhausts to re-enter the facility. In addition, air velocity measurements were taken at the center of the exhaust duct opening to evaluate the discharge velocity of the hood exhaust.

IV. RESULTS

Hood Velocity Measurements

The capture velocity of the hood is defined as the velocity created by the hood at the point of contaminant generation (Goodfellow and Tahti, 2001). For enclosing hoods, the capture velocity is the air velocity measured at the face of the hood. To provide uniform velocity across the face of a hood, exhaust slots are typically used. When designed properly, they distribute the suction evenly across the hood face providing uniform capture characteristics.

The average air velocity measured across the face of each hood is shown in Table 3. Average face velocities for each bench-top hood were well above the recommended capture velocity of 100 feet per minute (fpm). The highest average face velocity was 205 fpm for hood 5 while the lowest measured was 164 fpm at hood 2. These velocities were fairly uniform across the opening of each hood face. Average face velocities for the booth-type hoods were lower than the bench-top hoods and ranged from 69 fpm for hood 8 to 80 fpm for hood 6. Slot velocities were generally uniform across all slots for every hood. The slot velocities ranged from a low of 1030 fpm to a high of 2800 fpm across all hoods.

Airflow Visualization Test

The smoke tests indicated good capture for all bench-type hoods. Smoke was generally captured both directly and quickly when released in the interior of the hood and along the perimeter. However, turbulence due to cross drafts caused some leakage when testing hoods 1, 5 and 9. Tests performed using a five gallon container with smoke release showed good capture at each bench-top hood. This test was done to simulate pouring of chemicals inside the hood. The booth-type hoods also showed good capture although with generally more leakage along the outside perimeter of the hood. These leakages were likely due to cross draft turbulence and lower capture velocities at the face of these hoods than the bench-top hoods.

Tracer Gas Capture Test

The quantitative collection efficiencies are shown for each hood in Table 4. The capture efficiencies ranged from 89%-100% for all hoods tested under various test conditions. Multiple tests were conducted on hood 1 since it was believed that this hood was more likely to be affected by cross drafts than other hoods due to its proximity to the room opening (where makeup air was entering the room, see Figure 1). Tests were conducted with the SF6 ejector source located at the center of the bench as well as both the left and right side. The lowest capture efficiency was observed when the source was located on the bench top outside of the side baffle nearest to the room opening. In addition, a test was performed with and without a mannequin in front of hood 9 to assess the effect of the body wake on contaminant capture efficiency. The capture efficiencies with and without the mannequin were both greater than 98%. This test indicated that the presence of the mannequin did not have an appreciable effect on capture efficiency.

Control On/Off Test

The data show a clear reduction in exposure during pouring and whisking activities when the local exhaust ventilation system is activated (see Figure 9 a, b, and c). Three separate control on/control off tests were conducted to evaluate the effectiveness of these hoods under more realistic conditions. The first two tests were

conducted on bench-top exhaust hood 9 and the third test was on hood 2. The results from these tests are shown in Figure 10. When the ventilation system was activated, the task based average concentration was reduced by 96%, 93%, and 90% in tests 1, 2, and 3, respectively. The high relative standard deviations from the control off rests show the variability of exposure due to worker activities and turbulent room drafts. This was greatly reduced when the control was turned on. However, as Figure 9 indicates, there were still a few short high instantaneous exposures when the control was on. These concentration spikes were noted when the operator would pick up the 5 gallon bucket and moved the alcohol near the monitor probe which was below the breathing zone area. Once the pour started, however, the concentration dropped down to background.

Exhaust Re-entrainment Evaluation

The blower for each hood exhaust was located on the roof of the facility and connected to an exhaust duct that extended off the deck of the roof between 22 inches and 40 inches. The exhaust duct was angled at 90 degrees to exhaust air parallel to the roof line (see Figure 8). The centerline velocity measured in the exhaust outlet stream ranged from 2100 fpm to 3250 fpm (see Table 5). The smoke release indicated that under certain wind conditions, the exhaust could re-enter the building through a roof vent opening. However, given the variability of wind fields, the amount of exhaust which can be re-entrained is hard to predict.

V. DISCUSSION

Bench Top Hood Performance

The results of each of the performance tests discussed above indicated good overall performance of the bench-top exhaust hoods. The capture efficiency for each hood ranged from 89%-100% under the test conditions. The addition of these hoods without additional makeup air in the room resulted in considerable cross drafts which may affect hood performance, although this was not seen in the tests conducted. The bench-top hood face velocities were all well above the standard fume hood control velocity range of 80-100 fpm. While the high exhaust flowrates seen with these hoods increase capture velocity at distances further from the hood face, the additional velocity increases energy expenditure and produces cross drafts which may negatively impact the capture efficiency of the hoods in the room. Reducing the face velocities to 100 fpm nominally should improve the overall performance of the hoods, reduce energy costs for the system, and reduce system noise.

There are a few additional areas where changes in the system could improve performance or durability of the system. The bench top extends 5 inches beyond the end of the side baffles. This means that the work done closest to the employee may be affected by the considerable cross drafts measured in the room. By extending these side baffles, the effectiveness of these hoods would be increased. If accessibility is a concern, the additional side baffles could be made from a heavy duty strip curtain. Also, an observation of the hoods during the day showed the accumulation of mixing vessels and other items inside the hood which block the slots and decrease effectiveness of the hoods. The tests conducted during this evaluation were performed with a clean bench and thus reflect an ideal condition: hood performance may be different under actual usage conditions. It's important to provide the workers with training on proper use of the hoods to provide the best performance. In addition, the use of floor fans and wall mounted fans is discouraged as these can disturb airflow and reduce the effectiveness of the hood. Observations from the smoke tests indicated turbulence and swirling around hood 1 which may be due to the wall mounted fan in the corner of the room. The use of ceiling diffusers for cooling and general air movement would help reduce this turbulence and improve hood effectiveness.

Ventilated Booth Hood Performance

The results of each of the performance tests discussed above indicated good performance of the booth-type

exhaust hoods overall. The capture efficiency for each hood ranged from 96% to 100% under the test conditions. The booth hood face velocities ranged from 69-80 fpm and were generally below the standard fume hood control velocity range of 80-100 fpm. However, when work is done well within the booth, the influence of cross drafts should be minimized and these control velocities may be acceptable.

NIOSH investigators found that the booth hoods exhibited good capture when testing the emission of contaminants from a mixing tank. However, data from air sampling during the work shift indicated that some chemicals were not adequately captured by the system. As presented elsewhere (McKernan and Dunn, 2007) diacetyl exposures of approximately 17 ppm, 10 ppm, and 9 ppm were observed while a worker packaged or manually sifted powder product inside the booth-type hoods (see Figure 11). Additional details regarding these task-based samples can also found in Table 6 and in the NIOSH exposure assessment report.

Given the high diacetyl concentrations measured during powder packaging, it is possible that the exhaust fan was not operating during that task. The exhaust fans on these booths are activated when an object (such as a tank) comes within an inch or so of a proximity switch mounted on the back of the booth. This feature decreases electricity usage by shutting down the fans while the booths are not in use. If the powder packaging apparatus did not effectively engage this switch, the fan would not have come on and the contaminant would not have been captured. Therefore, it is possible that the dust and vapors emitted during this process were not adequately captured and contributed to the personal and area diacetyl concentrations measured during this operation. Unfortunately, the background noise levels in the room make it hard for operators to determine if the individual exhaust fans are on simply by listening. A visual indicator such as a fan operational light should be connected to the fan circuit and mounted on the booth to indicate to the employee that he/she is being adequately protected.

Another potential cause for high exposure to chemicals when working within these booths is the improper positioning of the flavoring ingredients and the worker. If the worker is positioned between the contaminant and the exhaust hood, the chemicals can be drawn directly through the worker breathing zone increasing exposure. Also, the process must be fully contained within these booths. A review of packaging activities performed in one of the booths showed that some operations extended beyond the booth side baffles and into the general mixing room area. When activities are conducted outside of the booth, the protection of the system is marginalized and chemicals may escape to other areas of the room potentially exposing other workers. Since these booths may not have been initially designed for packaging activities, these operations (as well as any others) occurring within the booth should be reviewed and the workers should be trained on proper work practices and to evaluate the operational status of the booth.

It is important to check and confirm that the system is operating as designed and that the workers are being adequately protected and to periodically measure hood airflows. A simple measurement called hood static pressure provides important information on the performance since any change in airflow will result in a change in hood static pressure. For hoods that prevent high exposures to hazardous airborne contaminants, the American Conference of Governmental Industrial Hygienists (ACGIH) Operation and Maintenance Manual recommends the installation of a fixed hood static pressure gauge (ACGIH 2007a).

In addition to monthly monitoring of the hood static pressure, the types of measurements which should be made to ensure adequate system performance include smoke tube testing, hood slot/face velocity and potentially duct velocity measurements using an anemometer. These system evaluation tasks must become part of a routine preventative maintenance schedule to check system performance.

The implementation of ventilated booths in the liquid production room provides a good engineering control which can be used for a variety of tasks including large tank ventilation. Other operations such as powder packaging

and pouring/redistribution of diacteyl and other high priority chemicals can be more safely completed in these booths once the workers have been properly trained on proper use and new operation safeguards such as the one mentioned above are implemented. Important topics for training include verifying fan operation status and making sure that the worker knows to always position the contaminant source between him and the exhaust hood.

Exhaust Re-entrainment

The ACGIH Ventilation Design Manual recommends that a good stack discharge velocity is 3000 fpm since it prevents downwash for winds up to 22 miles per hour (ACGIH 2007b). A stack velocity above 2600 fpm should prevent rain from entering the stack when the fan is operating. The best shape for a stack is a vertical straight cylinder. Rain caps are not recommended because they deflect the exhaust and affect the ability of the stack to adequately discharge the pollutant.
For stacks that are only operated intermittently, a stack design that includes a drain can be incorporated (ASHRAE 2007). The American National Standards Institute (ANSI)/American Industrial Hygiene Association (AIHA) standard Z9.5 recommends a minimum stack height of 10 feet above adjacent roof lines (ANSI/AIHA 2003). The stack height may be subject to local building codes—the acceptable stack height should be investigated before any changes are made.

Currently, the exhaust stack is routed at 90 degrees once it exits the fan on the roof, with a height above the roof deck of approximately 2-4 feet. This configuration may allow for some re-entrainment of the exhaust into the building through the roof vents depending on the wind speed and direction. During smoke tests, some re-entrainment was observed through these vents. Modifying these exhaust stacks in accordance with the ACGIH and ASHRAE recommendations would reduce the possibility of re-entrainment while protecting the system from rain.

VI. RECOMMENDATIONS

1) Evaluate the alternative uses of the booth-type hoods. Check all operations being conducted in these booths to evaluate whether the worker is being adequately protected during all tasks.
2) Install hood static pressure gauges on each hood to provide important information on hood performance. Place an indelible mark on each gauge indicating optimal static pressure. Include the recording of hood static pressure and performance of hood airflow checks into the preventative maintenance schedule.
3) Extend the bench-top hood side baffles to the edge of the bench. This can be done using flexible strip curtains if side accessibility or interference is a concern.
4) Discontinue the use of floor fans and wall-mounted fans as they can reduce hood performance by creating drafts within the room. Consider using ceiling-mounted supply registers to provide lower velocity and more uniform cooling/air movement in the compounding room.
5) Consider upgrading hood and duct materials to higher gauge galvanized steel when appropriate. Upgrading to a higher gauge (thicker) galvanized sheet metal will improve the system's ability to withstand the wear and tear of ordinary use.
6) Consider installing an indication of exhaust fan operating status (on/off) such as a light for each hood so that workers know that they are being protected when working with the hoods. Train workers on the new fan indication system so that they understand what the light(s) mean and what to look for before they begin work.
7) Provide worker training on proper techniques for using hoods such as clearing the bench of unnecessary chemicals/materials and as much as possible to reduce the obstruction of airflow into the slot exhaust.

Worker training should include a discussion of the proper use of booth type hoods such as proper orientation of worker and contaminants (e.g. worker should not get between the source of exposure and the exhaust hood).

8) Consider using the booth for packaging of liquid flavorings and pouring of high priority chemicals until other controls are in place for these tasks. Ensure that the workers use proper techniques and that the control system allows for activation of the exhaust fan when performing these tasks.

9) Consider reworking the roof-top exhaust stack design to ensure that hood exhaust is effectively discharged. This would include changing the design to a vertical stack with a discharge velocity of between 2000-3000 fpm and the addition of a stack rain drain (see ASHRAE Fundamentals, ASHRAE 2007).

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Table 1. Hood Characteristics and face velocity measurements.

		Dimensions					
Hood #	Type	H (in)	W (in)	D (in)	Face Area (ft^2)	# Slots	Slot Width (in)
1	Bench Top	37	44	17	11	4	5/8
2	Bench Top	37	44	17	11	4	5/8
3	Bench Top	38	44	17	11	4	5/8
5	Bench Top	37	44	22	11	4	5/8
6	Booth	79	48	46	26	6	5/8
7	Booth	90	48	49	30	6	5/8
8	Booh	91	60	48	38	6	5/8
9	Bench Top	35	45	15	11	4	5/8

Table 2. Test Methods and Objectives.

Method	Description	Objective
Hood velocity measurements	Hood Face velocities and slot velocities were measured with an air flow meter. Overall hood exhaust flow rates were measured by pitot traverse in the exhaust duct.	These measurements are made to evaluate contaminant capture velocity at the hood face. A capture velocity of 80-100 fpm is recommended. Slot velocities are measured to evaluate the proper design of the hood—even flow across the hood is evaluated. Velocity pressure measurements are made in the exhaust duct to measure the overall exhaust flowrate for each hood.
Airflow Visualization Test	Smoke was generated in and around the periphery of the hood opening using a Rosco Fog Generator.	This test provides qualitative evaluation of hood capture effectiveness. Criteria for performance evaluation include observation of effective smoke containment. Notes are made on the time required for smoke to clear out of hood and if any smoke escapes from the hood.
Tracer Gas Capture Test	Tracer gas was released inside hood to simulate process contaminant generation. Measurements of tracer gas concentration were made inside the exhaust duct.	Tracer gas testing provides a quantitative evaluation technique on contaminant capture. Tracer gas concentrations measured inside the exhaust duct provide a basis for evaluating % of contaminant captured.
Control On/Off Test	Tasks such as weighing and mixing of alcohol were performed inside of the bench-top hood. Real-time personal measurements of exposure were made during these tasks with the exhaust fan on and off.	This test measured the quantitative effectiveness of the hood during normal work tasks. Comparisons of personal exposures with the exhaust on versus off provide indication of hood effectiveness.
Exhaust Re-entrainment Test	Smoke was released in each hood using a Rosco Fog Generator. Air velocities from each exhaust stack were measured.	Rooftop observations of airflow help identify areas where contaminants might re-enter the facility. Exhaust stack air velocity measurements were compared to applicable design standards.

Table 3. Hood face velocity and exhaust flowrate measurements.

Hood #	Type	Average Face Velocity (fpm)	Standard Deviation	Exhaust Flow Rate (cfm)
1	Bench Top	191	21	1663
2	Bench Top	164	14	1552
3	Bench Top	177	30	1560
5	Bench Top	205	26	1581
6	Booth	80	15	2045
7	Booth	73	21	2028
8	Booh	69	18	2806
9	Bench Top	189	38	1506

Table 4. Hood tracer gas quantitative capture efficiency test results.

Hood Number (Type)	Capture Efficiency	Notes
Hood 1 (Bench top)	89-97%	Testing was performed with source at various locations within the hood. Lowest capture efficiency was obtained when source was placed at far right corner of hood near door opening.
Hood 2 (Bench top)	98%	Test performed without mannequin in front of hood. ASHRAE ejector source was located in middle of bench inside of side baffle.
Hood 3 (Bench top)	100%	Test performed with mannequin in front of hood. ASHRAE ejector source was located in middle of bench inside of side baffle.
Hood 5 (Bench top)	98%	Test performed with mannequin in front of hood. ASHRAE ejector source was located in middle of bench inside of side baffle.
Hood 6 (Booth-type)	97%	Test performed with area source (coiled dispersion tube) placed inside mixing tank.
Hood 7 (Booth-type)	96%	Test performed with area source (coiled dispersion tube) placed inside mixing tank.
Hood 8 (Booth-type)	98%	Test performed with area source (coiled dispersion tube) placed inside mixing tank.
Hood 9 (Bench top)	98-99%	Test was performed with and without mannequin.

Table 5. Roof-top stack exhaust discharge characteristics.

Hood #	Distance from base of exhaust opening to roof deck (in.)	Roof exhaust opening diameter (in.)	Exhaust outlet velocity (fpm)
1	22	20	3200
2	22	20	3250
3	22	20	3100
5	22	20	2100
6	40	24	2100
7	38	24	2500
8	39	24	2500
9	25	20	2500

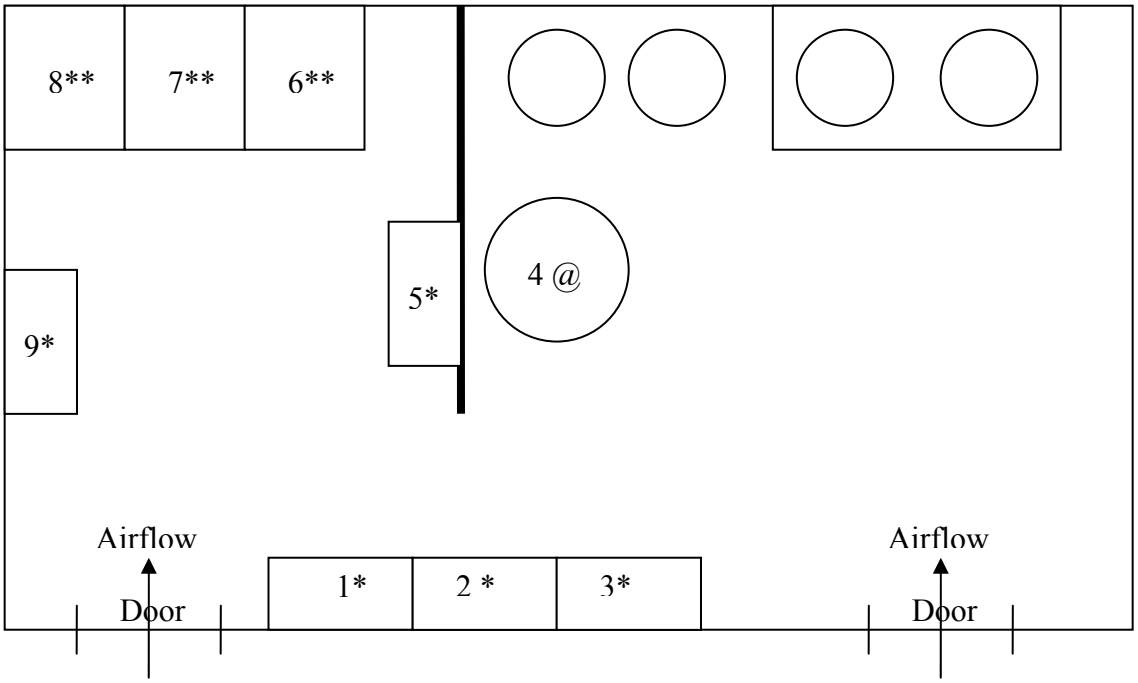
Note: There are several facility roof vent openings which are situated 4-8" from roof deck.

Table 6. July Site Visit Personal Task-Based Sampling Results

Area	Task Description	Duration (minutes)	Analyte	Result (ppm)	Batch Flavor
Liquid	Scooping butter from metal bin into boxes; Worker leaned into bin remove all powder	8	Diacetyl	17.38	Butter flavor natural wonf.
Liquid	Worker prepares for task (setting up boxes, moving equipment, etc). Worker scoops powder (one scoop at a time) over head into a mechanical sifter.	61	Diacetyl	9.32	Butter flavor N/A powder.
Liquid	Worker used exhaust hood to scoop out butter flavor powder into smaller packages.	10	Diacetyl	10.0	Butter Flavoring (powder).

Notes:
This information is synthesized from the Gold Coast Ingredients, Inc NIOSH exposure assessment report (McKernan and Dunn, 2007). Task based samples for diacetyl were collected according to a modified U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Method PV2118. This modified OSHA method used larger collection tubes (400/200 milligram silica gel tubes) which have greater collection capacity and minimize carryover of contaminant to the backup tube. Task based diacetyl samples were collected at a flow rate of 0.05 liters per minute (LPM) for the duration of the task or flavor formulation.

Figure 1. Liquid compounding room layout.



Note: Drawing not to scale. Numbers reflect exhaust hoods. Hood 4 was not fully installed during the survey and was not evaluated.

* Bench-top Hoods
** Booth Hoods
@ Hood not installed at time of evaluation

Figure 2. Bench top exhaust hood.

Figure 3. Ventilated booth-type exhaust hood.

Figure 4. Hood face velocity measurement grid layout. Note: dots represent measurement points.

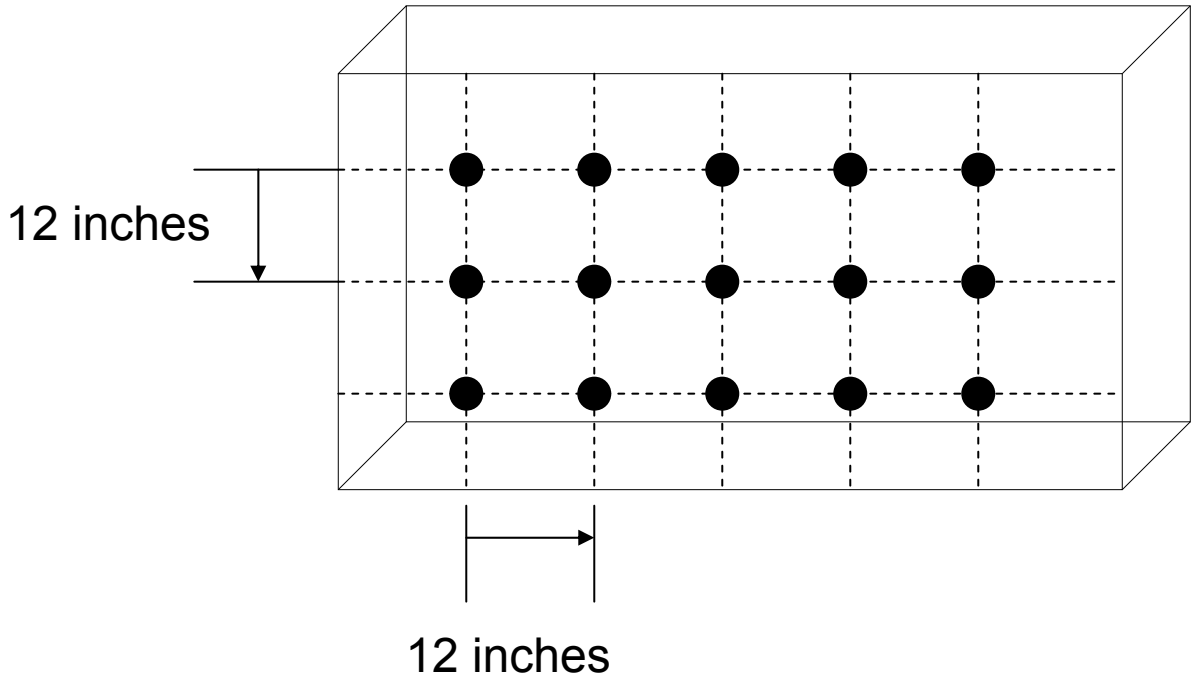


Figure 5. ASHRAE ejector setup with mannequin.

Figure 6. SF6 source coil for booth testing.

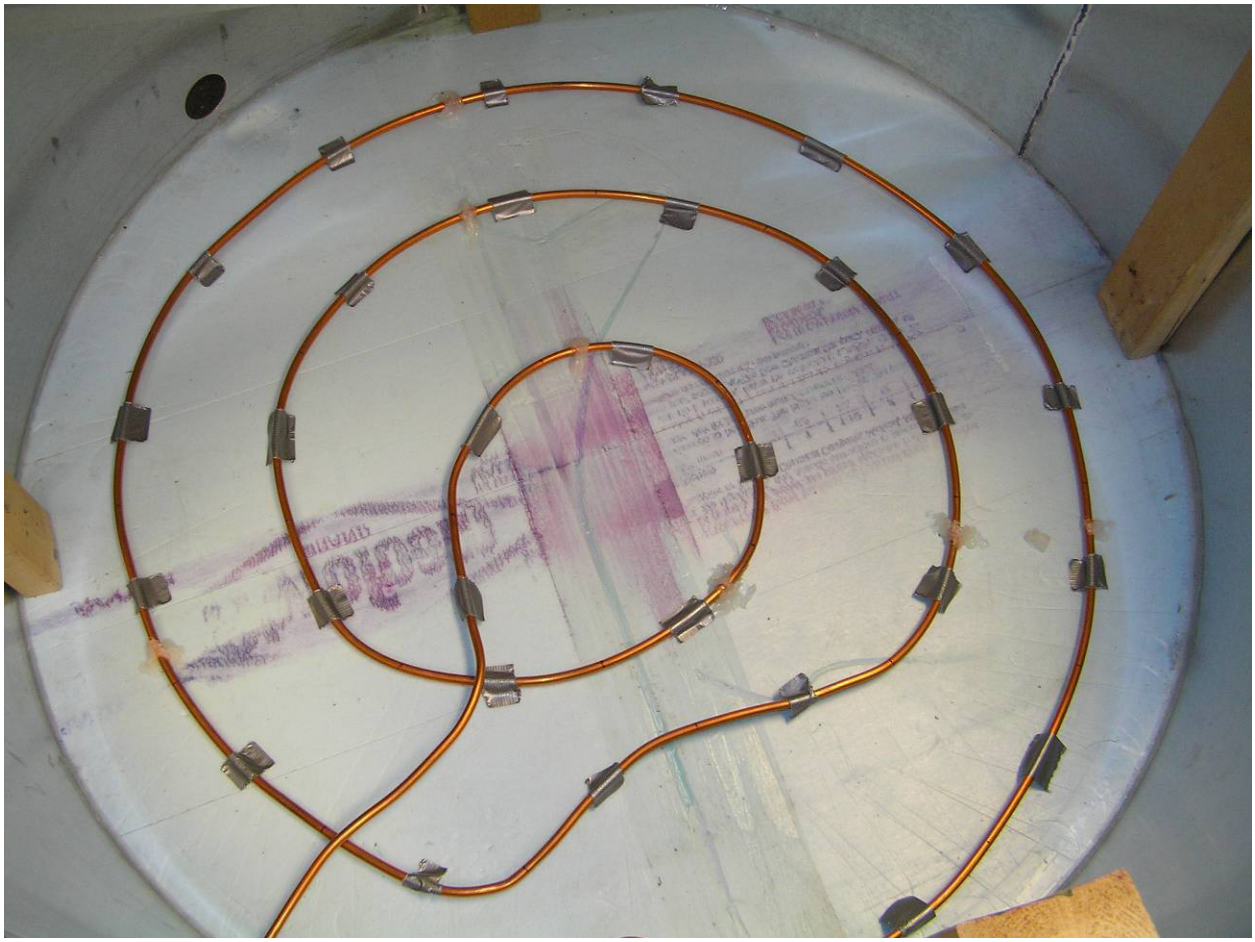


Figure 7. Example of tracer gas test plot.

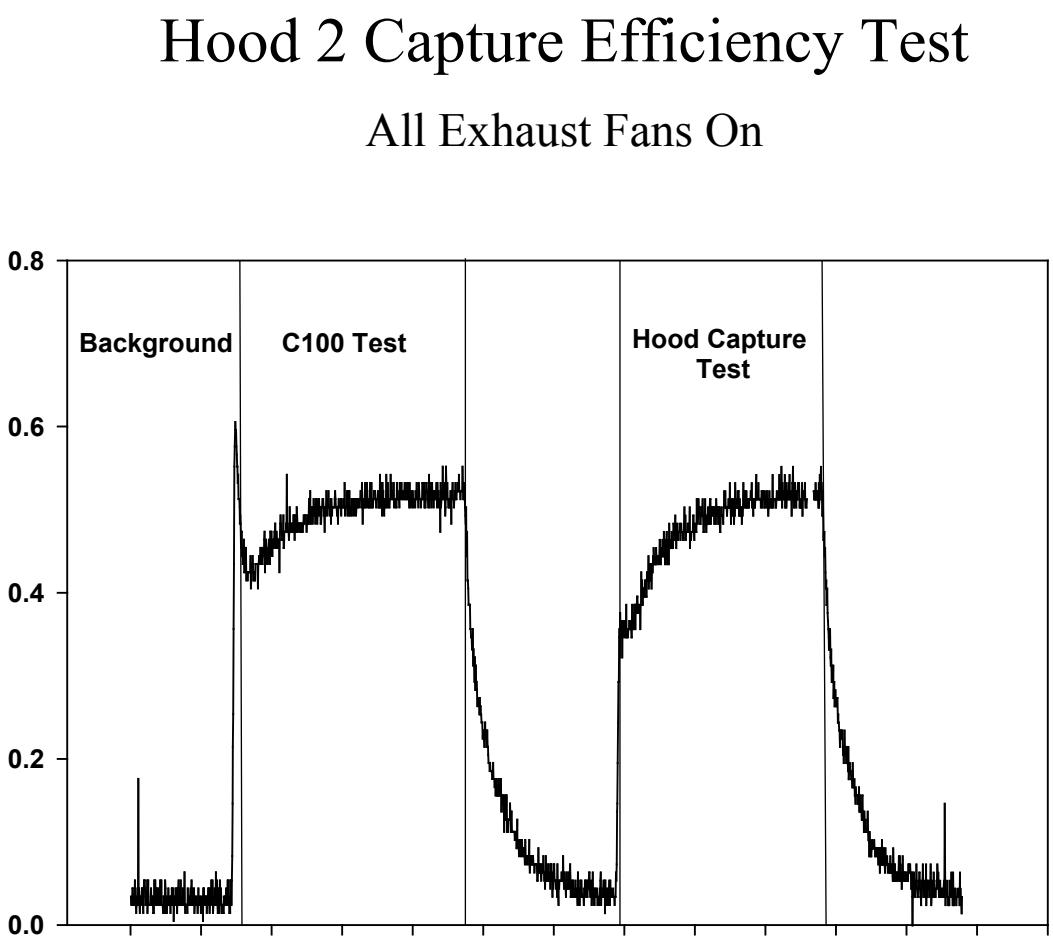


Figure 8. Rooftop re-entrainment smoke test.

Figure 9. Real-time evaluation of bench top exhaust hoods--control on/off.

a. Test 1—Hood 9 Control On/Off Test

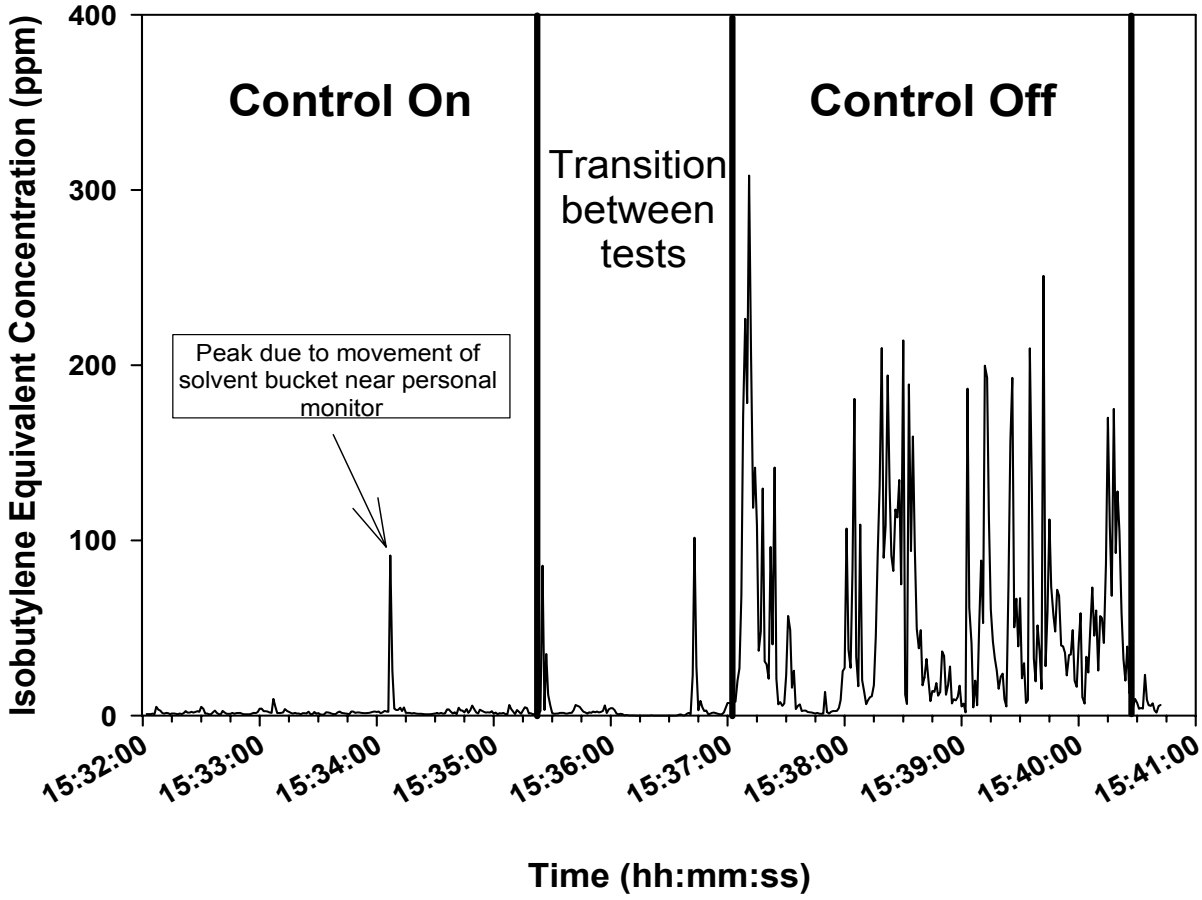


Figure 9. Real-time evaluation of bench top exhaust hoods--control on/off.

b. Test 2—Hood 9 Control On/Off

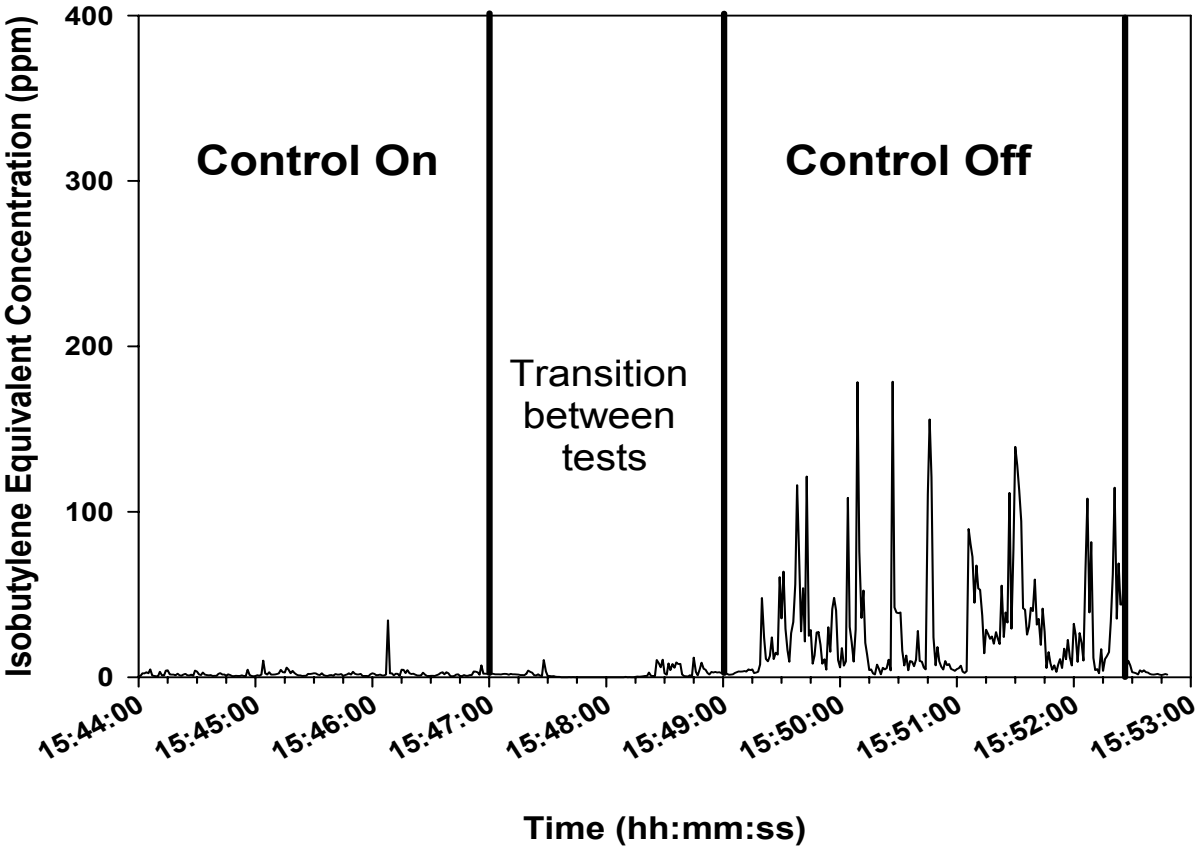


Figure 9. Real-time evaluation of bench top exhaust hoods--control on/off.

c. Test 3—Hood 2 Control On/Off Test

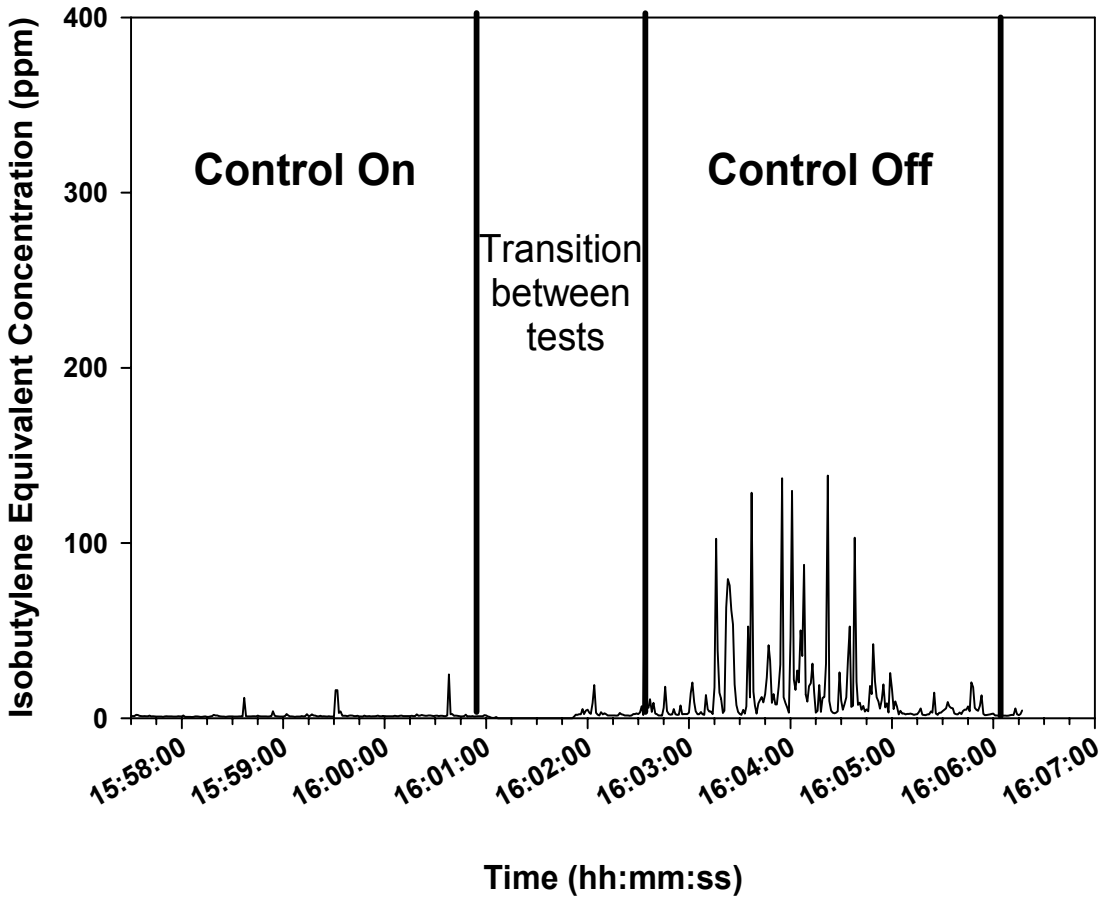


Figure 10. Average concentration and standard deviation for control on/off bench top tests.

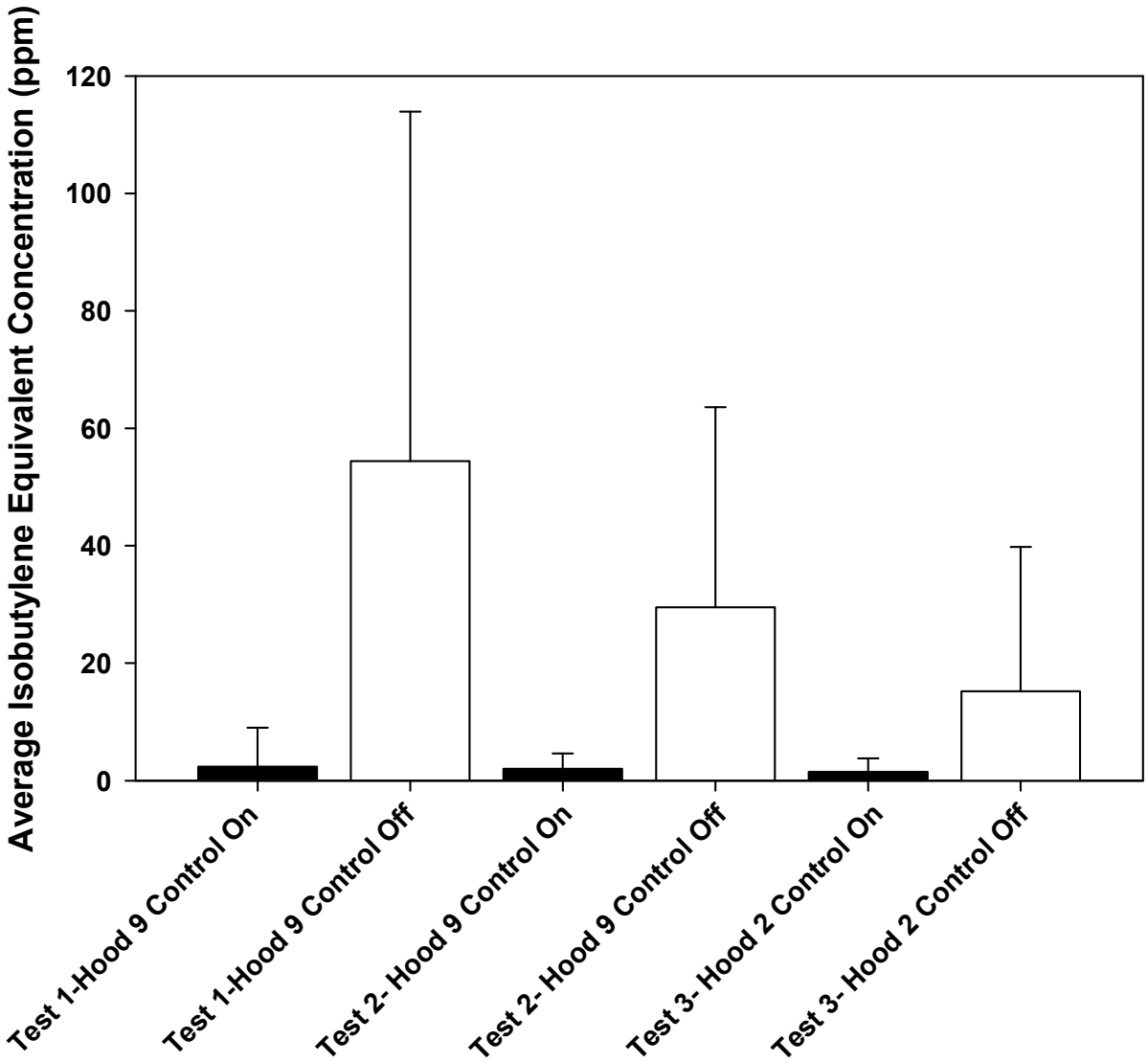


Figure 11. Employee packaging butter flavored powder inside ventilated booth.

Appendix III: NIOSH Medical Survey Questionnaire & Interim Communications

III-A: Medical Survey Questionnaire

ID:_________

RDHETA 2007 - 0033

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

Section I: Identification and Demographic Information

Name: ____________________________ ______________________ ____
(Last name) (First name) (MI)

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

_____________________ ______________ __________
(City) (State) (Zip Code)

Home Telephone Number: (   ) _______ - __________

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

Name: ____________________________ ______________________ ____
(Last name) (First name) (MI)

Relationship to you:____________________

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

_____________________ ______________ __________
(City) (State) (Zip Code)

Home Telephone Number: (   ) _______ - __________

~~~~~~

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

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

3. Are you Spanish, Hispanic, or Latino? 1.____Yes 2.____No.

4. Select <u>one or more</u> of the following categories to describe your race:

1. ___ American Indian or Alaska Native
2. ___ Asian
3. ___ African-American or Black
4. ___ Native Hawaiian or Other Pacific Islander
5. ___ White
~~~~~~

III-A: Medical Survey Questionnaire

ID:_____

Section II: Health Information

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

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

IF YES:

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

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

IF YES:

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

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

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

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

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

IF YES:

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

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

III-A: Medical Survey Questionnaire

ID:_____

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

IF YES:

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

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

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

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

I am now going to ask you some questions about your health during the last four weeks:

9. If you run, or climb stairs fast do you ever cough? 1. ___ Yes 0. ___ No
10. If you run, or climb stairs fast do you ever wheeze? 1. ___ Yes 0. ___ No
11. If you run, or climb stairs fast do you ever get tight in the chest? 1. ___ Yes 0. ___ No

12. Is your sleep ever broken by wheeze? 1. ___ Yes 0. ___ No
13. Is your sleep ever broken by difficulty with breathing? 1. ___ Yes 0. ___ No

14. Do you ever wake up in the morning (or from your sleep if a shift worker) with wheeze? 1. ___ Yes 0. ___ No
15. Do you ever wake up in the morning (or from your sleep if a shift worker) with difficulty breathing? 1. ___ Yes 0. ___ No

16. Do you ever wheeze if you are in a smoky room? 1. ___ Yes 0. ___ No
17. Do you ever wheeze if you are in a very dusty place? 1. ___ Yes 0. ___ No

III-A: Medical Survey Questionnaire

ID:_____

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

IF YES:

a) How often have you had the fever, chills, or night-sweats?
1. ___ Rarely
2. ___ Monthly
3. ___ Weekly
4. ___ Daily

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

IF YES:

a) How often have you had the unusual tiredness or fatigue?
1. ___ Rarely
2. ___ Monthly
3. ___ Weekly
4. ___ Daily

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

IF YES:

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

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

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

IF YES:

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

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

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

III-A: Medical Survey Questionnaire

ID:_____

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

IF YES:

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

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

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

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

IF YES:

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

b) Describe exposure(s):

_____

_____

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

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

IF YES:

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

b) Describe exposure(s):

_____

_____

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

III-A: Medical Survey Questionnaire

ID:_____

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

IF YES:

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

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

Describe: _____

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

Describe:_____

d) Were your breathing problems after the change:

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

III-A: Medical Survey Questionnaire

ID:_____

Section III. Work Information

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

29. Do you or did you work in the production room? 1. ___Yes 0. ___No

IF YES:

a) How many hours per day:
__ <1 hour
__ 2-3 hours
__4-8 hours
__> 8 hours

b) Do you mix or pour flavoring chemicals 1. ___Yes 0. ___No

IF YES:

c) Do you handle diacetyl? 1. ___Yes 0. ___No

IF YES:

d) How often do you handle diacetyl:
____ daily
____ 2-3 times per week
____ 2-3 times per month
____ < one time per month

e) Do you work mostly with:
___ liquids
___ powders
___ both

f) Do you wear a respirator or mask?
___ Yes, all of the time
___ Yes, some of the time
___ No

IF YES

g) Which type of respirator or mask do you wear:
___ Dust mask
___ N-95
___ Half-face piece
___ Full-face piece
___ PAPR
___ SCBA
___ Other
Describe other:
_____

h) When did you start wearing the respirator or mask?
___ / _____
(mm / yyyy)

i) Were you fit tested for this respirator? 1. ___Yes 0. ___No

III-A: Medical Survey Questionnaire

ID:_____

30. Do you or did you work in the lab? 1. ___Yes 0. ___No

IF YES:

a) Do you mix or pour flavoring chemicals? 1. ___Yes 0. ___No

IF YES:

b) Do you handle diacetyl? 1. ___Yes 0. ___No

IF YES:

c) How often do you handle diacetyl:
___ daily
___ 2-3 times per week
___ 2-3 times per month
___ < 1 one time per month

d) Do you wear a respirator or mask?
___ Yes, all of the time
___ Yes, some of the time
___ No

IF YES

e) Which type of respirator or mask do you wear:
___ Dust mask
___ N-95
___ Half-face piece
___ Full-face piece
___ PAPR
___ SCBA
___ Other
Describe other:
_____

f) When did you start wearing the respirator or mask? ___ / _____ (mm / yyyy)

g) Were you fit tested for this respirator? 1. ___Yes 0. ___No

31. Have you been exposed to any chemicals in this plant that make you cough or short of breath? 1. ___Yes 0. ___No

IF YES:

Which chemicals make you cough or short of breath?
_____
_____
_____

III-A: Medical Survey Questionnaire

ID:_____

32. If you do not currently work in the production room, do you ever enter the production room as part of another job? 1. ___Yes 0. ___No

IF YES:

a) How often do you enter the production room?
___ daily
___ 2-3 times per week
___ 2-3 times per month
___ < 1 time per month

IF DAILY

b) How many times per day?
___ 1 time per day
___ 2-3 times per day
___ 4-8 times per day
___ > 8 times per day

c) How many hours per day do you spend in the the production room?
___ < 1 hour per day
___ 2-3 hours per day
___ 4-8 hours per day
___ > 8 hours per day

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

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

IF YES:

What was the chemical?	What was the date of the spill? (mm/yyyy)	Did you have any symptoms from it?	If Yes, What were your symptoms?
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	

III-A: Medical Survey Questionnaire

ID:_____

35. Have you ever:

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

IF YES to Question j):

k) Describe the exposure:

_____

_____

III-A: Medical Survey Questionnaire

ID:_____

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.

	Job Number	Major Work Area	Job Title	Start Date (MM/YYYY)	End Date (MM/YYYY)	Comments

ID:_____

I'm now going to ask you some questions about all the jobs that you have had at other flavoring plants.

36. Have you ever worked at any other flavoring plants? 1. ___Yes 0. ___No

IF YES:

Job	Plant Name	Job Title	Start Date (mm / yyyy)	End Date (mm / yyyy)	Job Description
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Please fill out question 37 - 42 for each job listed in the above table. Enter the Job Number on each sheet for the corresponding job.

III-A: Medical Survey Questionnaire

ID:_____

Job Number _____

37. Did you work in the production room? 1. ___Yes 0. ___No

IF YES:

a) How many hours per day:
___ <1 hour
___ 2-3 hours
___ 4-8 hours
___ > 8 hours

b) Did you mix or pour flavoring chemicals 1. ___Yes 0. ___No

IF YES:

c) Did you handle diacetyl? 1. ___Yes 0. ___No

IF YES:

d) How often did you handle diacetyl:
____ daily
____ 2-3 times per week
____ 2-3 times per month
____ < one time per month

e) Did you work mostly with:
___ liquids
___ powders
___ both

f) Did you wear a respirator or mask?
___ Yes, all of the time
___ Yes, some of the time
___ No

IF YES

g) Which type of respirator or mask did you wear:
___ Dust mask
___ N-95
___ Half-face piece
___ Full-face piece
___ PAPR
___ SCBA
___ Other
Describe other:
_____

h) When did you start wearing the respirator or mask? ___ / _____
(mm / yyyy)

i) Were you fit tested for this respirator? 1. ___Yes 0. ___No

III-A: Medical Survey Questionnaire

ID:_____

Job Number _____

38. Did you work in the lab? 1. ___Yes 0. ___No

IF YES:

a) Did you mix or pour flavoring chemicals? 1. ___Yes 0. ___No

IF YES:

b) Did you handle diacetyl? 1. ___Yes 0. ___No

IF YES:

c) How often did you handle diacetyl:
___ daily
___ 2-3 times per week
___ 2-3 times per month
___ < 1 one time per month

d) Did you wear a respirator or mask?
___ Yes, all of the time
___ Yes, some of the time
___ No

IF YES

e) Which type of respirator or mask did you wear:
___ Dust mask
___ N-95
___ Half-face piece
___ Full-face piece
___ PAPR
___ SCBA
___ Other
Describe other:
_____

f) When did you start wearing the respirator or mask? ___ / _____ (mm / yyyy)

g) Were you fit tested for this respirator? 1. ___Yes 0. ___No

39. Did any chemicals make you cough or short of breath? 1. ___Yes 0. ___No

IF YES:

Which chemicals made you cough or short of breath?
_____
_____
_____

III-A: Medical Survey Questionnaire

ID:_____

Job Number _____

IF NO to Question 37 complete Question 40, else skip to Question 41

40. If you did not work in the production room, did you ever enter the production room as part of another job? 1. ___Yes 0. ___No

IF YES:

a) How often did you enter the production room?
___ daily
___ 2-3 times per week
___ 2-3 times per month
___ < 1 time per month

IF DAILY

b) How many times per day?
___ 1 time per day
___ 2-3 times per day
___ 4-8 times per day
___ > 8 times per day

c) How many hours per day did you spend in the the production room?
___ < 1 hour per day
___ 2-3 hours per day
___ 4-8 hours per day
___ > 8 hours per day

41. During an average work week, how many hours did you work? _____ Hours per week

42. Were you ever exposed to a spill or unusual chemical release at this job? 1.___ Yes 0.___ No

IF YES:

What was the chemical?	What was the date of the spill? (mm/yyyy)	Did you have any symptoms from it?	If Yes, What were your symptoms?
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	
		1.___ Yes 0.___ No	

III-A: Medical Survey Questionnaire

ID:_____

Section IV: Tobacco Use Information

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

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

IF YES:

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

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

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

IF NO:

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

Thank you for participating in this survey!

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Phone: (304) 285-5751
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Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
1095 Willowdale Road
Morgantown, WV 26505-2888

March 29, 2007
HETA 2007-0033
Interim Letter I

Mr. Jon Wellwood
Gold Coast Ingredients, Inc.
2429 Yates Avenue
Commerce, California 90040

Dear Mr. Wellwood:

The purpose of this letter is to convey a report on the progress of a National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation at the Gold Coast Ingredient, Inc. plant located in Commerce, California. NIOSH visited the plant from October 30, 2006 to November 1, 2006 to perform a medical survey consisting of an interview-administered questionnaire and spirometry (lung function) testing. We visited again on March 13-14, 2007 to perform follow-up spirometry and administer a paper questionnaire.

A copy of the interim report is enclosed. We recommend that you post the interim report in a prominent place accessible to the employees for a period of 30 calendar days.

We will continue to analyze the data from your plant and will be providing you with a final report in the future. If you have any questions or concerns, please feel free to contact me at (304) 285-5757.

Sincerely,

Rachel L. Bailey, D.O., M.P.H.
Lieutenant Commander
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Respiratory Disease Hazard Evaluation and
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Field Studies Branch
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cc:
Kelly Howard
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Kevin Dunn

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

HETA 2007-0033
Interim Report
March 29, 2007

Introduction

On October 24, 2006, Gold Coast Ingredients, Inc. requested a Health Hazard Evaluation (HHE) for medical screening for occupational lung disease at their Commerce, California plant. The company was participating in a voluntary special emphasis program called the Flavoring Industry Safety and Health Evaluation Program (FISHEP). In 2006, this program was initiated by the California Department of Health Services (CDHS) and the California Division of Occupational Safety and Health (Cal/OSHA) to identify workers with flavoring-related lung disease such as bronchiolitis obliterans (BO) and institute preventive measures in the California flavoring industry. Under FISHEP, companies must report to CDHS the results of employee medical screening and worksite industrial hygiene assessments, and implement control measures recommended by Cal/OSHA.

Background

Bronchiolitis obliterans (BO) is a rare life-threatening form of fixed obstructive lung disease that has previously been identified as an occupational hazard in microwave popcorn workers exposed to butter flavorings (1,2,3). In August 2004, the CDHS and the Cal/OSHA received the state's first report of a flavor manufacturing worker with BO. In April 2006, this was followed by a report of a second flavor manufacturing worker with BO at another California plant (http://www.dhs.ca.gov/ohb/flavoringcases.pdf). CDHS and Cal/OSHA are aware of at least eight cases of BO in California flavor manufacturing workers, and other possible cases are being evaluated. The flavor manufacturing workers were exposed to diacetyl, a chemical used in artificial butter and other flavorings. Exposure to diacetyl, either alone or in combination with other flavoring chemicals, has been shown to cause severe respiratory epithelial injury in animals (4,5).

Process Description

The Gold Coast Ingredients plant manufactures and distributes liquid and powdered flavors to other companies for use in the production of many different products. The plant started making flavorings in the 1990s. Over 800 different flavoring products are produced using over 1000 chemical or natural ingredients. The plant consists of a liquid production room, powder production room, color room, walk-in cooler and freezer, two spray-drying areas, raw materials warehouse, finished products warehouse, laboratory, quality control, and offices.

During the medical survey in 2006, 47 employees worked at the plant, including 15 office workers, 12 production workers, 1 production manager, 11 quality control (QC) and laboratory workers, 5 warehouse workers, and 3 maintenance/custodial workers. The production workers used open containers to pour and measure flavor ingredients which were then transferred to open tanks for liquid flavorings or to ribbon blenders for powdered flavorings. Computerized batch
tickets were used to pull ingredients for the various flavors. The liquid production room was approximately 58 x 20 feet. The powder production room and two spray-drying areas were much smaller. The powder production area had five ribbon blenders (two large stationary, and three smaller mobile). There were three spray dryers (one large and one medium stationary spray dryer, and one mobile spray dryer).

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

Methods

From October 30, 2006 through November 1, 2006, two medical officers and a spirometry technician from the NIOSH conducted a medical survey consisting of an interviewer-administered, computerized questionnaire and spirometry testing. An initial walkthrough of the plant was done by both medical officers prior to starting the medical survey. All workers were invited to participate in the medical survey. After obtaining signed informed consents from participants, NIOSH staff administered a standardized questionnaire to collect information on symptoms, medical diagnoses, smoking history, work history, and work-related exposures. This questionnaire included questions from the American Thoracic Society standardized adult respiratory symptoms questionnaire and the Third National Health and Nutrition Examination Survey (NHANES III) (6,7), with additional questions on asthma symptoms (8) and questions on skin, upper respiratory, and mucus-membrane irritation or problems. A Cal/OSHA staff member assisted with Spanish translation during the questionnaire and spirometry testing.

On the last day of the initial survey, November 1, 2006, another walkthrough was performed with two industrial hygienists from Cal/OSHA, and a closing meeting was completed with the company president, vice president of operations, general manager, production manager, and two Cal/OSHA industrial hygienists.

From March 13-14, 2007, one medical officer and one spirometry technician from NIOSH returned to the plant to conduct follow up spirometry testing. Workers completed a self-administered paper questionnaire (in English or Spanish) for CDHS and Cal/OSHA with assistance from NIOSH. These questionnaire results are not presented here. A Cal/OSHA employee assisted with Spanish translation during the questionnaire and spirometry testing. On the afternoon of March 13, 2007, NIOSH and CDHS medical officers did a walkthrough of the plant. On the last day, the NIOSH medical officer held a closing meeting with the company president and manager of operations.

Following ATS guidelines (9), spirometry testing was performed using a dry rolling-seal spirometer interfaced to a personal computer. Spirometry results were compared to reference values based on U.S. population data from NHANES III (10). Each participating worker's largest forced vital capacity (FVC) and forced expiratory volume in the first second of exhalation (FEV_1) were selected for analysis. Obstruction was defined as an FEV_1/FVC ratio and an FEV_1 below their respective lower limits of normal. Borderline obstruction was defined as a FEV_1/FVC ratio below the lower limit of normal with normal FEV_1 and FVC. Restriction was defined as an FVC below the lower limit of normal with normal FEV_1/FVC ratio. A mixed pattern (obstruction and restriction) was defined as an FEV_1/FVC ratio, FEV_1, and FVC all below their respective lower limits of normal. Workers with evidence of airways obstruction were administered albuterol, a bronchodilator medication used to treat obstructive lung diseases such as asthma, and were then re-tested within 10 minutes to see if the obstruction was reversible. Reversible obstruction was defined as an improvement in the FEV_1 of at least 12% and at least 200 milliliters after administration of albuterol. Fixed obstruction was defined as airways obstruction in which neither the FVC nor FEV_1 increased by 12% or more and at least 200 milliliters after the administration of albuterol. Within two to four weeks after the spirometry test, each participant was mailed a report which explained their individual spirometry results and provided recommendations for follow-up of abnormalities. Spanish speakers were mailed reports in both Spanish and English.

Data Analysis

We combined laboratory workers and quality control workers for analysis and labeled them *laboratory/QC workers*. These workers often tended to go back and forth between the laboratory and quality control areas while performing their job duties. Workers from the office work areas were combined and labeled *office workers*.

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

Warehouse workers, custodians, and the production manager who moved around the plant complex throughout the work day were combined into one category referred to as *warehouse/other*. Participants were placed in the *ever-production* category if they answered yes to "Do you or did you ever work in the production room?" and/or provided a work history that indicated they had worked in production. Participants were placed in the *ever-laboratory/QC* category if they answered yes to "Do you or did you work in the lab?" and/or provided a work history that indicated they had worked in the laboratory or quality control area. The *flavoring-exposed* worker category was defined as workers who ever worked in production or who entered the production area on a daily basis as part of another job.

We calculated prevalences of symptoms and spirometry results for all workers and for workers in each of the above categories. We compared prevalence of airways obstruction by severity level to U.S. population prevalence from NHANES III (7) U.S. population data, stratified by age.

In addition, we calculated prevalence rate ratios for symptoms for all workers, ever-production workers, and never-production workers by dividing the observed prevalences by expected prevalences based on data from NHANES III (7), controlling for age (less than 50 years of age/equal or greater than 50 years of age), gender, smoking status (ever-smoked / never-smoked), and race. Statistically increased rates in the worker groups are indicated by 95% confidence intervals that exclude the value 1.0.

Results

Walkthrough

During the initial walkthrough of the plant, the NIOSH medical officers noted workers in the production areas wearing various respirators including full-face, half-face, and N-95 filtering facepiece respirators. Production workers wore the full-face and half-face respirators with NIOSH-certified organic vapor cartridges but not always with particulate filters. Some production workers were not wearing respirators while co-workers performing the same tasks were wearing respirators. Pouring of liquid ingredients was observed in the corridor (pre-production area) outside of the liquid production area.

Management stated its policy was to require respirator use when acetoin, acetaldehyde, diacetyl, acetic acid, and benzaldehyde were used. Management stated that qualitative fit testing was done with isoamyl acetate (banana oil). No quantitative fit testing had been done.

During the walkthrough on November 1, 2006, production had ceased for the day. All of the workers performing cleaning activities in the production areas wore half-face or full-face respirators with organic vapor cartridges. Some had particulate filters, as well.

During the walkthrough on March 13, 2007, no production activities were occurring. All workers in the production rooms were wearing full-face respirators with organic vapor cartridges, and some had particulate filters. All the current production workers, except for one worker and the production manager, had been quantitatively fit tested for a Survivair Opti-Fit full-face respirator. Mention of company names or products does not constitute endorsement by NIOSH.

Medical Survey

Participation and Demographics

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

October-November 2006: Out of 47 workers employed at the plant, 41 (87%) participated in the medical survey (Table 1). Among participants, 61% were Hispanic, 24% Caucasian, 12% Asian, and 2% African American. Sixty-eight percent were male; the mean age was 38 years (range: 19-68); median age of production workers was 35 years; median age for all other workers was 36 years. The median tenure for production workers was 1.3 years; the median tenure for all other workers was 1.9 years. Twenty-seven (66%) participants were never-smokers; 2 (17%) production workers were current or former smokers; 12 (41%) other workers were current or former smokers.

March 2007: Out of 46 workers employed at the plant, 37 (80%) participated in the medical survey. Thirty-four participants participated for the second time, and 3 participants participated for the first time.

Work History

October-November 2006: Among the 41 participants, four workers reported previously working for other flavoring companies in the past.

Fourteen workers reported current or past work in the production room. Of these workers, 13 reported working four to eight hours (or more) per day in the production room. All reported mixing or pouring flavoring chemicals. Four reported handling diacetyl on a daily basis; 3 reported handling diacetyl two to three times per week; 2 two to three times per month, and 1 worker handled diacetyl less than once a month. Five reported using respirator or dust masks all the time when in the production room, and 9 reported wearing a respirator some of the time. Among the 12 current production workers, 4 reported using respirators or masks all the time, and 8 reported wearing respirators or masks some of the time.
Fourteen workers reported current or past work in the laboratory/QC. Thirteen of these workers reported they mixed or poured flavoring chemicals, including diacetyl. Four reported handling diacetyl on a daily basis; 4 reported handling diacetyl two to three times per week; 4 reported handling diacetyl two to three times a month, and 1 reported handling diacetyl less than once a month. Among the 11 current laboratory/QC workers, 6 reported wearing a respirator or mask some or all of the time.

Among the 23 current production and laboratory/QC workers, 18 reported using respirators or masks and 1 reported being respirator fit tested (qualitatively).

Twenty-six workers reported that they entered the production room regularly as part of another job. Fourteen reported entering the production room on a daily basis, 9 reported two to three times a week, 1 reported two to three times a month, and two reported entering the production room less than once a month.

Worker Symptoms

The percentage of workers reporting post-hire onset of eye and nasal irritation was high in all work areas (Table 1). Among all workers, 46% and 66% reported post-hire nasal and eye symptoms, respectively. Office workers (69%) and warehouse/other workers (60%) were the most likely to report post-hire nasal irritation. Over 80% of current laboratory/QC workers and more than 90% of current production workers reported post-hire eye symptoms. Chemicals reported by the workers to cause both eye and nasal irritation included diacetyl, acetaldehyde, benzaldehyde, acetoin, and capsicum.

Seventeen workers (41%) reported that chemicals in the plant made them cough or feel short of breath. These included diacetyl, acetaldehyde, benzaldehyde, acetoin, and capsicum. Some workers did not know the names of

the chemicals, or could not determine which chemicals specifically bothered them.

Skin problems were most common in production workers (25%), followed by warehouse/other workers (20%) (Table 1).

Table 2 shows worker symptoms, medical conditions, and spirometry (lung function) results by work history of ever/never production workers, ever/never flavoring exposed workers, and ever/never laboratory/QC workers. A persistent cough and shortness of breath when hurrying on level ground or walking up a slight hill were present in 7% of ever-production workers and 4%-7%, respectively, of never-production workers. Persist trouble breathing in the last 12 months was found in 7% of ever-production workers and not found in any never-production workers.

Prevalence rate ratios are shown in the Appendix for all workers, ever-production workers, and never-production workers for selected respiratory symptoms and conditions in comparison with NHANES III data (10). The populations of 36 non-Asian workers, 22 never-production workers, and 14 ever-production workers were small and none of the rate ratios were statistically significant, although increased prevalence ratios for production workers existed for shortness of breath on exertion, chronic chough, and physician-diagnosed bronchitis.

Spirometry Results

October-November 2006

Two (Employees A and B) of fourteen participants who had ever worked in the production room were found to have abnormal spirometry that was not reversible with bronchodilator. Employee A had borderline obstruction (normal FEV_1 and FVC but decreased FEV_1/FVC ratio). Employee B had severe fixed obstruction (FEV_1 of 17.9 percent predicted and a FEV_1/FVC ratio of 37.4%). Both workers had liquid and powder production experience. Employee B had worked as a flavoring compounder and developed shortness of breath and cough one to four years, respectively, after beginning employment. He never smoked and had no history of asthma. During his first year of employment, he did not wear respiratory protection. For the next four years, he wore an N-95 filtering facepiece respirator some of the time; he then began to wear a full-face piece respirator some of the time. For the first six years, he worked exclusively in powder production which involved adding liquid flavoring mixtures to large quantities of powder and monitoring the blending and packaging operations. Because of his respiratory symptoms, he was moved to liquid flavoring production where he worked for about five years. When he was no longer able to do the work and wear a respirator, he was transferred to a nonproduction job. At the time of our survey, he reported a chronic cough and the need to stop for breath after walking about 100 yards or a few minutes on level ground. In 2005, spirometry showed severe obstructive lung disease (FEV_1 of 20% predicted and FEV_1/FVC ratio of 47% without bronchodilator response). A lung specialist diagnosed bronchiectasis of unknown etiology based on high-resolution chest computerized tomography scan. The worker was hospitalized on two occasions due to exacerbation of his lung condition.

We found one worker with mild restriction who currently works in the laboratory/QC.

March 2007

Among the 34 workers tested a second time, one asymptomatic production worker had a more than one liter (25%) drop in FEV_1. This worker who previously had borderline airways obstruction now has mild fixed airways obstruction (Table 3). Among 3 newly hired workers who were tested for the first time, one worker was identified with borderline airways obstruction.

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

Combined October/November 2006 and March 2007 Surveys

Forty-four workers completed at least one survey. The results from the most recent spirometry test showed one worker with mild airways obstruction and one worker with severe airways obstruction. Among workers less than 50 years of age, the prevalence of severe airways obstruction was 2.7% (1/37) compared to the expected prevalence of 0.1% based on NHANES III data (Table 4).

Discussion

We found 2 workers with production work history that had fixed airways obstruction. The very severe case was not previously able to wear a respirator and had been transferred to a job with less exposure to flavoring chemicals. Such cases are sentinels of risk to co-workers. The second case evolved during FISHEP participation and demonstrates the importance of: 1) mandatory use of appropriate fit-tested respirators with both organic vapor/acid gas cartridges and particulate filters; and 2) implementation of engineering controls to lower exposure in plants with cases of fixed airways obstruction. This second case had an extreme drop in lung function into the abnormal range within a 4.5 month period of time and without symptoms.

In this facility, current production workers did not have an excess of chest symptoms compared to other workers, although the two cases developed during production work. When sick workers transfer to less physically demanding work or leave employment altogether, the remaining workers can look "healthier" in comparison to the rest of the workforce. This effect is common in cross-sectional studies and such findings should not be interpreted as an absence of risk in production workers. In this facility, the sickest employee transferred out of production, and thereby contributed his/her symptoms to a nonproduction employee grouping in Table 1. Considering the results of both spirometry surveys, the two cases of fixed obstruction arising in production employment are consistent with flavoring exposure being associated with risk.

Whether restrictive abnormalities are related to flavoring exposures remains unclear. No flavoring-exposed workforce studied to date has had a statistically significant excess of restrictive spirometry. However, individual cases with restriction have occurred in the microwave popcorn industry without explanation or alternate diagnosis (11,12). Longitudinal follow-up may clarify whether cases of restriction are coincidental, a stage of flavoring-related abnormalities, or a less common response to flavoring exposure. Similarly, longitudinal follow-up may establish whether borderline obstruction seen in two workers in production indicates higher risk of progression to fixed airways obstruction of bronchiolitis obliterans syndrome.

Recommendations

Many of the following recommendations were provided to you in a letter dated February 7, 2007 from Kevin H. Dunn of NIOSH (13).

1. Engineering Controls:

a. Ensure that exhaust hoods in the laboratory and quality control room meet the California Code of Regulations, Title 8 CCR, Section 5154.1 (http://www.dir.ca.gov/Title8/5154_1.html).

b. Install local exhaust systems in work areas where chemicals are poured, weighed, or mixed. Use design criteria as outlined in American Conference of Governmental Industrial Hygienists (ACGIH) Industrial Ventilation - A Manual of Recommended Practice (14).

c. Obtain engineering consultation to identify processes that could be effectively isolated or otherwise contained.

2. Work Practices:

a. Keep containers of flavorings and ingredients sealed when not in use. Keep empty flavoring containers sealed because they may contain residual flavorings. If these containers are to be washed, the worker or workers doing this should wear NIOSH-certified full-face respirators with organic vapor/acid gas cartridges and particulate filters (this is the minimum level of respiratory protection recommended).

b. Utilize cold water washes and cold storage of chemicals when feasible.

c. Promptly clean spills and leaks to minimize emissions of chemical vapors. Be sure to wear appropriate personal protective equipment including respirators.

3. Skin and Eye Protection: Enforce the use of chemical-resistant gloves and tight-fitting goggles by workers with potential skin and eye exposure to flavorings or their chemical ingredients.

4. Respiratory Protection:

a. Implement a formal Respiratory Protection Program that adheres to the requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134). This standard requires a written program, training of workers, medical evaluation, fit testing, and a program administrator. Details on the Respiratory Protection Standard and how a company can set up a respiratory protection program are available on the OSHA website (www.osha.gov).

b. Fit testing should use an approved quantitative method.

c. Replace respirator cartridges per manufacturer's recommendations.

d. Designate a trained employee or supervisor with responsibility to run the program and evaluate its effectiveness. Make sure that the responsible person's training or experience is appropriated to the level of complexity of the program.

e. Require mandatory respirator use (and fit testing) for all production workers and other employees that enter the production rooms (and spray-drying areas).

f. Restrict access to production rooms and spray-drying areas to only employees that need to be there and have been properly fit-tested with respirators.

g. Ensure that workers understand how and when to wear a respirator, the nature of the respiratory hazard associated with flavoring chemicals, and that a respirator must be used 100% of the time during the production operation. Workers who have not been fit-tested for an appropriate respirator should not enter the production rooms.

h. Ensure that workers perform positive and negative fit checks every time they put on their respirator.

i. A NIOSH-certified full-face respirator with organic vapor/acid gas cartridges and particulate filters is the minimum level of respiratory protection recommended. A loose-fitting powered air-purifying respirator (PAPR) with organic vapor/acid gas cartridges and particulate filters is an option for increased worker comfort and does not require fit testing.

5. Medical Surveillance:

a. Perform a baseline or preplacement spirometry test on all laboratory and production workers, as well as any other workers who enter the production area. Have a physician evaluate workers who have pre-existing lung disease or abnormal spirometry to determine the risk of progression of their lung disease from work exposures. The physician should also assess their possible increased vulnerability with respect to lung function impairment to any effects of work exposures. It is important that the spirometry test be performed by a healthcare provider who can assure high quality tests in order to compare results over time to determine whether lung function is remaining stable. This healthcare provider should provide documentation that the spirometry technician has attended a NIOSH-certified spirometry course, and that routine calibrations of their spirometer are performed as recommended by the American Thoracic Society. The provider should follow ATS guidelines for performance of high-quality spirometry.

b. Perform spirometry tests every 3 months on all production and laboratory workers until engineering controls are implemented and evaluated. This will identify any workers with falling lung function who should receive more intense monitoring, education on health effects of exposures, and/or removal from further exposure. In the near term, workers with FEV_1 falls of about 10% to 15% (depending on spirometry quality) from baseline should be medically evaluated.

c. Encourage workers to report respiratory symptoms such as persistent cough, shortness of breath, and wheezing to their supervisors, company-contracted physician, and personal physician. Workers should provide their personal physician with copies of information sheets (see 6.b., below) when reporting problems.

d. Workers with abnormal spirometry should be medically evaluated. Refer any symptomatic workers and any workers with abnormal or declining spirometry results meeting the above criteria for further medical evaluation. This evaluation should establish the likelihood of compensable work-related lung disease, and identify measures to prevent further injury or progression, including respiratory protection and relocation or exposure cessation.

6. Hazard Communication:

a. Employee education should comply with Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, 29 CFR 1910.1200 and/or the applicable Cal/OSHA standard (Title 8 CCR, Section 5194 at http://www.dir.ca.gov/title8/5194.html) when applicable.

b. Worker information sheets in both English and Spanish are available at CDHS's website, http://www.dhs.ca.gov/ohb/flavorings.htm and NIOSH's website, http://www.cdc.gov/niosh/topics/flavorings/.

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III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

Table 1. Prevalence of symptoms and medical conditions by current work area for 41 current workers, October-November 2006.

Health Outcome	Production (N=12)	Laboratory/ QC (N=11)	Warehouse/ Other* (N=5)	Office (N=13)
Trouble breathing in last 12 months[1]	0	2 (18%)	2 (40%)	3 (23%)
-Always resolves[2]	0	0	0	1 (8%)
-Persists[3]	0	0	1 (20%)	0
Shortness of breath on exertion (hurrying or walking up hill)[4]	2 (17%)	0	2 (40%)	4 (31%)
Shortness of breath on exertion (walking with people of same age)[5]	0	0	2 (40%)	1 (8%)
Chronic cough[6]	0	0	1 (20%)	1 (8%)
Wheeze[7]	0	1 (9%)	1 (20%)	1 (8%)
Asthma-like symptoms[8]				
-1 or more yes responses	1 (8%)	4 (36%)	3 (60%)	3 (23%)
-3 or more yes responses	0	1 (9%)	3 (60%)	1 (8%)
Acute bronchitis[9]	0	1 (9%)	2 (40%)	2 (15%)
Diagnosed chronic bronchitis[10]	0	1 (9%)	2 (40%)	0
Pneumonia[11]	0	0	1 (20%)	1 (8%)
Diagnosed asthma[12]	0	2 (18%)	2 (40%)	0
Post-hire nasal irritation[13]	2 (17%)	5 (45%)	3 (60%)	9 (69%)
Post-hire eye irritation[14]	11 (92%)	9 (82%)	2 (40%)	5 (38%)
Post-hire skin rash[15]	3 (25%)	2 (18%)	1 (20%)	2 (15%)

[1] During the last 12 months, have you had any trouble with your breathing?
[2] I have regular trouble with my breathing but it always gets completely better?
[3] My breathing is never quite right?
[4] Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
[5] Do you get short of breath walking with people of your own age on level ground?
[6] Do you usually cough on most days for 3 consecutive months or more during the year?
[7] During the last 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?
[8] If you run, or climb stairs fast do you ever cough? If you run, or climb stairs fast do you ever wheeze? If you run, or climb stairs fast do you ever get tight in the chest? Is your sleep ever broken by difficulty breathing? Do you ever wake up in the morning with wheeze? Do you ever wake up in the morning with difficulty breathing? Do you ever wheeze if you are in a smoky room? Do you ever wheeze if you are in a very dusty place?
[9] Since you began working at this plant, have you ever had attacks of bronchitis?
[10] Have you ever had chronic bronchitis (confirmed by a doctor)?
[11] Since you began working at this plant have you ever had pneumonia?
[12] Have you ever had asthma (confirmed by a doctor)?
[13] 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)?
[14] 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?
[15] Since working at this plant, have you developed any new skin rash or skin problems?

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

Table 2. Prevalence of symptoms, medical conditions, and lung function abnormalities by work history for 41 current workers, October-November, 2006

Health Outcome	Ever-Production (N=14)	Never-Production (N=27)	Flavoring-Exposed† (N=27)	Not Flavoring-Exposed (N=14)	Ever-Laboratory/QC (N=15)	Never-Laboratory/QC (N=26)
Trouble breathing in last 12 months[1]	1 (7%)	6 (22%)	2 (7%)	5 (36%)	3 (20%)	4 (15%)
-Always resolves[2]	0	1 (4%)	0	1 (7%)	1 (7%)	0
-Persists[3]	1 (7%)	0	1 (4%)	0	0	1 (4%)
Shortness of breath on exertion (hurrying or walking up hill)[4]	3 (21%)	5 (18%)	5 (19%)	3 (21%)	1 (7%)	7 (27%)
Shortness of breath on exertion (compared with people of same age)[5]	1 (7%)	2 (7%)	3 (11%)	0	0	3 (12%)
Chronic cough[6]	1 (7%)	1 (4%)	1 (4%)	1 (7%)	1 (7%)	2 (8%)
Wheeze[7]	0	3 (11%)	2 (7%)	1 (7%)	2 (13%)	1 (4%)
Asthma-like symptoms[8]						
-1 or more yes responses	2 (14%)	9 (33%)	7 (26%)	4 (29%)	6 (40%)	5 (19%)
-3 or more yes responses	1 (7%)	4 (15%)	4 (15%)	1 (7%)	2 (13%)	3 (12%)
Acute bronchitis[9]	1 (7%)	4 (15%)	3 (11%)	2 (14%)	2 (13%)	3 (12%)
Diagnosed chronic bronchitis[10]	1 (7%)	2 (7%)	3 (11%)	0	1 (7%)	2 (8%)
Pneumonia[11]	1 (7%)	1 (4%)	1 (11%)	1 (7%)	1 (7%)	1 (4%)
Diagnosed asthma[12]	0	4 (15%)	2 (7%)	2 (14%)	2 (13%)	2 (8%)
Post-hire nasal irritation[13]	3 (21%)	16 (59%)	11 (41%)	8 (57%)	8 (53%)	11(42%)
Post-hire eye irritation[14]	13 (93%)	15 (55%)	17 (63%)	10 (71%)	10 (67%)	17(65%)
Post-hire skin rash[15]	3 (21%)	5 (18%)	6 (22%)	2 (14%)	2 (13%)	6 (23%)
Obstruction or mixed pattern on spirometry	1 (7%)	0	1 (4%)	0	0	1 (4%)
Borderline obstruction	1 (7%)	0	1 (4%)	0	0	1 (4%)
Restriction on spirometry	0	1 (4%)	0	1 (7%)	1 (7%)	0

1-15: See Table 1 for symptom questions.

† Workers having entered the production work area on a daily basis as part of a non-production job or with a history of ever working in production.

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

Table 3. Longitudinal changes in FEV_1 and newly identified airways obstruction for 34 workers who had a second spirometry test during period March 13-14, 2007

Decline in FEV_1	Number of workers	Percent change in FEV_1	Number with newly identified airways obstruction
No decline	9	+0.8% to +15.6%	0
< 100 ml decline	13	-0.3% to -3.1%	0
≥ 100 ml to <200 ml decline	7	-3.2% to -4.3%	0
≥ 200 ml to <300 ml decline	4	-4.9% to -7.7%	0
≥ 300 ml to <1000 ml decline	0	0	0
> 1000 ml decline	1	-25.4%	1

Table 4. Prevalence (percent) of airways obstruction on most recent spirometry test by age and severity and NHANES III prevalences

Severity grade of airways obstruction	FEV_1 % predicted	Age 17-49 (n=37)	Age 50-69 (n=7)	Total (N=44)
Mild	65% to lower limit of normal	1 (2.7%) *[2.7%]*	0 (0%) *[5.0%]*	1 (2.3%) *[3.3%]*
Moderate	40% to 64%	0 (0%) *[0.7%]*	0 (0%) *[4.4%]*	0 (0%) *[1.7%]*
Severe	< 40%	1 (2.7%) *[0.1%]*	0 (0%) *[1.8%]*	1 (2.3%) *[0.5%]*
Total	Less than lower limit of normal	2 (5.4%) *[3.5%]*	0 (0%) *[11.3%]*	2 (4.5%) *[5.5%]*

APPENDIX

Table A. Prevalence ratios of observed to expected number of all workers with selected respiratory symptoms and conditions based on NHANES III data, adjusted for gender, race, age, and smoking categories.

Symptom/Condition	N*	Observed Number	Expected Number	Prevalence Ratio	CI†
Shortness of breath on exertion[1]	36	8	5.7	1.4	0.7 – 2.8
Chronic cough[2]	36	2	2.1	1.0	0.3 – 3.5
Wheeze[3]	36	5	4.6	1.1	0.5 – 2.6
Ever diagnosed with chronic bronchitis[4]	36	3	1.2	2.5	0.9 – 7.5
Ever diagnosed with asthma[5]	36	3	1.9	1.6	0.5 – 4.6

* Total number of workers with demographic characteristics comparable to NHANES III data. Five Asians excluded due to no reference rates for Asians.
† CI=95% confidence interval
[1] Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
[2] Do you usually cough on most days for 3 consecutive months or more during the year?
[3] During the 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?
[4] Have you ever had chronic bronchitis (confirmed by a doctor)?
[5] Have you ever had asthma (confirmed by a doctor)?

Table B. Prevalence ratios of observed to expected number of ever-production workers with selected respiratory symptoms and conditions based on NHANES III data, adjusted for gender, race, age, and smoking categories.

Symptom/Condition	N*	Observed Number	Expected Number	Prevalence Ratio	CI†
Shortness of breath on exertion[1]	14	3	1.4	2.1	0.7 – 6.2
Chronic cough[2]	14	1	0.6	1.7	0.3 – 9.1
Wheeze[3]	14	0	1.4	-	-
Ever diagnosed with chronic bronchitis[4]	14	1	0.3	3.3	0.6 – 17.7
Ever diagnosed with asthma[5]	14	0	0.6	-	-

* Total number of workers
† CI=95% confidence interval
[1] Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
[2] Do you usually cough on most days for 3 consecutive months or more during the year?
[3] During the 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?
[4] Have you ever had chronic bronchitis (confirmed by a doctor)?
[5] Have you ever had asthma (confirmed by a doctor)?

III-B: HETA 2007-0033—Interim Letter and Interim Report (March 29, 2007)

Table C. Prevalence ratios of observed to expected number of never-production workers with selected respiratory symptoms and conditions based on NHANES III data, adjusted for gender, race, age, and smoking categories.

Symptom/Condition	N*	Observed Number	Expected Number	Prevalence Ratio	CI†
Shortness of breath on exertion[1]	22	5	4.3	1.2	0.5 – 2.7
Chronic cough[2]	22	1	1.4	0.7	0.1 – 3.9
Wheeze[3]	22	5	3.2	1.6	0.7 – 3.6
Ever diagnosed with chronic bronchitis[4]	22	2	0.8	2.5	0.6 – 8.6
Ever diagnosed with asthma[5]	22	3	1.3	2.3	0.8 – 6.6

* Total number of workers with demographic characteristics comparable to NHANES III data. Five Asians excluded due to no reference rates for Asians.
† CI=95% confidence interval
[1] Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
[2] Do you usually cough on most days for 3 consecutive months or more during the year?
[3] During the 12 months, have you had this wheezing or whistling in your chest when you did not have a cold?
[4] Have you ever had chronic bronchitis (confirmed by a doctor)?
[5] Have you ever had asthma (confirmed by a doctor)?

III-C: HETA 2007-0033—Interim Letter 2 (August 27, 2007)

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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August 27, 2007
HETA 2007-0033
Interim Letter 2

Mr. Jon Wellwood
Gold Coast Ingredients, Inc.
2429 Yates Avenue
Commerce, California 90040

Dear Mr. Wellwood:

On July 11-12, 2007, a field team from the National Institute for Occupational Safety and Health (NIOSH) visited the Gold Coast Ingredients, Inc. plant located in Commerce, California to perform environmental sampling. We are writing to update you on this round of sampling and our concerns about the higher than expected diacetyl concentrations in some areas of the plant.

Methods

The NIOSH field team collected area air samples from the powder production room, liquid production room, pre-production corridor, spray drying room, and distribution warehouse. Diagram 1 shows sample locations. The area samples were collected using three diacetyl methods (NIOSH method #2557, Occupational Safety and Health Administration (OSHA) method PV2118, and a modified OSHA method) to assess the comparability of the three methods. In this interim letter, we will only report the results from the OSHA modified method. NIOSH continues to evaluate the other two methods for the effects of relative humidity and sorbent volume on recovery of diacetyl. The OSHA modified method is similar to the OSHA method PV2118 but uses larger collection tubes (400/200 milligram silica gel tubes) which have greater collection capacity and minimize significant concentrations in the backup tube. Area air samples were collected over approximately two hours at a flow rate of 0.050 liters per minute for a total volume of 6 liters.

Results

Table 1 shows sampling results. Two hour time-weighted average (TWA) measurements for diacetyl ranged from non-detectable levels to 6.33 parts per million (ppm). The highest diacetyl level was recorded in the spray drying room when spray drying was in operation in the early morning hours of July 11, 2007. The highest recorded diacetyl level for powder production was during the early afternoon hours of July 12, 2007 where the 2-hr TWA was 1.55 ppm. For liquid production, the highest diacetyl level was 1.04 ppm during the late morning hours on July 11, 2007. In the pre-production corridor, diacetyl was at detectable concentrations only on July 11, 2007. The diacetyl concentration in this work area was highest during the early morning hours when spray drying was in

operation. Measurable diacetyl concentrations in the distribution warehouse occurred during the late morning and early afternoon hours of July 12, 2007.

Discussion

The high diacetyl concentration (6.33 ppm) observed in the spray drying area suggests that diacetyl is present in some batches in this operation. Diacetyl may be in premixed bases and mixed or used indirectly. Additional measurements and more attention should be given to operations in the spray drying areas.

The diacetyl concentration of 0.38 ppm measured in the pre-production corridor early on the first day of sampling may have been due to migration of diacetyl from the spray drying operation. Pouring and open transfer of flavoring chemicals or spills in the pre-production corridor also could explain these measurable concentrations. On the late morning and early afternoon of July 12, the source of the diacetyl concentrations in the distribution warehouse is unknown. Migration was not likely the source as the adjacent pre-production corridor had non-detectable concentrations during those sampling periods.

Since a safe diacetyl level has not been established, we suggest a precautionary approach. Work practices or work activities contributing to diacetyl exposures in the distribution warehouse and the pre-production corridor need to be identified and controlled or relocated to a production room where engineering controls are used. For example, containers containing ingredients on the Flavor and Extract Manufacturer's Association (FEMA) high priority list should not be opened either in the warehouse or the pre-production corridor. Also empty barrels or containers that contained high priority ingredients should not be stored in the distribution warehouse or the pre-production corridor unless they have been thoroughly cleaned and sealed. The measurements in this report indicate that exposure to diacetyl is possible in the pre-production corridor and warehouse areas. Other areas (including the finished products warehouse) may need to be evaluated for workers who require re-assignment due to medical restriction.

Diacetyl concentrations measured during this site visit underscore the importance of engineering controls and work practices to reduce the diacetyl and other flavoring chemical exposures. It is paramount that workers are informed and trained regarding potential workplace hazards and know how to protect themselves with safe practices, procedures, and protective measures. Enforcement of safe practices, procedures, and protective measures such as respirator use is imperative.

To date, engineering controls have been implemented in the liquid production room. Eight local exhaust ventilation hoods have been installed in the room and have been operational since June 2007. These hoods include five bench-top, fume-type hoods for control of exposure while workers perform small batch mixing and weighing. In addition, three large kettle booth-type hoods are in place for capture of flavoring chemicals during pouring and mixing. The current sampling results reiterate the importance of implementing engineering controls in the spray drying and powder production areas. Additionally, the diacetyl concentrations in the liquid production room may also demonstrate the need for improved work practices to more fully utilize the installed controls. For example, the engineering control stations should be free of clutter when workers are using them. Diacetyl pouring should only occur within the engineering control-ventilated workstations and not in the general liquid production room to reduce concentrations in the liquid production room.

Spirometry is key to identifying flavoring-related bronchiolitis obliterans where shortness of breath is progressive

III-C: HETA 2007-0033—Interim Letter 2 (August 27, 2007)

and may not initially be noticed by the worker. NIOSH has performed baseline and one follow-up spirometry testing on workers at Gold Coast Ingredients. The University of California-Irvine, Center of Occupational and Environmental Health (UCI/COEH) has completed one subsequent round of spirometry on some of the workers. These spirometry tests will be compared by UCI/COEH to spirometry tests completed by NIOSH to assess their comparability with different equipment and technicians and to identify any excessive declines in lung function among the workers.

Workers with symptoms or interval spirometry declines (FEV_1 falls of 10% or more) need medical restriction from exposure to flavoring chemicals or ingredients. On the basis of these measurements, potential restricted areas include working in or entering the pre-production corridor, liquid production room, powder production room, spray drying areas, and the distribution warehouse. Physicians placing medical restrictions can judge whether an affected worker can use respiratory protection in the distribution warehouse, in view of the worker's level of impairment, likelihood of respirator compliance, and further information about the source of diacetyl exposure and interventions in work practices in this warehouse.

Recommendations

1. Medical Surveillance:

1) Perform preplacement spirometry testing on all new production workers, laboratory/quality control workers, and any other workers who enter the pre-production corridor, liquid production room, powder production room, spray drying areas, or distribution warehouse.

2) Perform spirometry every 3 months on all production workers, laboratory/quality control workers, and any other workers who enter the pre-production corridor, liquid production room, powder production room, spray drying areas, or distribution warehouse. Workers with FEV_1 falls of 10% or more should be removed from exposure to flavoring chemicals or ingredients until medically evaluated for appropriate medical restrictions. Workers with symptoms such as shortness of breath, wheezing, or persistent cough should also be removed from exposure to flavoring chemicals or ingredients until medically evaluated for appropriate medical restrictions.

3) Provide workers with information sheets regarding flavoring-related lung disease to take to their healthcare providers. Informational handouts are available at the California Department of Health Services (CDHS) website (http://www.dhs.ca.gov/ohb/flavorings.htm) and NIOSH's website (http://www.cdc.gov/niosh/topics/flavorings/).

2. Engineering Controls:

1) Implement engineering controls in the spray drying areas and powder production room.

3. Work Practices:

1) Avoid open pouring, measuring and transfer of high priority flavoring chemicals in the pre-production and warehouse areas. Consider moving larger pouring and weigh out activities with these chemicals to the large ventilated, kettle booths in the liquid production room.

2) Add diacetyl and other high priority chemicals into a batch last to minimize volatization.

4. Respiratory Protection:

1) Relocate the respirator storage and cartridge re-load area from outside the powder production room/ pre-production corridor to an alternate area with known lower exposures.

2) Restrict access to the pre-production corridor, liquid production room, powder production room, spray-drying areas, and distribution warehouse to only employees that need to be there.

3) Ensure production and distribution warehouse workers have been properly quantitatively fit-tested with respirators.

4) In accordance with Cal/OSHA direction, "full-facepiece respirators fit-tested with an approved quantitative method are needed as minimal protection for employees exposed to flavoring ingredients in this industry. All employees entering flavor formulation areas or unprotected areas (e.g., packaging areas) must wear respirators" (FISHEP correspondence from K. Howard dated Oct. 13, 2006). Employees should continue to use full-face respirators with organic vapor cartridges and particulate filters. Information about respirators is available at the NIOSH website (http://www.cdc.gov/niosh/npptl/topics/respirators/ and http://www.cdc.gov/niosh/docs/2005-100/default.html). Details on the OSHA Respiratory Protection Standard are available on the OSHA website (http://www.osha.gov/).

5. Eye and Skin Protection:

1) Enforce eye and skin protection in the laboratory, quality controls areas, and production areas. Full face respirators provide eye protection in the production areas.

6. Hazard Communication:

1) Ensure workers understand the hazards associated with flavoring chemicals and how to protect themselves. The California Code of Regulations, Title 8, Section 5194, Hazard Communication, is available at http://www.dir.ca.gov/title8/5194b.html.

We appreciate the continued excellent cooperation from both you and your employees during our surveys. If you have any questions or concerns regarding the information in this report, please feel free to contact us. Rachel Bailey may be reached at RLBailey@cdc.gov or (304) 285-5757, Lauralynn Taylor McKernan at LMcKernan@cdc.gov or (513) 841-4571, and Kevin Dunn at KDunn@cdc.gov or (513) 841-4152.

III-C: HETA 2007-0033—Interim Letter 2 (August 27, 2007)

Sincerely,

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Diagram 1. Plant layout

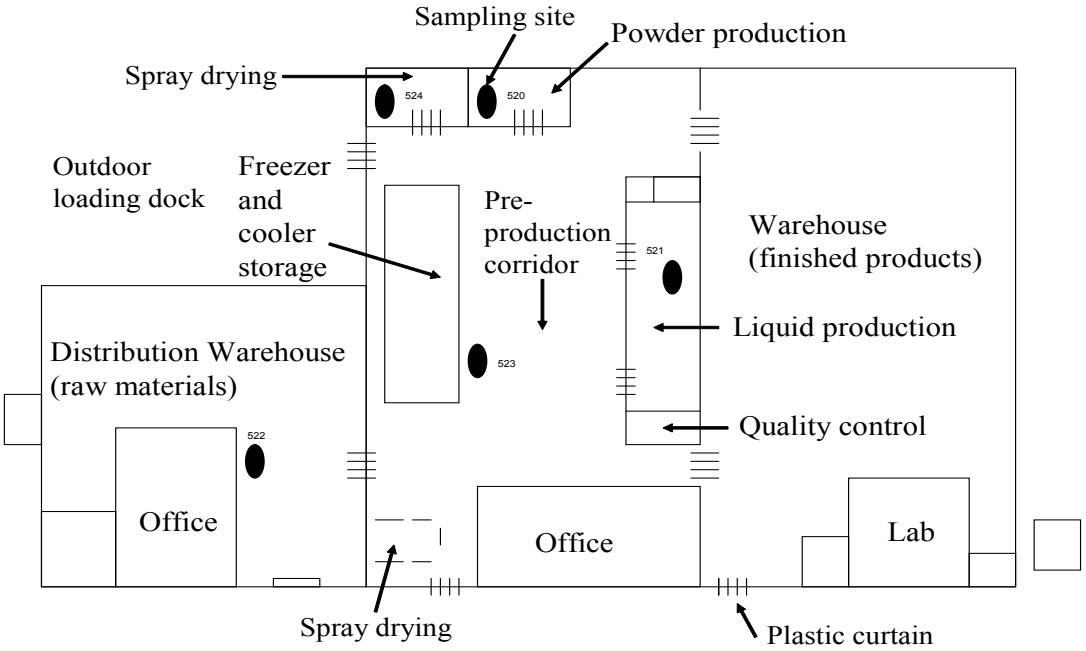

Table 1. Work area sample results for diacetyl in parts per million parts air as 2 hour time-weighted averages

	July 11, 2007			July 12, 2007		
Work Area	**7:30-9:30am**	**9:45-11:45am**	**Noon-2pm**	**7:30-9:30am**	**9:45-11:45am**	**Noon-2pm**
Powder Production (520)	0.62	0.22	0.09	0.28	0.10	1.55
Liquid Production (521)	0.67	1.04	0.28	0.58	0.33	0.31
Distribution Warehouse (522)	ND*	ND*	ND*	ND*	0.06	0.14
Pre-production Corridor (523)	0.38	0.17	ND*	ND*	ND*	ND*
Spray Dry Area (524)	6.33	ND*	ND*	0.04	0.03	ND*

*ND=Result below limit of detection.

Acknowledgements and Availability of Report

The Respiratory Disease Hazard Evaluation and Technical Assistance Program (RDHETAP) of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health (OSH) Act of 1970, 29 U.S.C. 669(a)(6), or Section 501(a)(11) of the Federal Mine Safety and Health Act of 1977, 30 U.S.C. 951(a)(11), which authorizes 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 any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH).

This report was prepared by Rachel Bailey, Nancy Sahakian, and Kathleen Kreiss of RDHETAP, Division of Respiratory Disease Studies (DRDS); Lauralynn Taylor McKernan of the Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS); and Kevin H. Dunn of the Division of Applied Research and Technology (DART). Field assistance was provided by Richard Kanwal, Brian Tift, and Jim Taylor of DRDS, Thomas Kim of CDPH, and Violeta Pisani and Scott Ratigan of Cal/OSHA. Analytical support was performed by Nicole Edwards and Kathy Fedan of RDHETAP, DRDS. Desktop publishing was performed by Tia McClelland and Nicole Edwards of RDHETAP, DRDS. We would like to thank Chris Piacitelli, Greg Kullman, and Robert Castellan of DRDS for their input and assistance.

Copies of this report have been sent to employee and management representatives at Gold Coast Ingredients, Inc., and to CDPH and to Cal/OSHA. This report is not copyrighted and may be freely reproduced. The report may be viewed and printed from the following internet address: http://www.cdc.gov/niosh/hhe. Copies may be purchased from the National Technical Information Service (NTIS) at 5825 Port Royal Road, Springfield, Virginia 22161. Information regarding the NTIS stock number may be obtained from the NIOSH Publications Office at the Cincinnati address.

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